

**Summary of European Union decisions on marketing authorisations in respect of medicinal products
from 1 January 2021 to 31 January 2021**

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

(2021/C 67/03)

— Issuing, maintenance or modification of a national marketing authorisation

Date of the decision	Name(s) of the medicinal product	INN (International Non-Proprietary Name)	Holder(s) of the marketing authorisation	Member State concerned	Date of notification
18.1.2021	Valbazen	Albendazole	See Annex I	See Annex I	20.1.2021
11.1.2021	ulipristal acetate 5 mg	ulipristal acetate 5 mg	See Annex II	See Annex II	12.1.2021

⁽¹⁾ OJ L 311, 28.11.2001, p. 67.

⁽²⁾ OJ L 311, 28.11.2001, p. 1.

ANNEX I

List of the names, pharmaceutical form, strengths of the veterinary medicinal products, animal species, route of administration, marketing authorisation holders in the Member States

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Austria	Zoetis Österreich GmbH Floridsdorfer Hauptstraße 1 A- 1210 Wien Österreich	Valbazen 100 mg/ml-Suspension zum Eingeben für Rinder	Albendazole	100 mg/ml	Oral suspension	Cattle	Oral use
Austria	AniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Albendazol-aniMedica 100 mg/ml Suspension zum Eingeben für Rinder	Albendazole	100 mg/ml	Oral suspension	Cattle	Oral use
Austria	Chanelle Pharmaceuticals Manufacturing Ltd IDA Industrial Estate Dublin Road, Loughrea Co Galway H62 H771 Ireland	Albex Gold 200 mg/ml Oral Suspension for Cattle	Albendazole	200 mg/ml	Oral suspension	Cattle	Oral use
Belgium	Elanco GmbH Heinz-Lohmann-Straße 4 27472 Cuxