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*(Notices)*NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND
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EUROPEAN COMMISSION

**Summary of European Union decisions on marketing authorisations in respect of medicinal products
from 1 June 2016 to 30 June 2016***(Published pursuant to Article 13 or Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of
the Council ⁽¹⁾)*

(2016/C 277/01)

⁽¹⁾ OJ L 136, 30.4.2004, p. 1.

— Issuing of a marketing authorization (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): **Accepted**

Date of the decision	Name of the medicinal product	INN (International Non-Proprietary Name)	Holder of the marketing authorization	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
21.6.2016	Odefsey	emtricitabine/rilpivirine/tenofovir alafenamide	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/16/1112	Film-coated tablet	J05AR19	23.6.2016
24.6.2016	Ongentys	opicapone	Bial — Portela & C ^a , SA A Av. da Siderurgia Nacional 4745-457 S. Mamede do Coronado, Portugal	EU/1/15/1066	Capsule, hard	Pending	28.6.2016
24.6.2016	Zavicefta	ceftazidime/avibactam	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/16/1109	Powder for concentrate for solution for infusion	J01DD52	28.6.2016
29.6.2016	Enzepi	pancreas powder	APTALIS PHARMA SAS 5/6 Place de l'Iris — La Défense 5 92400 Courbevoie France	EU/1/16/1113	Capsule, hard, gastro-resistant	A09AA02	1.7.2016

— **Issuing of a marketing authorization** (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): **Rejected**

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
24.6.2016	Dropcys	Lucane Pharma 172 rue de Charonne, 75011 Paris, France		28.6.2016

— **Modification of a marketing authorization** (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): **Accepted**

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
1.6.2016	Cotellic	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/15/1048	3.6.2016
1.6.2016	HyQvia	Baxalta Innovations GmbH Industriestrasse 67, A-1221 Wien, Österreich	EU/1/13/840	6.6.2016
1.6.2016	Revlimid	Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge, Middlesex UB11 1DB, United Kingdom	EU/1/07/391	3.6.2016
1.6.2016	Zinforo	AstraZeneca AB SE-151 85 Södertälje, Sverige	EU/1/12/785	3.6.2016
2.6.2016	Adrovance	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/06/364	6.6.2016
2.6.2016	Altargo	Glaxo Group Ltd 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	EU/1/07/390	6.6.2016
2.6.2016	Avastin	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/04/300	6.6.2016
2.6.2016	Capecitabine Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	EU/1/12/762	6.6.2016
2.6.2016	Clopidogrel BGR	Laboratoires BIOGARAN 15 boulevard Charles de Gaulle, 92707 Colombes Cedex, France	EU/1/09/558	6.6.2016
2.6.2016	Clopidogrel Krka	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/556	7.6.2016
2.6.2016	Clopidogrel ratio-pharm GmbH	Archie Samuel s.r.o. Slunná 16, CZ-61700 Brno, Česká republika	EU/1/09/541	6.6.2016

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
2.6.2016	Imatinib Actavis	Actavis Group PTC ehf. Reykjavíkurvegi 76-78, 220 Hafnarfjörður, Ísland	EU/1/13/825	6.6.2016
2.6.2016	Kineret	Swedish Orphan Biovitrum AB (publ) SE-112 76 Stockholm, Sverige	EU/1/02/203	7.6.2016
2.6.2016	Kiovig	Baxter AG Industriestrasse 67, A-1221 Wien, Österreich	EU/1/05/329	6.6.2016
2.6.2016	Lonquex	UAB 'Sicor Biotech' Molėtų pl. 5, LT-08409 Vilnius, Lietuva	EU/1/13/856	6.6.2016
2.6.2016	Neuraceq	Piramal Imaging Limited Langstone Technology Park, Langstone Road, Havant, Hampshire, PO9 1SA, United Kingdom	EU/1/13/906	6.6.2016
2.6.2016	Tasigna	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/07/422	6.6.2016
2.6.2016	Temozolomide Accord	Accord Healthcare Limited Sage House, 319 Pinner Road, North Harrow, Middlesex, HA1 4HF, United Kingdom	EU/1/10/615	6.6.2016
2.6.2016	Vimpat	UCB Pharma S.A. Allée de la Recherche 60, 1070 Bruxelles, Belgique/Researchdreef 60, 1070 Brussel, België	EU/1/08/470	6.6.2016
9.6.2016	Cubicin	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/05/328	13.6.2016
9.6.2016	Telmisartan Teva Pharma	Teva B.V. Swensweg 5, 2031 GA Haarlem, Nederland	EU/1/11/719	13.6.2016
9.6.2016	VPRIV	Shire Pharmaceuticals Ireland Limited 5 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/10/646	13.6.2016
9.6.2016	Zyllt	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/09/553	13.6.2016
13.6.2016	Gazyvaro	Roche Registration Limited 6 Falcon Way, Shire Park, Welwyn Garden City, AL7 1TW, United Kingdom	EU/1/14/937	15.6.2016
16.6.2016	Advagraf	Astellas Pharma Europe B.V. Sylviusweg 62, NL-2333 BE Leiden, Nederland	EU/1/07/387	20.6.2016
16.6.2016	Avonex	Biogen Idec Limited Innovation House, 70 Norden Road, Maidenhead, Berkshire SL6 4AY, United Kingdom	EU/1/97/033	20.6.2016

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
16.6.2016	Protopic	Leo Pharma A/S Industriparken 55, DK-2750 Ballerup, Danmark	EU/1/02/201	20.6.2016
16.6.2016	Tesavel	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/435	20.6.2016
16.6.2016	Xelevia	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/382	20.6.2016
21.6.2016	Eurartesim	Sigma-Tau Industrie Farmaceutiche Riunite S.p.A Viale Shakespeare 47, 00144 Roma, Italia	EU/1/11/716	23.6.2016
21.6.2016	Irbesartan Zentiva	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France	EU/1/06/376	23.6.2016
21.6.2016	Karvea	Sanofi-Aventis groupe 54 rue La Boétie, F-75008 Paris, France	EU/1/97/049	23.6.2016
21.6.2016	Lemtrada	Genzyme Therapeutics Ltd 4620 Kingsgate, Cascade Way, Oxford Business Park South, Oxford OX4 2SU, United Kingdom	EU/1/13/869	23.6.2016
21.6.2016	Modigraf	Astellas Pharma Europe B.V. Sylviusweg 62, NL-2333 BE Leiden, Nederland	EU/1/09/523	23.6.2016
21.6.2016	Reyataz	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Ux- bridge UB8 1DH, United Kingdom	EU/1/03/267	23.6.2016
21.6.2016	Zometa	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/01/176	23.6.2016
24.6.2016	ADCETRIS	Takeda Pharma A/S Dybendal Alle 10, 2630 Taastrup, Danmark	EU/1/12/794	28.6.2016
24.6.2016	Advate	Baxter AG Industriestrasse 67, A-1221 Wien, Österreich	EU/1/03/271	28.6.2016
24.6.2016	Aprovel	Sanofi Clir SNC 54 rue La Boétie, F-75008 Paris, France	EU/1/97/046	28.6.2016
24.6.2016	Cubicin	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/05/328	28.6.2016
24.6.2016	Daklinza	Bristol-Myers Squibb Pharma EEIG Uxbridge Business Park, Sanderson Road, Ux- bridge UB8 1DH, United Kingdom	EU/1/14/939	28.6.2016

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
24.6.2016	Emtriva	Gilead Sciences International Limited Cambridge CB21 6GT, United Kingdom	EU/1/03/261	28.6.2016
24.6.2016	Grepid	Pharmathen S.A. 6 Dervenakion, 15351 Pallini Attiki, Ελλάδα	EU/1/09/535	28.6.2016
24.6.2016	Humira	AbbVie Ltd Maidenhead, SL6 4UB, United Kingdom	EU/1/03/256	28.6.2016
24.6.2016	Imnovid	Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge, Middlesex UB11 1DB, United Kingdom	EU/1/13/850	28.6.2016
24.6.2016	Januvia	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/07/383	28.6.2016
24.6.2016	Rasilez	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/07/405	28.6.2016
24.6.2016	Rasilez HCT	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/08/491	28.6.2016
24.6.2016	Relvar Ellipta	Glaxo Group Ltd 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	EU/1/13/886	28.6.2016
24.6.2016	Revinty Ellipta	Glaxo Group Ltd 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom	EU/1/14/929	28.6.2016
24.6.2016	Simponi	Janssen Biologics B.V. Einsteinweg 101, NL-2333 CB Leiden, Nederland	EU/1/09/546	28.6.2016
24.6.2016	Tolura	Krka, d. d., Novo Mesto Šmarješka cesta 6, 8501 Novo mesto, Slovenija	EU/1/10/632	28.6.2016
24.6.2016	Tysabri	Biogen Idec Limited Innovation House, 70 Norden Road, Maidenhead, Berkshire SL6 4AY, United Kingdom	EU/1/06/346	28.6.2016
24.6.2016	Zoledronic acid Hospira	Hospira UK Limited Horizon, Honey Lane, Hurley, Maidenhead, SL6 6RJ, United Kingdom	EU/1/12/800	28.6.2016
29.6.2016	Champix	Pfizer Limited Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom	EU/1/06/360	1.7.2016

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
29.6.2016	Incivo	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/11/720	1.7.2016
29.6.2016	Kivexa	ViiV Healthcare UK Limited 980 Great West Road, Brentford, Middlesex TW8 9GS, United Kingdom	EU/1/04/298	1.7.2016
29.6.2016	Kyprolis	Amgen Europe B.V. Minervum 7061, NL-4817 ZK Breda, Nederland	EU/1/15/1060	1.7.2016
29.6.2016	Matever	Pharmathen S.A. 6 Dervenakion, 15351 Pallini Attiki, Ελλάδα	EU/1/11/711	1.7.2016
29.6.2016	Memantine Mylan	Generics [UK] Limited Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom	EU/1/13/827	8.7.2016
29.6.2016	Mycamine	Astellas Pharma Europe B.V. Sylviusweg 62, NL-2333 BE Leiden, Nederland	EU/1/08/448	1.7.2016
29.6.2016	PegIntron	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/00/131	1.7.2016
29.6.2016	Revestive	NPS Pharma Holdings Limited 5 Riverwalk, Citywest Business Campus, Dublin 24, Ireland	EU/1/12/787	1.7.2016
29.6.2016	Tyverb	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/07/440	1.7.2016
29.6.2016	Vidaza	Celgene Europe Limited 1 Longwalk Road, Stockley Park, Uxbridge UB11 1DB, United Kingdom	EU/1/08/488	1.7.2016
29.6.2016	ViraferonPeg	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/00/132	4.7.2016
29.6.2016	Yondelis	Pharma Mar S.A. Avda de los Reyes 1, Polígono Industrial La Mina, E-28770 Colmenar Viejo, Madrid, España	EU/1/07/417	1.7.2016
29.6.2016	Zoledronic acid medac	medac Gesellschaft für klinische Spezialpräparate mbH Theaterstr. 6, D-22880 Wedel, Deutschland	EU/1/12/779	1.7.2016
30.6.2016	Ceplene	Meda AB Box 906, SE-170 09 Solna, Sverige	EU/1/08/477	5.7.2016
30.6.2016	Dacogen	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/12/792	4.7.2016

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
30.6.2016	Efficib	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/457	4.7.2016
30.6.2016	Eylea	Bayer Pharma AG D-13342 Berlin, Deutschland	EU/1/12/797	4.7.2016
30.6.2016	Filgrastim Hexal	Hexal AG Industriestrasse 25, D-83607 Holzkirchen, Deutschland	EU/1/08/496	4.7.2016
30.6.2016	Hycamtin	Novartis Europharm Limited Frimley Business Park, Camberley GU16 7SR, United Kingdom	EU/1/96/027	4.7.2016
30.6.2016	Janumet	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/455	4.7.2016
30.6.2016	OLYSIO	Janssen-Cilag International NV Turnhoutseweg 30, B-2340 Beerse, België	EU/1/14/924	4.7.2016
30.6.2016	Ristaben	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/10/621	4.7.2016
30.6.2016	Toujeo	Sanofi-Aventis Deutschland GmbH D-65926 Frankfurt am Main, Deutschland	EU/1/00/133	4.7.2016
30.6.2016	Velmetia	Merck Sharp & Dohme Limited Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, United Kingdom	EU/1/08/456	4.7.2016
30.6.2016	Yentreve	Eli Lilly Nederland B.V. Papendorpseweg 83, 3528 BJ Utrecht, Nederland	EU/1/04/280	4.7.2016
30.6.2016	Zarzio	Sandoz GmbH Biochemiestrasse 10, A-6250 Kundl, Österreich	EU/1/08/495	4.7.2016

— **Withdrawal of a marketing authorization** (Article 13 of Regulation (EC) No 726/2004 of the European Parliament and of the Council)

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
1.6.2016	Clopidogrel/Acetylsalicylic acid Teva	Teva Pharma B.V. Swensweg 5, 2031GA Haarlem, Nederland	EU/1/14/942	3.6.2016
21.6.2016	Capecitabine SUN	Sun Pharmaceutical Industries Europe BV Polarisavenue 87, NL-2132 JH Hoofddorp, Nederland	EU/1/13/831	23.6.2016
30.6.2016	Krystexxa	Crealta Pharmaceuticals Ireland Limited Commercial House, Millbank Business Park, Lower Lucan Road, Lucan, Co.Dublin, Ireland	EU/1/12/810	4.7.2016
30.6.2016	Opgenra	Olympus Biotech International Limited 40 Upper Mount Street, Dublin 2, Ireland	EU/1/08/489	4.7.2016

— Issuing of a marketing authorization (Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): **Accepted**

Date of the decision	Name of the medicinal product	INN (International Non-Proprietary Name)	Holder of the marketing authorization	Number of the entry in the Community Register	Pharmaceutical form	ATC code (Anatomical Therapeutic Chemical Code)	Date of notification
21.6.2016	Sevocalm	sevoflurane	Chanelle Pharmaceuticals Manufacturing Limited Loughrea, Co. Galway, Ireland	EU/2/16/196	Inhalation vapour, liquid	Pending	24.6.2016

— **Modification of a marketing authorization** (Article 38 of Regulation (EC) No 726/2004 of the European Parliament and of the Council): **Accepted**

Date of the decision	Name of the medicinal product	Holder of the marketing authorization	Number of the entry in the Community Register	Date of notification
3.6.2016	Nobivac L4	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	EU/2/12/143	7.6.2016
21.6.2016	Emdocam	Emdoka bvba J. Lijsenstraat 16, B-2321 Hoogstraten, België	EU/2/11/128	23.6.2016
21.6.2016	Metacam	Boehringer Ingelheim Vetmedica GmbH D-55216 Ingelheim am Rhein, Deutschland	EU/2/97/004	23.6.2016
22.6.2016	Nobilis Influenza H5N2	Intervet International B.V. Wim de Körverstraat 35, NL-5831 AN Boxmeer, Nederland	EU/2/06/061	24.6.2016
24.6.2016	Loxicom	Norbrook Laboratories Ltd Station Works, Newry, Co. Down, BT35 6JP, United Kingdom	EU/2/08/090	29.6.2016

Anyone wishing to consult the public assessment report on the medicinal products in question and the decisions relating thereto is invited to contact:

European Medicines Agency
30 Churchill Place
Canary Wharf
London E14 5EU
United Kingdom

**Summary of European Union decisions on marketing authorisations in respect of medicinal products
from 1 June 2016 to 30 June 2016**

(Decisions taken pursuant to Article 34 of Directive 2001/83/EC⁽¹⁾ or Article 38 of Directive 2001/82/EC⁽²⁾)

(2016/C 277/02)

— Issuing, maintenance or modification of a national marketing authorization

Date of the decision	Name(s) of the medicinal product	INN (International Non-Proprietary Name)	Holder(s) of the marketing authorization	Member State concerned	Date of notification
29.6.2016	Inhaled corticosteroids	beclomethasone, budesonide, flunisolide, fluticasone propionate, fluticasone furoate	See Annex I	See Annex I	30.6.2016
10.6.2016	CattleMarker IBR Inactivated emulsion for injection	Inactivated gE Bovine Herpes Virus type 1 (BoHV-1), strain Difivac	See Annex II	See Annex II	13.6.2016
24.6.2016	Novantrone and associated names	mitoxantrone	See Annex III	See Annex III	27.6.2016
24.6.2016	Irbesartan	Irbesartan	Not applicable	Not applicable	27.6.2016
29.6.2016	Zoledronic acid	Zoledronic acid	Not applicable	Not applicable	30.6.2016

⁽¹⁾ OJ L 311, 28.11.2001, p. 67.

⁽²⁾ OJ L 311, 28.11.2001, p. 1.

ANNEX I

List of nationally authorised medicinal products

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Austria	3m Health Care Ltd	Aerocortin	Beclometasone Dipropionate 50 µg/50 µl	Pressurised Inhalation, Solution
Austria	Allen Pharmazeutika Gesellschaft M.B.H.	Fluticasonepropionat	Fluticasone Propionate 50 µg Dose	Pressurised Inhalation, Suspension
Austria	Allen Pharmazeutika Gesellschaft M.B.H.	Fluticasonepropionat Diskus Forte Allen	Fluticasone Propionate 500 µg Dose	Inhalation Powder
Austria	Allen Pharmazeutika Gesellschaft M.B.H.	Fluticasonepropionat Diskus Junior Allen	Fluticasone Propionate 100 µg Dose	Inhalation Powder
Austria	Allen Pharmazeutika Gesellschaft M.B.H.	Fluticasonepropionat 'al-len'	Fluticasone Propionate 125 µg Dose	Pressurised Inhalation, Suspension
Austria	Allen Pharmazeutika Gesellschaft M.B.H.	Fluticasonepropionat 'al-len'	Fluticasone Propionate 250 µg Dose	Inhalation Powder
Austria	Allen Pharmazeutika Gesellschaft M.B.H.	Fluticasonepropionat 'al-len'	Fluticasone Propionate 250 µg Dose	Pressurised Inhalation, Suspension
Austria	Allen Pharmazeutika Gesellschaft M.B.H.	Samtoral Diskus Standard	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Austria	Astrazeneca österreich GmbH	Pulmicort	Budesonide 400 µg Dose	Inhalation Powder
Austria	Astrazeneca österreich GmbH	Pulmicort Turbohaler	Budesonide 100 µg Dose	Inhalation Powder

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Austria	Astrazeneca österreich Gmbh	Pulmicort Turbohaler	Budesonide 200 µg Dose	Inhalation Powder
Austria	Astrazeneca österreich Gmbh	Pulmicort Turbohaler	Budesonide 400 µg Dose	Inhalation Powder
Austria	Astrazeneca österreich Gmbh	Symbicort Forte Turbohaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Austria	Astrazeneca österreich Gmbh	Symbicort Turbohaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Austria	Chiesi Pharmaceuticals Gmbh	Budair	Budesonide 0,2 mg/0,05ml	Pressurised Inhalation, Solution
Austria	Chiesi Pharmaceuticals Gmbh	Budair Jet	Budesonide 0,2 mg/0,05 ml	Pressurised Inhalation, Solution
Austria	Chiesi Pharmaceuticals Gmbh	Foster	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Austria	Elpen Pharmaceutical Co. Inc.	Salmeson	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Austria	Elpen Pharmaceutical Co. Inc.	Salmeson	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Austria	Glaxosmithkline Pharma Gmbh.	Flixotide	Fluticasone Propionate 125 µg Inhalation	Pressurised Inhalation, Suspension

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Austria	Glaxosmithkline Pharma Gmbh.	Flixotide	Fluticasone Propionate 250 µg Dose	Inhalation Powder, Pre-Dispensed
Austria	Glaxosmithkline Pharma Gmbh.	Flixotide	Fluticasone Propionate 250 µg Inhalation	Pressurised Inhalation, Suspension
Austria	Glaxosmithkline Pharma Gmbh.	Flixotide Diskus Forte	Fluticasone Propionate 500 µg Dose	Inhalation Powder
Austria	Glaxosmithkline Pharma Gmbh.	Flixotide Diskus Junior	Fluticasone Propionate 100 µg Dose	Inhalation Powder
Austria	Glaxosmithkline Pharma Gmbh.	Flixotide Junior	Fluticasone Propionate 125 µg Inhalation	Pressurised Inhalation, Suspension
Austria	Glaxosmithkline Pharma Gmbh.	Seretide Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Austria	Pari Pharma Gmbh	Buparid	Budesonide 0,25 mg Ampoule	Nebuliser Suspension
Austria	Pari Pharma Gmbh	Buparid	Budesonide 0,5 mg Ampoule	Nebuliser Suspension
Austria	Pari Pharma Gmbh	Buparid	Budesonide 1 mg Ampoule	Nebuliser Suspension
Austria	Sandoz Gmbh	Airflusal Forspiro	Fluticasone Propionate 233 µg Dose, Salmeterol 45 µg Dose	Inhalation Powder

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Austria	Sandoz GmbH	Airflusal Forspiro	Fluticasone Propionate 465 µg Dose, Salmeterol 45 µg Dose	Inhalation Powder
Belgium	Chiesi Sa-Nv	Inuvair	Formoterol Fumarate Dihydrate 6 µg Actuation, Beclomethasone Dipropionate Anhydrous 100 µg Actuation	Pressurised Inhalation, Solution
Belgium	Cipla Europe Nv	Salmeterol/Fluticasone Cipla	Salmeterol 25 µg/Dose; Fluticasone Propionate 125 µg/Dose	Pressurised Inhalation, Suspension
Belgium	Elpen Pharmaceutical Co. Inc.	Flusalio	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Belgium	Elpen Pharmaceutical Co. Inc.	Flusalio	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Belgium	Glaxosmithkline Pharmaceuticals S.A.	Flixotide	Fluticasone Propionate 0,05 mg/2ml	Nebuliser Solution
Belgium	Glaxosmithkline Pharmaceuticals S.A.	Flixotide	Fluticasone Propionate 250 µg Inhalation	Pressurised Inhalation, Suspension
Belgium	Glaxosmithkline Pharmaceuticals S.A.	Flixotide	Fluticasone Propionate 2 mg/2ml	Nebuliser Solution
Belgium	Glaxosmithkline Pharmaceuticals S.A.	Flixotide	Fluticasone Propionate 50 µg Inhalation	Pressurised Inhalation, Suspension
Belgium	Glaxosmithkline Pharmaceuticals S.A.	Flixotide Diskus	Fluticasone Propionate 100 µg Dose	Inhalation Powder

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Belgium	Glaxosmithkline Pharmaceuticals S.A.	Flixotide Diskus	Fluticasone Propionate 250 µg Dose	Inhalation Powder
Belgium	Glaxosmithkline Pharmaceuticals S.A.	Flixotide Diskus	Fluticasone Propionate 500 µg Dose	Inhalation Powder
Belgium	Glaxosmithkline Pharmaceuticals S.A.	Seretide Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Belgium	Nv Astrazeneca Sa	Pulmicort Turbohaler	Budesonide 200 µg Dose	Inhalation Powder
Belgium	Nv Astrazeneca Sa	Symbicort Forte Turbohaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Belgium	Nv Astrazeneca Sa	Symbicort Turbohaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Belgium	Orion Corporation	Buformix Easyhaler	Budesonide 160 µg Inhalation, Formoterol Fumarate Dihydrate 4,5 µg Inhalation	Inhalation Powder
Belgium	Orion Corporation	Buformix Easyhaler	Budesonide 320 µg Inhalation, Formoterol Fumarate Dihydrate 9 µg Inhalation	Inhalation Powder
Belgium	Pari Pharma Gmbh	Buparid	Budesonide 0,25 mg Ampoule	Nebuliser Suspension
Belgium	Pari Pharma Gmbh	Buparid	Budesonide 0,5 mg Ampoule	Nebuliser Suspension

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Belgium	Pari Pharma Gmbh	Buparid	Budesonide 1 mg Ampoule	Nebuliser Suspension
Belgium	Sandoz N.V.	Airflusal Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone 500 µg Dose	Inhalation Powder
Bulgaria	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Bulgaria	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Bulgaria	Chiesi Pharmaceuticals Gmbh	Foster	Formoterol Fumarate Dihydrate 6 µg Actuation, Beclometasone Dipropionate Anhydrous 100 µg Actuation	Pressurised Inhalation, Solution
Bulgaria	Elpen Pharmaceutical Co. Inc.	Flusamer	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Bulgaria	Elpen Pharmaceutical Co. Inc.	Flusamer	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Bulgaria	Glaxosmithkline Eood	Seretide Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Bulgaria	Orion Oyj	Bufomix Easyhaler	Budesonide 160 µg Inhalation, Formoterol Fumarate Dihydrate 4,5 µg Inhalation	Inhalation Powder
Bulgaria	Orion Oyj	Bufomix Easyhaler	Budesonide 320 µg Inhalation, Formoterol Fumarate Dihydrate 9 µg Inhalation	Inhalation Powder
Bulgaria	Sandoz Pharmaceuticals D.D.	Airflusal Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone 500 µg Dose	Inhalation Powder
Bulgaria	Sopharma Ad	Flixotide	Fluticasone Propionate 250 µg Inhalation	Pressurised Inhalation, Suspension
Croatia	Astrazeneca D.O.O	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Croatia	Astrazeneca D.O.O	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Croatia	Clinres Farmacija D.O.O.	Dimenium	Fluticasone Propionate 100 Mcg Dose, Salmeterol Xinafoate 50 Mcg Dose	Inhalation Powder, Pre-Dispensed
Croatia	Clinres Farmacija D.O.O.	Dimenium	Fluticasone Propionate 250 Mcg Dose, Salmeterol Xinafoate 50 Mcg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Croatia	Clinres Farmacija D.O.O.	Dimenium	Fluticasone Propionate 500 Mcg Dose, Salmeterol Xinafoate 50 Mcg Dose	Inhalation Powder, Pre-Dispensed
Croatia	Glaxosmithkline D.O.O.	Salmeterol/Flutikazon-propionat Diskus Glaxosmithkline	Fluticasone Propionate 500 µg Dose, Salmeterol Dose	Inhalation Powder, Pre-Dispensed
Croatia	Glaxosmithkline D.O.O.	Seretide Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Croatia	Providens D.O.O.	Foster	Formoterol Fumarate Dihydrate 6 µg Actuation, Beclometasone Dipropionate Anhydrous 100 µg Actuation	Pressurised Inhalation, Solution
Croatia	Salvus D.O.O.	Saldisk	Fluticasone Propionate 100 Mcg Dose, Salmeterol Xinafoate 50 Mcg Dose	Inhalation Powder, Pre-Dispensed
Croatia	Salvus D.O.O.	Saldisk	Fluticasone Propionate 250 Mcg Dose, Salmeterol Xinafoate 50 Mcg Dose	Inhalation Powder, Pre-Dispensed
Croatia	Salvus D.O.O.	Saldisk	Fluticasone Propionate 500 Mcg Dose, Salmeterol Xinafoate 50 Mcg Dose	Inhalation Powder, Pre-Dispensed
Croatia	Sandoz D.O.O.	Airflusal Forspiro	Fluticasone Propionate 233 µg Dose, Salmeterol 45 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Croatia	Sandoz D.O.O.	Airflusal Forspiro	Fluticasone Propionate 465 µg Dose, Salmeterol 45 µg Dose	Inhalation Powder, Pre-Dispensed
Cyprus	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Cyprus	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Cyprus	Costakis Tsisios & Co. Ltd	Fluticapen	Fluticasone Propionate 250 µg Dose	Inhalation Powder, Pre-Dispensed
Cyprus	Costakis Tsisios & Co. Ltd	Fluticapen	Fluticasone Propionate 500 µg Dose	Inhalation Powder, Pre-Dispensed
Cyprus	Costakis Tsisios & Co. Ltd	Pulmoton	Budesonide 100 µg Dose, Formoterol Fumarate Dihydrate 6 µg Dose	Inhalation Powder, Pre-Dispensed
Cyprus	Costakis Tsisios & Co. Ltd	Pulmoton	Budesonide 200 µg Dose, Formoterol Fumarate Dihydrate 6 µg Dose	Inhalation Powder, Pre-Dispensed
Cyprus	Costakis Tsisios & Co. Ltd	Pulmoton	Budesonide 400 µg Dose, Formoterol Fumarate Dihydrate 12 µg Dose	Inhalation Powder, Pre-Dispensed
Cyprus	Costakis Tsisios & Co. Ltd	Rolenium	Fluticasone Propionate 100 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Cyprus	Costakis Tsisios & Co. Ltd	Rolenium	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Cyprus	Costakis Tsisios & Co. Ltd	Rolenium	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Cyprus	Glaxo Group Limited	Flixotide Diskus	Fluticasone Propionate 100 µg Dose	Inhalation Powder
Cyprus	Glaxo Group Limited	Flixotide Diskus	Fluticasone Propionate 250 µg Dose	Inhalation Powder
Cyprus	Glaxo Group Limited	Seretide	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Cyprus	Orion Corporation	Buformix Easyhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate Ph.Eur. 4,5 µg Dose	Inhalation Powder
Cyprus	Orion Corporation	Buformix Easyhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate Ph.Eur. 9 µg Dose	Inhalation Powder
Cyprus	Orion Corporation	Orest Easyhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate Ph.Eur. 4,5 µg Dose	Inhalation Powder
Cyprus	Orion Corporation	Orest Easyhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate Ph.Eur. 9 µg Dose	Inhalation Powder
Czech Republic	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Czech Republic	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Czech Republic	Chiesi Pharmaceuticals GmbH	Combair	Formoterol Fumarate Dihydrate 1,08 Mg, Beclomethasone Dipropionate 18 Mg	Pressurised Inhalation, Solution
Czech Republic	Elpen Pharmaceutical Co. Inc.	Dimenium	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Czech Republic	Elpen Pharmaceutical Co. Inc.	Dimenium	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Czech Republic	Glaxo Group Limited	Flixotide	Fluticasone Propionate 125 µg	Pressurised Inhalation, Suspension
Czech Republic	Glaxo Group Limited	Flixotide	Fluticasone Propionate 250 µg	Pressurised Inhalation, Suspension
Czech Republic	Glaxo Group Limited	Flixotide	Fluticasone Propionate 50 µg	Pressurised Inhalation, Suspension
Czech Republic	Glaxo Group Limited	Flixotide Diskus	Fluticasone Propionate 100 µg	Inhalation Powder
Czech Republic	Glaxo Group Limited	Flixotide Diskus	Fluticasone Propionate 250 µg	Inhalation Powder
Czech Republic	Glaxo Group Limited	Flixotide Diskus	Fluticasone Propionate 500 µg	Inhalation Powder

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Czech Republic	Glaxo Group Limited	Seretide Diskus	Fluticasone Propionate 500 µg, Salmeterol Xinafoate 72,5 µg	Inhalation Powder
Czech Republic	Sandoz S.R.O.	Airflusan Forspiro	Fluticasone Propionate 0,25 Mg, Salmeterol Xinafoate 0,073 Mg	Inhalation Powder, Pre-Dispensed
Czech Republic	Sandoz S.R.O.	Airflusan Forspiro	Fluticasone Propionate 0,5 Mg, Salmeterol Xinafoate 0,073 Mg	Inhalation Powder, Pre-Dispensed
Denmark	Astrazeneca A-S	Symbicort Forte Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Denmark	Astrazeneca A-S	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Denmark	Chiesi Farmaceutici S.P.A.	Innovair	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Denmark	Elpen Pharmaceutical Co. Inc.	Flusaterol	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Denmark	Elpen Pharmaceutical Co. Inc.	Flusaterol	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose, Lactose Monohydrate 24,677 mg Dose	Inhalation Powder, Pre-Dispensed
Denmark	Glaxosmithkline Pharma A-S	Seretide	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Denmark	Orion Oyj	Bufomix Easyhaler	Budesonide 160 µg Inhalation, Formoterol Fumarate Dihydrate 4,5 µg Inhalation	Inhalation Powder
Denmark	Orion Oyj	Bufomix Easyhaler	Budesonide 320 µg Inhalation, Formoterol Fumarate Dihydrate 9 µg Inhalation	Inhalation Powder
Denmark	Sandoz A-S	Airflusal Forspiro	Fluticasone Propionate 233 µg Dose, Salmeterol 45 µg Dose	Inhalation Powder, Pre-Dispensed
Denmark	Sandoz A-S	Airflusal Forspiro	Fluticasone Propionate 465 µg Dose, Salmeterol 45 µg Dose	Inhalation Powder, Pre-Dispensed
Estonia	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Estonia	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Estonia	Chiesi Pharmaceuticals Gmbh	Foster	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Estonia	Elpen Pharmaceutical Co. Inc.	Flusamer	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Estonia	Elpen Pharmaceutical Co. Inc.	Flusamer	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Estonia	Glaxo Wellcome Ltd	Flixotide Diskus	Fluticasone Propionate 250 µg Dose	Inhalation Powder
Estonia	Glaxo Wellcome Ltd	Seretide Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Estonia	Sandoz Pharmaceuticals D.D.	Airflusal Forspiro	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Estonia	Sandoz Pharmaceuticals D.D.	Airflusal Forspiro	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Finland	Astrazeneca Oy	Symbicort Forte Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Finland	Astrazeneca Oy	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Finland	Chiesi Farmaceutici S.P.A.	Innovair	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Finland	Chiesi Farmaceutici S.P.A.	Innovair Nexthaler	Formoterol Fumarate Dihydrate 6 µg Dose, Beclometasone Dipropionate Anhydrous 100 µg Dose	Inhalation Powder
Finland	Elpen Pharmaceutical Co. Inc.	Salmeson	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Finland	Elpen Pharmaceutical Co. Inc.	Salmeson	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Finland	Glaxosmithkline Oy	Seretide Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Finland	Orion Oyj	Buformix Easyhaler	Budesonide 160 µg Inhalation, Formoterol Fumarate Dihydrate 4,5 µg Inhalation	Inhalation Powder
Finland	Orion Oyj	Buformix Easyhaler	Budesonide 320 µg Inhalation, Formoterol Fumarate Dihydrate 9 µg Inhalation	Inhalation Powder
France	Astrazeneca France	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
France	Astrazeneca France	Symbicort Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
France	Chiesi S.A.	Formodual	Formoterol Fumarate Dihydrate 6 µg Dose, Beclomethasone Dipropionate Anhydrous 100 µg Dose	Pressurised Inhalation, Solution
France	Chiesi S.A.	Innovair	Formoterol Fumarate Dihydrate 6 µg Dose, Beclomethasone Dipropionate Anhydrous 100 µg Dose	Pressurised Inhalation, Solution
France	Laboratoire Glaxosmithkline S.A.S.	Seretide Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Germany	3m Health Care Ltd	Bronchocort Novo	Beclometasone Dipropionate 100 µg/50 µl	Pressurised Inhalation, Solution
Germany	3m Health Care Ltd	Junik	Beclometasone Dipropionate 100 µg Actuation	Pressurised Inhalation, Solution
Germany	Abz-Pharma Gmbh	Beclomethasone Dipropionate Ct	Beclometasone Dipropionate 0,05 mg/18,7 G	Pressurised Inhalation, Solution
Germany	Meda Pharma Gmbh & Co. Kg	Budecort Novolizer	Budesonide, Micronised 0,2 mg Actuation	Inhalation Powder
Germany	Meda Pharma Gmbh & Co. Kg	Budecort Novolizer	Budesonide, Micronised 0,4 mg Actuation	Inhalation Powder
Germany	Astrazeneca Gmbh	Pulmicort Budesonide	Budesonide 0,5 Mg	Nebuliser Suspension
Germany	Astrazeneca Gmbh	Pulmicort Budesonide	Budesonide 1,0 Mg	Nebuliser Suspension
Germany	Astrazeneca Gmbh	Pulmicort	Budesonide 400 µg Dose	Inhalation Powder
Germany	Astrazeneca Gmbh	Pulmicort Turbohaler	Budesonide 200 µg Dose	Inhalation Powder
Germany	Astrazeneca Gmbh	Symbicort Turbohaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Germany	Astrazeneca Gmbh	Symbicort Turbohaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Germany	Chiesi Farmaceutici S.P.A.	Kantos	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Germany	Chiesi Farmaceutici S.P.A.	Kantos Master	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Germany	Chiesi Gmbh	Budair	Budesonide 200 µg Spray	Pressurised Inhalation, Solution
Germany	Chiesi Gmbh	Foster	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Germany	Chiesi Gmbh	Ribuvent	Budesonide 200 µg Puff	Pressurised Inhalation, Solution
Germany	Chiesi Gmbh	Sanasthmax	Beclometasone Dipropionate 250 µg/59,2 Mg	Pressurised Inhalation, Solution
Germany	Chiesi Gmbh	Sanasthmax Junior	Beclometasone Dipropionate 50 µg/59 Mg	Pressurised Inhalation, Solution
Germany	Elpen Pharmaceutical Co. Inc.	Flusalio	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Germany	Elpen Pharmaceutical Co. Inc.	Flusalio	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Germany	Elpen Pharmaceutical Co. Inc.	Rolenium	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Germany	Elpen Pharmaceutical Co. Inc.	Rolenium	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Germany	Glaxosmithkline Gmbh & Co. Kg	Flixotide Diskus	Fluticasone Propionate 250 µg Dose	Inhalation Powder
Germany	Glaxosmithkline Gmbh & Co. Kg	Flixotide Forte	Fluticasone Propionate 250 µg Inhalation	Pressurised Inhalation, Suspension
Germany	Glaxosmithkline Gmbh & Co. Kg	Flixotide Forte Diskus	Fluticasone Propionate 500 µg Dose	Inhalation Powder
Germany	Glaxosmithkline Gmbh & Co. Kg	Flutide Diskus	Fluticasone Propionate 250 µg Dose	Inhalation Powder, Pre-Dispensed
Germany	Glaxosmithkline Gmbh & Co. Kg	Flutide Forte	Fluticasone Propionate 220 µg Puff	Pressurised Inhalation, Suspension
Germany	Glaxosmithkline Gmbh & Co. Kg	Flutide Forte Diskus	Fluticasone Propionate 500 µg Dose	Inhalation Powder, Pre-Dispensed
Germany	Glaxosmithkline Gmbh & Co. Kg	Viani Forte	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Germany	Heumann Pharma Gmbh & Co. Generica Kg	Budesonid	Budesonide 0,2 Mg	Inhalation Powder
Germany	Hexal Ag	Airflusal Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone 500 µg Dose	Inhalation Powder

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Germany	Hexal Ag	Budes N	Budesonide 0,2 mg Dose	Pressurised Inhalation, Solution
Germany	Janssen-Cilag GmbH	Inuvair	Beclometasone Dipropionate 100 µg Inhalation, Formoterol Fumarate 6 µg Inhalation	Pressurised Inhalation, Solution
Germany	Meda Pharma GmbH & Co. Kg	Budesonid Novolizer Meda Pharma GmbH & Co. Kg	Budesonide 400 µg Inhalation	Inhalation Powder
Germany	Meda Pharma GmbH & Co. Kg	Novopulmon Novolizer	Budesonide 200 µg Dose	Inhalation Powder
Germany	Meda Pharma GmbH & Co. Kg	Novopulmon Novolizer	Budesonide 400 µg Dose	Inhalation Powder
Germany	Mylan Dura GmbH	Budesonid Mylan	Budesonide 0,2 Mg	Inhalation Powder
Germany	Orion Corporation	Beclomet Easyhaler	Beclometasone Dipropionate 0,2 mg Dose	Inhalation Powder
Germany	Pari Pharma GmbH	Buparid	Budesonide 0,25 mg Ampoule	Nebuliser Suspension
Germany	Pari Pharma GmbH	Buparid	Budesonide 0,5 mg Ampoule	Nebuliser Suspension
Germany	Pari Pharma GmbH	Buparid	Budesonide 1 mg Ampoule	Nebuliser Suspension
Germany	Pb Pharma GmbH	Budesonid	Budesonide 0,92 Mg	Inhalation Powder, Hard Capsule

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Germany	Pb Pharma Gmbh	Cyclocaps Beclometason	Beclometasone Dipropionate 100 µg Units	Inhalation Powder, Hard Capsule
Germany	Pb Pharma Gmbh	Cyclocaps Beclometason	Beclometasone Dipropionate 200 µg Units	Inhalation Powder, Hard Capsule
Germany	Pb Pharma Gmbh	Cyclocaps Beclometason	Beclometasone Dipropionate 400 µg Units	Inhalation Powder, Hard Capsule
Germany	Pb Pharma Gmbh	Cyclocaps Budesonid	Budesonide 0,8 mg Capsule	Inhalation Powder, Hard Capsule
Germany	Pb Pharma Gmbh	Cyclocaps Budesonid	Budesonide 100 µg Units	Inhalation Powder, Hard Capsule
Germany	Pb Pharma Gmbh	Cyclocaps Budesonid	Budesonide 800 µg Units	Inhalation Powder, Hard Capsule
Germany	Ratiopharm Gmbh	Beclometason Ratiopharm	Beclometasone Dipropionate 0,25 mg/18,7 g	Pressurised Inhalation, Solution
Germany	Ratiopharm Gmbh	Beclomethasone Dipropionate Ratiopharm	Beclometasone Dipropionate 0,05 mg/18,7 g	Pressurised Inhalation, Solution
Germany	Ratiopharm Gmbh	Beclomethasone Dipropionate Ratiopharm	Beclometasone Dipropionate 0,1 mg/18,7 g	Pressurised Inhalation, Solution
Germany	Ratiopharm Gmbh	Beclomethasone Dipropionate Ratiopharm	Beclometasone Dipropionate 0,2 mg/18,7 g	Pressurised Inhalation, Solution
Germany	Teva Gmbh	Aerobec N	Beclometasone Dipropionate 100 g/5ml	Pressurised Inhalation, Solution

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Germany	Teva Gmbh	Beclometason-Ct	Beclometasone Dipropionate 0,1 Mg	Pressurised Inhalation, Solution
Germany	Teva Gmbh	Beclometason-Ct	Beclometasone Dipropionate 0,2 Mg	Pressurised Inhalation, Solution
Germany	Teva Gmbh	Ventolair	Beclometasone Dipropionate 100 g/10ml	Pressurised Inhalation, Solution
Germany	Teva Gmbh	Ventolair	Beclometasone Dipropionate 100 g/18,7 g	Pressurised Inhalation, Solution
Germany	Teva Gmbh	Ventolair	Beclometasone Dipropionate 100 g/5ml	Pressurised Inhalation, Solution
Germany	Teva Gmbh	Ventolair	Beclometasone Dipropionate 250 g/18,7 g	Pressurised Inhalation, Solution
Germany	Teva Gmbh	Ventolair	Beclometasone Dipropionate 250 g/78 mg	Pressurised Inhalation, Solution
Germany	Teva Gmbh	Ventolair Mite	Beclometasone Dipropionate 50 g/18,7 g	Pressurised Inhalation, Solution
Germany	Teva Gmbh	Ventolair Mite	Beclometasone Dipropionate 50 g/78 mg	Pressurised Inhalation, Solution
Germany	Ucb Pharma Gmbh (Monheim De)	Atmadisc Forte Diskus	Fluticasone Propionate 500 µg Inhalation, Salmeterol 50 µg Inhalation	Inhalation Powder
Greece	Anfarm Hellas Sa	Talgan	Budesonide 100 µg Dose	Inhalation Powder
Greece	Astrazeneca S.A.	Pulmicort Turbuhaler	Budesonide 100 µg Dose	Inhalation Powder
Greece	Astrazeneca S.A.	Pulmicort Turbuhaler	Budesonide 200 µg Dose	Inhalation Powder
Greece	Astrazeneca S.A.	Pulmicort Turbuhaler	Budesonide 400 µg Dose	Inhalation Powder

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Greece	Astrazeneca S.A.	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Greece	Astrazeneca S.A.	Symbicort Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Greece	Chiesi Hellas A.E.B.E.	Foster	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Greece	Chiesi Hellas A.E.B.E.	Foster Nexthaler	Formoterol Fumarate Dihydrate 6 µg Dose, Beclometasone Dipropionate Anhydrous 100 µg Dose	Inhalation Powder
Greece	Chiesi Hellas A.E.B.E.	Inuvair	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Greece	Chiesi Hellas A.E.B.E.	Inuvair Nexthaler	Formoterol Fumarate Dihydrate 6 µg Dose, Beclometasone Dipropionate Anhydrous 100 µg Dose	Inhalation Powder
Greece	D.A.S.T. Biotech Pharm ερε	Flihaler	Fluticasone Propionate 250mcg/Dose	Pressurised Inhalation, Suspension
Greece	Elpen Pharmaceutical Co. Inc.	Fluticapen	Fluticasone Propionate 250 µg Dose	Inhalation Powder, Pre-Dispensed
Greece	Elpen Pharmaceutical Co. Inc.	Fluticapen	Fluticasone Propionate 500 µg Dose	Inhalation Powder, Pre-Dispensed
Greece	Elpen Pharmaceutical Co. Inc.	Pulmoton	Budesonide 100 µg Dose, Formoterol Fumarate Dihydrate 6 µg Dose	Inhalation Powder, Pre-Dispensed
Greece	Elpen Pharmaceutical Co. Inc.	Pulmoton	Budesonide 200 µg Dose, Formoterol Fumarate Dihydrate 6 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Greece	Elpen Pharmaceutical Co. Inc.	Pulmoton	Budesonide 400 µg Dose, Formoterol Fumarate Dihydrate 12 µg Dose	Inhalation Powder, Pre-Dispensed
Greece	Elpen Pharmaceutical Co. Inc.	Rolenium	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Greece	Elpen Pharmaceutical Co. Inc.	Rolenium	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Greece	Glaxosmithkline Aebe	Flixotide	Fluticasone Propionate 100 µg Dose	Inhalation Powder
Greece	Glaxosmithkline Aebe	Flixotide	Fluticasone Propionate 125 µg Dose	Pressurised Inhalation
Greece	Glaxosmithkline Aebe	Flixotide	Fluticasone Propionate 250 µg Dose	Inhalation Powder
Greece	Glaxosmithkline Aebe	Flixotide	Fluticasone Propionate 250 µg Dose	Pressurised Inhalation
Greece	Glaxosmithkline Aebe	Flixotide	Fluticasone Propionate 500 µg Dose	Inhalation Powder
Greece	Glaxosmithkline Aebe	Flixotide	Fluticasone Propionate 50 µg Dose	Pressurised Inhalation
Greece	Glaxosmithkline Aebe	Flixotide Diskus	Fluticasone Propionate 100 µg Dose	Inhalation Powder
Greece	Glaxosmithkline Aebe	Flixotide Diskus	Fluticasone Propionate 250 µg Dose	Inhalation Powder
Greece	Glaxosmithkline Aebe	Flixotide Diskus	Fluticasone Propionate 500 µg Dose	Inhalation Powder
Greece	Glaxosmithkline Aebe	Seretide	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Greece	Iasis Pharma	Olfo Haler	Budesonide 200 µg Dose	Inhalation Powder
Greece	Iasis Pharma	Olfo Haler	Budesonide 400 µg Dose	Inhalation Powder
Greece	Medicair Bioscience Laboratories S.A	Bocacort-S	Fluticasone Propionate 250mcg/Dose	Pressurised Inhalation, Suspension
Greece	Orion Corporation	Bufo mix	Budosenide 160mcg, Formoterol Fumarate Dihydrate 4,5mcg	Inhalation Powder
Greece	Orion Corporation	Bufo mix	Budosenide 320mcg, Formoterol Fumarate Dihydrate 9mcg	Inhalation Powder
Greece	Orion Corporation	Orest	Budosenide 160mcg, Formoterol Fumarate Dihydrate 4,5mcg	Inhalation Powder
Greece	Orion Corporation	Orest	Budosenide 320mcg, Formoterol Fumarate Dihydrate 9mcg	Inhalation Powder
Greece	Png Gerolymatos Medical A.E.	Asmaflex	Fluticasone Propionate 250mgg	Pressurised Inhalation, Suspension
Greece	Rafarm Sa.	Resata	Budesonide 200 µg Dose	Inhalation Powder, Pre-Dispensed
Greece	Rafarm Sa.	Resata	Budesonide 400 µg Dose	Inhalation Powder, Pre-Dispensed
Greece	Verisfield (Uk) Ltd	Flixocort	Fluticasone Propionate 50 µg Dose	Nasal Spray, Suspension
Greece	Verisfield (Uk) Ltd	Flixocort	Fluticasone Propionate 125 µg Dose	Pressurised Inhalation, Suspension
Greece	Verisfield (Uk) Ltd	Flixocort	Fluticasone Propionate 250 µg Dose	Pressurised Inhalation, Suspension
Greece	Verisfield (Uk) Ltd	Pulmihal	Budesonide 200 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Greece	Win Medica Ltd	Flusalair	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder
Greece	Win Medica Ltd	Flusalair	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Greece	Win Medica Ltd	Flutiresp	Fluticasone Propionate 250mcg/Dose	Inhalation Powder
Greece	Win Medica Ltd	Flutiresp	Fluticasone Propionate 500 µg Inhalation	Inhalation Powder
Greece	Zwitter Pharmaceuticals επε	Salenga	Fluticasone Propionate 250 µg Dose	Pressurised Inhalation, Suspension
Greece	Pharmanel Commercial Pharmaceutical S.A.	Vernoral	Budesonide 200 µg Dose	Inhalation Powder
Greece	Pharmanel Commercial Pharmaceutical S.A.	Vernoral	Budesonide 400 µg Dose	Inhalation Powder
Hungary	Astrazeneca Kft.	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Hungary	Astrazeneca Kft.	Symbicort Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Hungary	Chiesi Pharmaceuticals Gmbh	Formodual	Formoterol Fumarate Dihydrate 6 µg Actuation, Beclometasone Dipropionate Anhydrous 100 µg Actuation	Pressurised Inhalation, Solution
Hungary	Chiesi Pharmaceuticals Gmbh	Foster	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Hungary	Elpen Pharmaceutical Co. Inc.	Dimenio	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder
Hungary	Elpen Pharmaceutical Co. Inc.	Dimenio	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder
Hungary	Elpen Pharmaceutical Co. Inc.	Flumetor	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Hungary	Elpen Pharmaceutical Co. Inc.	Flumetor	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Hungary	Glaxosmithkline Kft.	Seretide Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Hungary	Montrose Kft	Thoreus Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Hungary	Orion Oyj	Buformix Easyhaler	Budesonide 160 µg Inhalation, Formoterol Fumarate Dihydrate 4,5 µg Inhalation	Inhalation Powder
Hungary	Orion Oyj	Buformix Easyhaler	Budesonide 320 µg Inhalation, Formoterol Fumarate Dihydrate 9 µg Inhalation	Inhalation Powder
Hungary	Sandoz Hungária Kft	Airflusol Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone 500 µg Dose	Inhalation Powder
Iceland	Astrazeneca A-S	Symbicort Forte Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Iceland	Astrazeneca A-S	Symbicort Mite Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Iceland	Elpen Pharmaceutical Co. Inc.	Relanio	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Iceland	Elpen Pharmaceutical Co. Inc.	Relanio	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Iceland	Glaxosmithkline Ehf.	Flixotide	Fluticasone Propionate 250 µg Dose	Pressurised Inhalation, Suspension
Iceland	Glaxosmithkline Ehf.	Flixotide Diskus	Fluticasone Propionate 100 µg Dose	Inhalation Powder
Iceland	Glaxosmithkline Ehf.	Flixotide Diskus	Fluticasone Propionate 250 µg Dose	Inhalation Powder
Iceland	Glaxosmithkline Ehf.	Flixotide Diskus	Fluticasone Propionate 500 µg Dose	Inhalation Powder
Iceland	Glaxosmithkline Ehf.	Seretide Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Ireland	Astrazeneca Uk Limited	Pulmicort Turbohaler	Budesonide 100 µg Dose	Inhalation Powder
Ireland	Astrazeneca Uk Limited	Pulmicort Turbohaler	Budesonide 200 µg Dose	Inhalation Powder
Ireland	Astrazeneca Uk Limited	Pulmicort Turbohaler	Budesonide 400 µg Dose	Inhalation Powder
Ireland	Astrazeneca Uk Limited	Symbicort Turbohaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Ireland	Astrazeneca Uk Limited	Symbicort Turbohaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Ireland	Elpen Pharmaceutical Co. Inc.	Flamerio	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Ireland	Elpen Pharmaceutical Co. Inc.	Flamerio	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose, Lactose Monohydrate 24,677 mg Dose	Inhalation Powder, Pre-Dispensed
Ireland	Glaxosmithkline (Ireland) Limited	Flixotide Diskus	Fluticasone Propionate 250 µg Blister	Inhalation Powder, Pre-Dispensed
Ireland	Glaxosmithkline (Ireland) Limited	Flixotide Diskus	Fluticasone Propionate 500 µg Blister	Inhalation Powder, Pre-Dispensed
Ireland	Glaxosmithkline (Ireland) Limited	Flixotide Evohaler	Fluticasone Propionate 250 µg Dose	Pressurised Inhalation, Suspension
Ireland	Glaxosmithkline (Ireland) Limited	Seretide Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Ireland	Glaxosmithkline (Ireland) Limited	Viani Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Ireland	Orion Oyj	Bufomix Easyhaler	Budesonide 160 µg Inhalation, Formoterol Fumarate Dihydrate 4,5 µg Inhalation	Inhalation Powder
Ireland	Orion Oyj	Bufomix Easyhaler	Budesonide 320 µg Inhalation, Formoterol Fumarate Dihydrate 9 µg Inhalation	Inhalation Powder

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Ireland	Rowex Ltd	Airflusal Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone 250 µg Dose	Inhalation Powder
Ireland	Rowex Ltd	Airflusal Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone 500 µg Dose	Inhalation Powder
Italy	Astrazeneca S.P.A	Sinestic	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Italy	Astrazeneca S.P.A	Sinestic	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Italy	Astrazeneca S.P.A	Symbicort	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Italy	Astrazeneca S.P.A	Symbicort	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Italy	Elpen Pharmaceutical Co. Inc.	Flamerio	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Italy	Elpen Pharmaceutical Co. Inc.	Flamerio	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Italy	Elpen Pharmaceutical Co. Inc.	Rolenium	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Italy	Elpen Pharmaceutical Co. Inc.	Rolenium	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Italy	Glaxosmithkline S.P.A.	Seretide	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Italy	Menarini International Operations Luxembourg S.A.	Aliflus Diskus	Fluticasone Propionate 100 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Italy	Menarini International Operations Luxembourg S.A.	Aliflus Diskus	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Italy	Menarini International Operations Luxembourg S.A.	Aliflus Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Italy	Promedica S.R.L.	Clenil Compositum	Beclometasone Dipropionate 0,8 mg/2 Ml, Salbutamol Sulfate 1,928 mg/2 Ml	Nebuliser Suspension
Italy	Promedica S.R.L.	Clenil Compositum	Beclometasone Dipropionate 50 µg Actuation, Salbutamol Sulfate 120 µg Actuation	Pressurised Inhalation, Solution
Italy	Simesa S.P.A.	Assieme	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Italy	Simesa S.P.A.	Assieme	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Italy	Valeas S.P.A.	Plenaer	Flunisolide 25 mg Bottle, Salbutamol 10 mg Bottle	Pressurised Inhalation, Suspension
Italy	Valeas S.P.A.	Plenaer	Salbutamol Sulfate 0,602 mg Vial, Flunisolide 0,5 mg Vial	Nebuliser Solution
Latvia	Astrazeneca Ab	Pulmicort Turbuhaler	Budesonide 100 µg Dose	Inhalation Powder

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Latvia	Astrazeneca Ab	Pulmicort Turbuhaler	Budesonide 200 µg Dose	Inhalation Powder
Latvia	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Latvia	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Latvia	Chiesi Pharmaceuticals GmbH	Foster	Beclomethasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Latvia	Elpen Pharmaceutical Co. Inc.	Flamerio	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Latvia	Elpen Pharmaceutical Co. Inc.	Flamerio	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Latvia	Glaxosmithkline Latvia Sia	Flixotide	Fluticasone Propionate 250 µg Inhalation	Pressurised Inhalation, Suspension
Latvia	Glaxosmithkline Latvia Sia	Flixotide Diskus	Fluticasone Propionate 250 µg Dose	Inhalation Powder
Latvia	Glaxosmithkline Latvia Sia	Flixotide Diskus	Fluticasone Propionate 500 µg Dose	Inhalation Powder
Latvia	Glaxosmithkline Latvia Sia	Flosal	Fluticasone Propionate 250 µg Inhalation, Salmeterol Xinafoate 25 µg Inhalation	Pressurised Inhalation, Suspension
Latvia	Glaxosmithkline Latvia Sia	Flosal	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder
Latvia	Glaxosmithkline Latvia Sia	Seretide	Fluticasone Propionate 250 µg Inhalation, Salmeterol Xinafoate 25 µg Inhalation	Pressurised Inhalation, Suspension

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Latvia	Glaxosmithkline Latvia Sia	Seretide	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder
Latvia	Novartis Finland Oy	Miflonide	Budesonide 200 µg	Inhalation Powder, Hard Capsule
Latvia	Novartis Finland Oy	Miflonide	Budesonide 400 µg	Inhalation Powder, Hard Capsule
Latvia	Orion Corporation	Buformix Easyhaler	Budesonide 160 µg Inhalation, Formoterol Fumarate Dihydrate 4,5 µg Inhalation	Inhalation Powder
Latvia	Orion Corporation	Buformix Easyhaler	Budesonide 320 µg Inhalation, Formoterol Fumarate Dihydrate 9 µg Inhalation	Inhalation Powder
Latvia	Sandoz Pharmaceuticals D.D.	Airflusal Forspiro	Fluticasone Propionate 233 µg Dose, Salmeterol 45 µg Dose	Inhalation Powder, Pre-Dispensed
Latvia	Sandoz Pharmaceuticals D.D.	Airflusal Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone 500 µg Dose	Inhalation Powder, Pre-Dispensed
Lithuania	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Lithuania	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Lithuania	Chiesi Pharmaceuticals Gmbh	Foster	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Lithuania	Elpen Pharmaceutical Co. Inc.	Flamerio	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Lithuania	Elpen Pharmaceutical Co. Inc.	Flamerio	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Lithuania	Glaxosmithkline Lietuva Uab	Flixotide	Fluticasone Propionate 250 µg Inhalation	Pressurised Inhalation, Suspension
Lithuania	Glaxosmithkline Lietuva Uab	Flixotide Diskus	Fluticasone Propionate 250 µg Dose	Inhalation Powder, Pre-Dispensed
Lithuania	Glaxosmithkline Lietuva Uab	Flixotide Diskus	Fluticasone Propionate 500 µg Dose	Inhalation Powder, Pre-Dispensed
Lithuania	Glaxosmithkline Lietuva Uab	Seretide	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Lithuania	Novartis Finland Oy	Mifflonide	Budesonide 200 µg	Inhalation Powder, Hard Capsule
Lithuania	Novartis Finland Oy	Mifflonide	Budesonide 400 µg	Inhalation Powder, Hard Capsule
Lithuania	Orion Oyj	Buformix Easyhaler	Budesonide 160 µg Inhalation, Formoterol Fumarate Dihydrate 4,5 µg Inhalation	Inhalation Powder
Lithuania	Orion Oyj	Buformix Easyhaler	Budesonide 160 µg, Formoterol Fumarate Dihydrate 4,5 µg	Inhalation Powder
Lithuania	Orion Oyj	Buformix Easyhaler	Budesonide 320 µg Inhalation, Formoterol Fumarate Dihydrate 9 µg Inhalation	Inhalation Powder
Lithuania	Orion Oyj	Buformix Easyhaler	Budesonide 320 µg, Formoterol Fumarate Dihydrate 9 µg	Inhalation Powder
Lithuania	Sandoz Pharmaceuticals D.D.	Airflusal Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone 250 µg Dose	Inhalation Powder

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Lithuania	Sandoz Pharmaceuticals D.D.	Airflusal Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone 500 µg Dose	Inhalation Powder
Luxembourg	Chiesi Sa-Nv	Inuvair	Formoterol Fumarate Dihydrate 6 µg Actuation, Beclometasone Dipropionate Anhydrous 100 µg Actuation	Pressurised Inhalation, Solution
Luxembourg	Elpen Pharmaceutical Co. Inc.	Flusamer	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Luxembourg	Elpen Pharmaceutical Co. Inc.	Flusamer	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Luxembourg	Glaxosmithkline Pharmaceuticals S.A.	Flixotide	Fluticasone Propionate 250 µg Inhalation	Pressurised Inhalation, Suspension
Luxembourg	Glaxosmithkline Pharmaceuticals S.A.	Flixotide	Fluticasone Propionate 50 µg Inhalation	Pressurised Inhalation, Suspension
Luxembourg	Glaxosmithkline Pharmaceuticals S.A.	Flixotide Diskus	Fluticasone Propionate 100 µg Dose	Inhalation Powder
Luxembourg	Glaxosmithkline Pharmaceuticals S.A.	Flixotide Diskus	Fluticasone Propionate 250 µg Dose	Inhalation Powder
Luxembourg	Glaxosmithkline Pharmaceuticals S.A.	Flixotide Diskus	Fluticasone Propionate 500 µg Dose	Inhalation Powder
Luxembourg	Glaxosmithkline Pharmaceuticals S.A.	Seretide Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Luxembourg	Nv Astrazeneca Sa	Pulmicort Turbohaler	Budesonide 200 µg Dose	Inhalation Powder
Luxembourg	Nv Astrazeneca Sa	Symbicort Turbohaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Luxembourg	Nv Astrazeneca Sa	Symbicort Forte Turbohaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Luxembourg	Orion Corporation	BufoMix Easyhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate Ph.Eur. 4,5 µg Dose	Inhalation Powder
Luxembourg	Orion Corporation	BufoMix Easyhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate Ph.Eur. 9 µg Dose	Inhalation Powder
Luxembourg	Orion Corporation	Orest Easyhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate Ph.Eur. 4,5 µg Dose	Inhalation Powder
Luxembourg	Orion Corporation	Orest Easyhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate Ph.Eur. 9 µg Dose	Inhalation Powder
Malta	Astrazeneca Ab	Pulmicort Turbuhaler	Budesonide 100 µg Dose	Inhalation Powder
Malta	Astrazeneca Ab	Pulmicort Turbuhaler	Budesonide 200 µg Dose	Inhalation Powder
Malta	Astrazeneca Ab	Symbicort Turbohaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Malta	Astrazeneca Ab	Symbicort Turbohaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Malta	Elpen Pharmaceutical Co. Inc.	Rolenium	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Malta	Elpen Pharmaceutical Co. Inc.	Rolenium	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Malta	Glaxosmithkline (Ireland) Limited	Flixotide Evohaler	Fluticasone Propionate 250 µg Dose	Pressurised Inhalation, Suspension
Malta	Glaxosmithkline (Ireland) Limited	Seretide Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Malta	Novartis Pharmaceuticals UK Limited	Miflonide	Budesonide 200 µg Capsule	Inhalation Powder, Hard Capsule
Malta	Novartis Pharmaceuticals UK Limited	Miflonide	Budesonide 400 µg	Inhalation Powder, Hard Capsule
Malta	Orion Oyj	Buformix Easyhaler	Budesonide 160 µg Inhalation, Formoterol Fumarate Dihydrate 4,5 µg Inhalation	Inhalation Powder
Malta	Orion Oyj	Buformix Easyhaler	Budesonide 320 µg Inhalation, Formoterol Fumarate Dihydrate 9 µg Inhalation	Inhalation Powder

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Malta	Orion Oyj	Orest Easyhaler	Budesonide 160 µg Inhalation, Formoterol Fumarate Dihydrate 4,5 µg Inhalation	Inhalation Powder
Malta	Orion Oyj	Orest Easyhaler	Budesonide 320 µg Inhalation, Formoterol Fumarate Dihydrate 9 µg Inhalation	Inhalation Powder
Netherlands	Astrazeneca Bv	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Netherlands	Astrazeneca Bv	Symbicort Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Netherlands	Glaxosmithkline B.V.	Fluticasonepropionate Inhalator GSK	Fluticasone Propionate 125 µg Dose	Aerosol
Netherlands	Glaxosmithkline B.V.	Fluticasonepropionate Inhalator GSK	Fluticasone Propionate 250 µg Dose	Aerosol
Netherlands	Glaxosmithkline B.V.	Fluticasonepropionate Inhalator GSK	Fluticasone Propionate 50 µg Dose	Aerosol
Netherlands	Chiesi Pharmaceuticals B.V.	Formodual	Formoterol Fumarate Dihydrate 6 µg Actuation, Beclometasone Dipropionate Anhydrous 100 µg Actuation	Pressurised Inhalation, Solution
Netherlands	Chiesi Pharmaceuticals B.V.	Foster	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Netherlands	Elpen Pharmaceutical Co. Inc.	Salmeterol/Fluticasonepropionate Elpen	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Netherlands	Elpen Pharmaceutical Co. Inc.	Salmeterol/Fluticasone-propionate Elpen	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Netherlands	Glaxosmithkline B.V.	Flixotide	Fluticasone Propionate 250 µg Inhalation	Pressurised Inhalation, Suspension
Netherlands	Glaxosmithkline B.V.	Flixotide Diskus	Fluticasone Propionate 500 µg Dose	Inhalation Powder, Pre-Dispensed
Netherlands	Glaxosmithkline B.V.	Seretide	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Norway	Astrazeneca As	Symbicort Forte Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Norway	Astrazeneca As	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Norway	Chiesi Farmaceutici S.P.A.	Inuxair	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Norway	Elpen Pharmaceutical Co. Inc.	Salmeson	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Norway	Elpen Pharmaceutical Co. Inc.	Salmeson	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Norway	Glaxosmithkline As	Seretide Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Norway	Sandoz A-S	Airflusal Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone Propionate 250 µg Dose	Inhalation Powder
Norway	Sandoz A-S	Airflusal Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone Propionate 500 µg Dose	Inhalation Powder
Poland	Adamed Sp. Z O.O.	Flutixon	Fluticasone Propionate 125 µg Capsule	Inhalation Powder, Hard Capsule
Poland	Adamed Sp. Z O.O.	Flutixon	Fluticasone Propionate 250 µg Capsule	Inhalation Powder, Hard Capsule
Poland	Astrazeneca Ab	Pulmicort Turbuhaler	Budesonide 100 µg Dose	Inhalation Powder
Poland	Astrazeneca Ab	Pulmicort Turbuhaler	Budesonide 200 µg Dose	Inhalation Powder
Poland	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Poland	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Poland	Celon Pharma S.A.	Salmex	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder
Poland	Chiesi Pharmaceuticals Gmbh	Formodual	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Poland	Chiesi Pharmaceuticals GmbH	Fostex	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Poland	Elpen Pharmaceutical Co. Inc.	Salmeson	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Poland	Elpen Pharmaceutical Co. Inc.	Salmeson	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Poland	Glaxosmithkline Export Ltd	Flixotide	Fluticasone Propionate 250 µg Dose	Inhalation Powder, Pre-Dispensed
Poland	Glaxosmithkline Export Ltd	Flixotide	Fluticasone Propionate 250 µg Inhalation	Pressurised Inhalation, Suspension
Poland	Glaxosmithkline Export Ltd	Flixotide Dysk	Fluticasone Propionate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Poland	Glaxosmithkline Export Ltd	Seretide Dysk	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder
Poland	Meda Pharma GmbH & Co. Kg	Budelin Novolizer	Budesonide 200 µg Dose	Inhalation Powder
Poland	Novartis Poland Sp. Z O. O.	Miflonide	Budesonide 200 µg	Inhalation Powder, Hard Capsule
Poland	Novartis Poland Sp. Z O. O.	Miflonide	Budesonide 400 µg	Inhalation Powder, Hard Capsule
Poland	Orion Corporation	Orest Easyhaler	Budesonide 160 µg Inhalation, Formoterol Fumarate Dihydrate 4,5 µg Inhalation	Inhalation Powder
Poland	Orion Corporation	Orest Easyhaler	Budesonide 320 µg Inhalation, Formoterol Fumarate Dihydrate 9 µg Inhalation	Inhalation Powder

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Poland	Polfarmex S.A.	Asaris	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder
Poland	Przedsiębiorstwo Farmaceutyczne Lek-Am Sp. Z O.O.	Budezonid Lek-Am	Budesonide 200 µg Inhalation	Inhalation Powder, Hard Capsule
Poland	Przedsiębiorstwo Farmaceutyczne Lek-Am Sp. Z O.O.	Budezonid Lek-Am	Budesonide 400 µg Inhalation	Inhalation Powder, Hard Capsule
Portugal	Astrazeneca Produtos Farmacêuticos, Lda.	Assieme Turbohaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Portugal	Astrazeneca Produtos Farmacêuticos, Lda.	Assieme Turbohaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Portugal	Astrazeneca Produtos Farmacêuticos Limitada	Pulmicort Turbohaler	Budesonide 200 µg Dose	Inhalation Powder
Portugal	Astrazeneca Produtos Farmacêuticos Limitada	Pulmicort Turbohaler	Budesonide 400 µg Dose	Inhalation Powder
Portugal	Astrazeneca Produtos Farmacêuticos, Lda.	Symbicort Turbohaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Portugal	Astrazeneca Produtos Farmacêuticos, Lda.	Symbicort Turbohaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Portugal	Bialfar — Produtos Farmacêuticos, Sociedade Anónima	Brisomax Diskus	Fluticasone Propionate 100 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Portugal	Bialfar — Produtos Farmacêuticos, Sociedade Anónima	Brisomax Diskus	Fluticasone Propionate 250 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Portugal	Bialfar — Produtos Farmacéuticos, Sociedade Anónima	Brisomax Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Portugal	Elpen Pharmaceutical Co. Inc.	Dimenium	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Portugal	Elpen Pharmaceutical Co. Inc.	Dimenium	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Portugal	Farmoz — Sociedade Técnico Medicinal, S.A.	Budesonida Farmoz	Budesonide 200 µg Dose	Inhalation Powder
Portugal	Farmoz — Sociedade Técnico Medicinal, S.A.	Budesonida Farmoz	Budesonide 400 µg Dose	Inhalation Powder
Portugal	Glaxo Wellcome Farmacéutica, Limitada	Seretaide Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Portugal	Glaxosmithkline — Produtos Farmacéuticos, Limitada	Maizar Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Portugal	Orion Corporation	Bufomix Easyhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Portugal	Orion Corporation	Bufomix Easyhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Portugal	Orion Corporation	Orest Easyhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Portugal	Orion Corporation	Orest Easyhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Portugal	Pentafarma — Sociedade Tecnico-Medicinal S.A.	Budesonida Tecnicort	Budesonide 200 µg Dose	Inhalation Powder
Portugal	Pentafarma — Sociedade Tecnico-Medicinal S.A.	Budesonida Tecnicort	Budesonide 400 µg Dose	Inhalation Powder
Portugal	Sandoz Farmacêutica, Limitada	Airflusal Forspiro	Fluticasone Propionate 250 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Portugal	Sandoz Farmacêutica, Limitada	Airflusal Forspiro	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Romania	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Romania	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Romania	Chiesi Pharmaceuticals Gmbh	Foster	Formoterol Fumarate Dihydrate 6 µg Actuation, Beclometasone Dipropionate Anhydrous 100 µg Actuation	Pressurised Inhalation, Solution
Romania	Elpen Pharmaceutical Co. Inc.	Flusamer	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Romania	Elpen Pharmaceutical Co. Inc.	Flusamer	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Romania	Glaxo Wellcome Ltd	Flixotide	Fluticasone Propionate 250 µg Inhalation	Pressurised Inhalation, Suspension

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Romania	Glaxo Wellcome Ltd	Flixotide Diskus	Fluticasone Propionate 250 µg Dose	Inhalation Powder
Romania	Glaxo Wellcome Ltd	Flixotide Diskus	Fluticasone Propionate 500 µg Dose	Inhalation Powder
Romania	Glaxo Wellcome Ltd	Seretide	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Romania	Medochemie Romania S.R.L.	Frenolyn	Budesonide, Micronised 200 µg Dose	Inhalation Powder
Romania	Medochemie Romania S.R.L.	Frenolyn	Budesonide, Micronised 400 µg Dose	Inhalation Powder
Romania	Orion Oyj	Bufomix Easyhaler	Budesonide 160 µg Inhalation, Formoterol Fumarate Dihydrate 4,5 µg Inhalation	Inhalation Powder
Romania	Orion Oyj	Bufomix Easyhaler	Budesonide 320 µg Inhalation, Formoterol Fumarate Dihydrate 9 µg Inhalation	Inhalation Powder
Romania	S.C. Sandoz S.R.L.	Airflusal Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone 500 µg Dose	Inhalation Powder
Slovakia	Astrazeneca Ab	Pulmicort Turbohaler	Budesonide 100 µg Dose	Inhalation Powder
Slovakia	Astrazeneca Ab	Pulmicort Turbohaler	Budesonide 200 µg Dose	Inhalation Powder
Slovakia	Astrazeneca Ab	Pulmicort Turbohaler	Budesonide 400 µg Dose	Inhalation Powder
Slovakia	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Slovakia	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Slovakia	Chiesi Pharmaceuticals GmbH	Foster	Beclomethasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Slovakia	Elpen Pharmaceutical Co. Inc.	Dimenium	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Slovakia	Elpen Pharmaceutical Co. Inc.	Dimenium	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Slovakia	Elpen Pharmaceutical Co. Inc.	Flumetor	Fluticasone Propionate 250 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Slovakia	Elpen Pharmaceutical Co. Inc.	Flumetor	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Slovakia	Glaxo Group Limited	Flixotide	Fluticasone Propionate 125 µg Inhalation	Pressurised Inhalation, Suspension
Slovakia	Glaxo Group Limited	Flixotide	Fluticasone Propionate 250 µg Inhalation	Pressurised Inhalation, Suspension
Slovakia	Glaxo Group Limited	Flixotide	Fluticasone Propionate 50 µg Inhalation	Pressurised Inhalation, Suspension
Slovakia	Glaxo Group Limited	Seretide	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Slovakia	Glaxosmithkline Slovakia S.R.O.	Flixotide Diskus	Fluticasone Propionate 100 µg Dose	Inhalation Powder
Slovakia	Glaxosmithkline Slovakia S.R.O.	Flixotide Diskus	Fluticasone Propionate 250 µg Dose	Inhalation Powder
Slovakia	Glaxosmithkline Slovakia S.R.O.	Flixotide Diskus	Fluticasone Propionate 500 µg Dose	Inhalation Powder
Slovakia	Glaxosmithkline Slovakia S.R.O.	Flixotide Diskus	Fluticasone Propionate 50 µg Dose	Inhalation Powder
Slovakia	Meda Pharma Spol. S R.O.	Budelin Novolizer	Budesonide 200 µg Dose	Inhalation Powder

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Slovakia	Novartis, S.R.O.	Miflonid	Budesonide 200 µg	Inhalation Powder, Hard Capsule
Slovakia	Novartis, S.R.O.	Miflonid	Budesonide 400 µg	Inhalation Powder, Hard Capsule
Slovakia	Sandoz Pharmaceuticals D.D.	Airflusal Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone 250 µg Dose	Inhalation Powder
Slovakia	Sandoz Pharmaceuticals D.D.	Airflusal Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone 500 µg Dose	Inhalation Powder
Slovenia	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Slovenia	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Slovenia	Chiesi Pharmaceuticals Gmbh	Formodual	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Slovenia	Chiesi Pharmaceuticals Gmbh	Foster	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Slovenia	Elpen Pharmaceutical Co. Inc.	Flamerio	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Slovenia	Elpen Pharmaceutical Co. Inc.	Flamerio	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Slovenia	Glaxosmithkline D.O.O., Ljubljana	Flixotide	Fluticasone Propionate 250 µg Spray	Pressurised Inhalation, Suspension
Slovenia	Glaxosmithkline D.O.O., Ljubljana	Seretide Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Slovenia	Lek Pharmaceuticals D.D. Ljubljana	Airflusan Forspiro	Salmeterol 50 µg Dose, Fluticasone Propionate 500 µg Dose	Inhalation Powder
Slovenia	Meda Pharma GmbH & Co. Kg	Budelin Novolizer	Budesonide 200 µg Dose	Inhalation Powder; Pre-Dispensed
Spain	Allen Farmaceutica, S.A.	Anasma Accuhaler	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder; Pre-Dispensed
Spain	Almirall, S.A.	Plusvent	Fluticasone Propionate 50 µg Dose, Salmeterol Xinafoate 25 µg Dose	Pressurised Inhalation, Suspension
Spain	Almirall, S.A.	Plusvent	Fluticasone Propionate 250 µg Dose, Salmeterol Xinafoate 25 µg Dose	Pressurised Inhalation, Suspension
Spain	Almirall, S.A.	Plusvent	Fluticasone Propionate 125 µg Dose, Salmeterol Xinafoate 25 µg Dose	Pressurised Inhalation, Suspension
Spain	Almirall, S.A.	Plusvent	Fluticasone Propionate 100 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder; Pre-Dispensed
Spain	Almirall, S.A.	Plusvent	Fluticasone Propionate 250 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder; Pre-Dispensed
Spain	Almirall, S.A.	Plusvent	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder; Pre-Dispensed
Spain	Astrazeneca Farmacéutica Spain, S.A.	Pulmicort Turbuhaler	Budesonide 100 µg Dose	Inhalation Powder
Spain	Astrazeneca Farmacéutica Spain, S.A.	Pulmicort Turbuhaler	Budesonide 200 µg Dose	Inhalation Powder
Spain	Astrazeneca Farmacéutica Spain, S.A.	Pulmicort Turbuhaler	Budesonide 400 µg Dose	Inhalation Powder

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Spain	Astrazeneca Farmacéutica Spain, S.A.	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Spain	Astrazeneca Farmacéutica Spain, S.A.	Symbicort Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Spain	Chiesi España, S.A.	Formodual	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Spain	Chiesi España, S.A.	Foster	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Dose	Pressurised Inhalation, Solution
Spain	Glaxosmithkline S.A.	Brisair Accuhaler	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Spain	Glaxosmithkline S.A.	Brisair Accuhaler	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Spain	Glaxosmithkline S.A.	Flixotide	Fluticasone Propionate 125 µg Inhalation	Pressurised Inhalation, Suspension
Spain	Glaxosmithkline S.A.	Flixotide	Fluticasone Propionate 250 µg Inhalation	Pressurised Inhalation, Suspension
Spain	Glaxosmithkline S.A.	Flixotide	Fluticasone Propionate 50 µg Inhalation	Pressurised Inhalation, Suspension
Spain	Glaxosmithkline S.A.	Flixotide Accuhaler	Fluticasone Propionate 100 µg Dose	Inhalation Powder
Spain	Glaxosmithkline S.A.	Flixotide Accuhaler	Fluticasone Propionate 250 µg Dose	Inhalation Powder
Spain	Glaxosmithkline S.A.	Flixotide Accuhaler	Fluticasone Propionate 500 µg Dose	Inhalation Powder
Spain	Glaxosmithkline S.A.	Flusonal	Fluticasone Propionate 250 µg Inhalation	Pressurised Inhalation, Suspension

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Spain	Glaxosmithkline S.A.	Flusonal	Fluticasone Propionate 50 µg Inhalation	Pressurised Inhalation, Suspension
Spain	Glaxosmithkline S.A.	Flusonal Accuhaler	Fluticasone Propionate 100 µg Dose	Inhalation Powder
Spain	Glaxosmithkline S.A.	Flusonal Accuhaler	Fluticasone Propionate 500 µg Dose	Inhalation Powder
Spain	Glaxosmithkline S.A.	Inalacor	Fluticasone Propionate 250 µg Inhalation	Pressurised Inhalation, Suspension
Spain	Glaxosmithkline S.A.	Inalacor	Fluticasone Propionate 50 µg Dose	Pressurised Inhalation, Suspension
Spain	Glaxosmithkline S.A.	Inalacor Accuhaler	Fluticasone Propionate 100 µg Dose	Inhalation Powder
Spain	Glaxosmithkline S.A.	Inalacor Accuhaler	Fluticasone Propionate 500 µg Dose	Inhalation Powder
Spain	Glaxosmithkline S.A.	Inaladuo Accuhaler	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Spain	Glaxosmithkline S.A.	Seretide Accuhaler	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Spain	Laboratorio Tau, S.A.	Rilast Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Spain	Orion Corporation	Bufomix Easyhaler	Budesonide 160 µg Inhalation, Formoterol Fumarate Dihydrate 4,5 µg Inhalation	Inhalation Powder
Spain	Orion Corporation	Bufomix Easyhaler	Budesonide 320 µg Inhalation, Formoterol Fumarate Dihydrate 9 µg Inhalation	Inhalation Powder
Spain	Orion Corporation	Orest Easyhaler	Budesonide 160 µg Inhalation, Formoterol Fumarate Dihydrate 4,5 µg Inhalation	Inhalation Powder
Spain	Orion Corporation	Orest Easyhaler	Budesonide 320 µg Inhalation, Formoterol Fumarate Dihydrate 9 µg Inhalation	Inhalation Powder

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Spain	Smithkline Beecham Farma S.A.	Trialona	Fluticasone Propionate 250 µg Dose	Pressurised Inhalation, Suspension
Spain	Smithkline Beecham Farma S.A.	Trialona	Fluticasone Propionate 50 µg Dose	Pressurised Inhalation, Suspension
Spain	Smithkline Beecham Farma S.A.	Trialona Accuhaler	Fluticasone Propionate 100 µg Dose	Inhalation Powder
Spain	Smithkline Beecham Farma S.A.	Trialona Accuhaler	Fluticasone Propionate 500 µg Dose	Inhalation Powder
Sweden	Astrazeneca Ab	Gardette	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Sweden	Astrazeneca Ab	Gardette Forte	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Sweden	Astrazeneca Ab	Symbicort Forte Turbuhaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
Sweden	Astrazeneca Ab	Symbicort Turbuhaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
Sweden	Chiesi Farmaceutici S.P.A.	Innovair	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
Sweden	Elpen Pharmaceutical Co. Inc.	Flusamer	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Sweden	Elpen Pharmaceutical Co. Inc.	Flusamer	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Sweden	Elpen Pharmaceutical Co. Inc.	Flusaterol	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Sweden	Elpen Pharmaceutical Co. Inc.	Flusaterol	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Sweden	Elpen Pharmaceutical Co. Inc.	Relanio	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Sweden	Elpen Pharmaceutical Co. Inc.	Relanio	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Sweden	Elpen Pharmaceutical Co. Inc.	Salmeson	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose, Lactose Monohydrate 24,677 mg Dose	Inhalation Powder, Pre-Dispensed
Sweden	Elpen Pharmaceutical Co. Inc.	Salmeson	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Sweden	Glaxosmithkline Ab	Flutide Diskus	Fluticasone Propionate 250 µg Dose	Inhalation Powder, Pre-Dispensed
Sweden	Glaxosmithkline Ab	Flutide Diskus	Fluticasone Propionate 500 µg Dose	Inhalation Powder, Pre-Dispensed
Sweden	Glaxosmithkline Ab	Seretide Diskus	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Sweden	Glaxosmithkline Ab	Viani Diskus Forte	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
Sweden	Hexal Ag	Salmeterol/Fluticasone Hexal	Salmeterol Xinafoate 50 µg Dose, Fluticasone 500 µg Dose	Inhalation Powder

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Sweden	Orion Corporation	Bufomix Easyhaler	Budesonide 160 µg Inhalation, Formoterol Fumarate Dihydrate 4,5 µg Inhalation	Inhalation Powder
Sweden	Orion Corporation	Bufomix Easyhaler	Budesonide 320 µg Inhalation, Formoterol Fumarate Dihydrate 9 µg Inhalation	Inhalation Powder
Sweden	Orion Corporation	Orest Easyhaler	Budesonide 160 µg Inhalation, Formoterol Fumarate Dihydrate 4,5 µg Inhalation	Inhalation Powder
Sweden	Orion Corporation	Orest Easyhaler	Budesonide 320 µg Inhalation, Formoterol Fumarate Dihydrate 9 µg Inhalation	Inhalation Powder
Sweden	Sandoz A-S	Aesalfluca Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone 500 µg Dose	Inhalation Powder
Sweden	Sandoz A-S	Airflusal Forspiro	Fluticasone Propionate 250 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Sweden	Sandoz A-S	Airflusal Forspiro	Fluticasone Propionate 500 µg Dose, Salmeterol 50 µg Dose	Inhalation Powder, Pre-Dispensed
Sweden	Sandoz A-S	Flaxxone Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone 250 µg Dose	Inhalation Powder
Sweden	Sandoz A-S	Flaxxone Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone 500 µg Dose	Inhalation Powder
Sweden	Sandoz A-S	Lastenol Forspiro	Fluticasone Propionate 500 Microgram, Salmeterol Xinafoate 50 Microgram	Inhalation Powder

Member State in EEA	Marketing authorisation holder	Product name	Active substance + Strength	Pharmaceutical form
Sweden	Sandoz A-S	Molduo Forspiro	Salmeterol Xinafoate 50 µg Dose, Fluticasone 250 µg Dose	Inhalation Powder
Sweden	Sandoz A-S	Salmeterol/Fluticasone Sandoz	Salmeterol Xinafoate 50 µg Dose, Fluticasone 500 µg Dose	Inhalation Powder
Sweden	Sandoz A-S	Setirenol	Salmeterol Xinafoate 50 µg Dose, Fluticasone 250 µg Dose	Inhalation Powder
Sweden	Sandoz A-S	Setirenol	Salmeterol Xinafoate 50 µg Dose, Fluticasone 500 µg Dose	Inhalation Powder
United Kingdom	Astrazeneca Uk Limited	Symbicort Turbohaler	Budesonide 320 µg Dose, Formoterol Fumarate Dihydrate 9 µg Dose	Inhalation Powder
United Kingdom	Astrazeneca Uk Limited	Symbicort Turbohaler	Budesonide 160 µg Dose, Formoterol Fumarate Dihydrate 4,5 µg Dose	Inhalation Powder
United Kingdom	Chiesi Limited	Formodual	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
United Kingdom	Chiesi Limited	Fostair	Beclometasone Dipropionate 100 µg Actuation, Formoterol Fumarate Dihydrate 6 µg Actuation	Pressurised Inhalation, Solution
United Kingdom	Glaxo Wellcome Ltd	Seretide	Fluticasone Propionate 100 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
United Kingdom	Glaxo Wellcome Ltd	Seretide	Fluticasone Propionate 250 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed
United Kingdom	Glaxo Wellcome Ltd	Seretide Accuhaler	Fluticasone Propionate 500 µg Dose, Salmeterol Xinafoate 50 µg Dose	Inhalation Powder, Pre-Dispensed

ANNEX II

List of the names, pharmaceutical form, strength of the veterinary medicinal product, animal species, route of administration, applicant/marketing authorisation holder in the Member States

Member State EU/EEA	Applicant/marketing authorisation holder	Name	Strength	Pharmaceutical form	Animal species	Route of administration
Belgium	Zoetis Belgium SA Rue Laid Burniat 1 1348 Louvain-la-Neuve Belgium	CattleMarker IBR Inactivated emulsion for injection for cattle	Each 2 ml dose contains: Inactivated gE Bovine Herpes Virus type 1 (BoHV-1), strain Difivac, to induce a geometric mean seroneutralising titre $\geq 5,5 \log_2$	Emulsion for injection	Cattle	Subcutaneous use
Bulgaria	Zoetis Belgium SA Rue Laid Burniat 1 1348 Louvain-la-Neuve Belgium	CattleMarker IBR Inactivated emulsion for injection for cattle	Each 2 ml dose contains: Inactivated gE Bovine Herpes Virus type 1 (BoHV-1), strain Difivac, to induce a geometric mean seroneutralising titre $\geq 5,5 \log_2$	Emulsion for injection	Cattle	Subcutaneous use
Croatia	Zoetis Belgium SA Rue Laid Burniat 1 1348 Louvain-la-Neuve Belgium	CattleMarker IBR Inactivated emulsion for injection for cattle	Each 2 ml dose contains: Inactivated gE Bovine Herpes Virus type 1 (BoHV-1), strain Difivac, to induce a geometric mean seroneutralising titre $\geq 5,5 \log_2$	Emulsion for injection	Cattle	Subcutaneous use
France	Zoetis Belgium SA Rue Laid Burniat 1 1348 Louvain-la-Neuve Belgium	CattleMarker IBR Inactivated emulsion for injection for cattle	Each 2 ml dose contains: Inactivated gE Bovine Herpes Virus type 1 (BoHV-1), strain Difivac, to induce a geometric mean seroneutralising titre $\geq 5,5 \log_2$	Emulsion for injection	Cattle	Subcutaneous use

Member State EU/EEA	Applicant/marketing authorisation holder	Name	Strength	Pharmaceutical form	Animal species	Route of administration
Germany	Zoetis Belgium SA Rue Laid Burniat 1 1348 Louvain-la-Neuve Belgium	CattleMarker IBR Inactivated emulsion for injection for cattle	Each 2 ml dose contains: Inactivated gE Bovine Herpes Virus type 1 (BoHV-1), strain Difivac, to induce a geometric mean seroneutralising titre $\geq 5,5 \log_2$	Emulsion for injection	Cattle	Subcutaneous use
Ireland	Zoetis Belgium SA Rue Laid Burniat 1 1348 Louvain-la-Neuve Belgium	CattleMarker IBR Inactivated emulsion for injection for cattle	Each 2 ml dose contains: Inactivated gE Bovine Herpes Virus type 1 (BoHV-1), strain Difivac, to induce a geometric mean seroneutralising titre $\geq 5,5 \log_2$	Emulsion for injection	Cattle	Subcutaneous use
Italy	Zoetis Belgium SA Rue Laid Burniat 1 1348 Louvain-la-Neuve Belgium	CattleMarker IBR Inactivated emulsion for injection for cattle	Each 2 ml dose contains: Inactivated gE Bovine Herpes Virus type 1 (BoHV-1), strain Difivac, to induce a geometric mean seroneutralising titre $\geq 5,5 \log_2$	Emulsion for injection	Cattle	Subcutaneous use
The Netherlands	Zoetis Belgium SA Rue Laid Burniat 1 1348 Louvain-la-Neuve Belgium	CattleMarker IBR Inactivated emulsion for injection for cattle	Each 2 ml dose contains: Inactivated gE Bovine Herpes Virus type 1 (BoHV-1), strain Difivac, to induce a geometric mean seroneutralising titre $\geq 5,5 \log_2$	Emulsion for injection	Cattle	Subcutaneous use
Poland	Zoetis Belgium SA Rue Laid Burniat 1 1348 Louvain-la-Neuve Belgium	CattleMarker IBR Inactivated emulsion for injection for cattle	Each 2 ml dose contains: Inactivated gE Bovine Herpes Virus type 1 (BoHV-1), strain Difivac, to induce a geometric mean seroneutralising titre $\geq 5,5 \log_2$	Emulsion for injection	Cattle	Subcutaneous use

Member State EU/EEA	Applicant/marketing authorisation holder	Name	Strength	Pharmaceutical form	Animal species	Route of administration
Portugal	Zoetis Belgium SA Rue Laid Burniat 1 1348 Louvain-la-Neuve Belgium	CattleMarker IBR Inactivated emulsion for injection for cattle	Each 2 ml dose contains: Inactivated gE Bovine Herpes Virus type 1 (BoHV-1), strain Difivac, to induce a geometric mean seroneutralising titre $\geq 5,5 \log_2$	Emulsion for injection	Cattle	Subcutaneous use
Romania	Zoetis Belgium SA Rue Laid Burniat 1 1348 Louvain-la-Neuve Belgium	CattleMarker IBR Inactivated emulsion for injection for cattle	Each 2 ml dose contains: Inactivated gE Bovine Herpes Virus type 1 (BoHV-1), strain Difivac, to induce a geometric mean seroneutralising titre $\geq 5,5 \log_2$	Emulsion for injection	Cattle	Subcutaneous use
Slovenia	Zoetis Belgium SA Rue Laid Burniat 1 1348 Louvain-la-Neuve Belgium	CattleMarker IBR Inactivated emulsion for injection for cattle	Each 2 ml dose contains: Inactivated gE Bovine Herpes Virus type 1 (BoHV-1), strain Difivac, to induce a geometric mean seroneutralising titre $\geq 5,5 \log_2$	Emulsion for injection	Cattle	Subcutaneous use
Spain	Zoetis Belgium SA Rue Laid Burniat 1 1348 Louvain-la-Neuve Belgium	CattleMarker IBR Inactivated emulsion for injection for cattle	Each 2 ml dose contains: Inactivated gE Bovine Herpes Virus type 1 (BoHV-1), strain Difivac, to induce a geometric mean seroneutralising titre $\geq 5,5 \log_2$	Emulsion for injection	Cattle	Subcutaneous use
United Kingdom	Zoetis Belgium SA Rue Laid Burniat 1 1348 Louvain-la-Neuve Belgium	CattleMarker IBR Inactivated emulsion for injection for cattle	Each 2 ml dose contains: Inactivated gE Bovine Herpes Virus type 1 (BoHV-1), strain Difivac, to induce a geometric mean seroneutralising titre $\geq 5,5 \log_2$	Emulsion for injection	Cattle	Subcutaneous use

ANNEX III

List of the names, pharmaceutical forms, strength of the medicinal products, routes of administration, Marketing Authorisation Holders in the Member States

Member State in EEA	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Cyprus	MEDA Pharmaceuticals S.A. 3, Eyritanias Str. GR-15231 Chalandri-Attiki Greece	Novantrone	2 mg/ml	Concentrate for solution for infusion	Intravenous use	20 mg/10 ml
Finland	MEDA Oy Vaisantie 4 FIN-02130 Espoo Finland	Novantrone	2 mg/ml	Concentrate for solution for infusion	Intravenous use	20 mg/10 ml
Finland	MEDA Oy Vaisantie 4 FIN-02130 Espoo Finland	Novantrone	2 mg/ml	Concentrate for solution for infusion	Intravenous use	10 mg/5 ml
France	MEDA Pharma S.A.S. 25, Boulevard de l'Amiral Bruix F-75016 Paris France	Novantrone 10 mg/ 5 ml, solution à diluer pour perfusion	2 mg/ml	Concentrate for solution for infusion	Intravenous use	20 mg/10 ml

Member State in EEA	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
France	MEDA Pharma S.A.S. 25, Boulevard de l'Amiral Bruix F-75016 Paris France	Novantrone 20 mg/ 10 ml, solution à diluer pour perfusion	2 mg/ml	Concentrate for solution for infusion	Intravenous use	20 mg/10 ml
France	MEDA Pharma S.A.S. 25, Boulevard de l'Amiral Bruix F-75016 Paris France	Elsep 2 mg/ml, solution à diluer pour perfusion	2 mg/ml	Concentrate for solution for infusion	Intravenous use	20 mg/10 ml
Germany	MEDA Pharma GmbH & Co. KG Benzstrasse 1 61352 Bad Homburg Germany	Novantron 10 mg/5 ml	2 mg/ml	Concentrate for solution for infusion or solution for intrapleural or intra- peritoneal use	Intravenous use In- trapleural use Intraperitoneal use	10 mg/5 ml
Germany	MEDA Pharma GmbH & Co. KG Benzstrasse 1 61352 Bad Homburg Germany	Novantron 20 mg/10 ml	2 mg/ml	Concentrate for solution for infusion or solution for intrapleural or intra- peritoneal use	Intravenous use In- trapleural use Intraperitoneal use	20 mg/10 ml
Germany	MEDA Pharma GmbH & Co. KG Benzstrasse 1 61352 Bad Homburg Germany	Ralenova 2 mg/ml	2 mg/ml	Concentrate for solution for infusion	Intravenous use	20 mg/10 ml
Germany	MEDA Pharma GmbH & Co. KG Benzstrasse 1 61352 Bad Homburg Germany	Ralenova 2 mg/ml	2 mg/ml	Concentrate for solution for infusion	Intravenous use	10 mg/5 ml

Member State in EEA	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Greece	MEDA Pharmaceuticals S.A. 3, Evritanias Str. GR-15231 Chalandri-Attiki Greece	Novantrone	2 mg/ml	Concentrate for solution for infusion	Intravenous use	20 mg/10 ml
Iceland	MEDA AB Pipers vag 2A, Box 906 SE-170 09 Solna Sweden	Novantrone	2 mg/ml	Concentrate for solution for infusion	Intravenous use	20 mg/10 ml
Iceland	MEDA AB Pipers vag 2A, Box 906 SE-170 09 Solna Sweden	Novantrone	2 mg/ml	Concentrate for solution for infusion	Intravenous use	10 mg/5 ml
Italy	MEDA Pharma S.p.A. Viale Brenta 18 IT-20139 Milano Italy	Novantrone	2 mg/ml	Concentrate for solution for infusion	Intravenous use	10 mg/5 ml
Italy	MEDA Pharma S.p.A. Viale Brenta 18 IT-20139 Milano Italy	Novantrone	2 mg/ml	Concentrate for solution for infusion	Intravenous use	20 mg/10 ml

Member State in EEA	Marketing authorisation holder	Invented name	Strength	Pharmaceutical form	Route of administration	Content (concentration)
Norway	MEDA A/S Askerveien 61 NO-1384 Asker Norway	Novantrone	2 mg/ml	Concentrate for solution for infusion	Intravenous use	10 mg/5 ml
Romania	MEDA Pharma GmbH & Co. KG Benzstrasse 1 61352 Bad Homburg Germany	Novantrone	2 mg/ml	Concentrate for solution for infusion	Intravenous use	20 mg/10 ml
Slovenia	MEDA Pharma GmbH & Co. KG Benzstrasse 1 61352 Bad Homburg Germany	Novantrone	2 mg/ml	Concentrate for solution for injection/infusion	Intravenous use	20 mg/10 ml
Spain	MEDA Pharma S.A.U. Edificio Berlin — Parque Empresarial San Fernando, Avda Castilla 2, 2ª planta E-28830 SAN FERNANDO DE HENARES (MADRID) Spain	Novantrone 20 mg so- lución inyectable	2 mg/ml	Concentrate for solution for infusion	Intravenous use	20 mg/10 ml
Sweden	MEDA AB Pipers vag 2A, Box 906 SE-170 09 Solna Sweden	Novantrone	2 mg/ml	Concentrate for solution for infusion	Intravenous use	20 mg/10 ml
Sweden	MEDA AB Pipers vag 2A, Box 906 SE-170 09 Solna Sweden	Novantrone	2 mg/ml	Concentrate for solution for infusion	Intravenous use	10 mg/5 ml

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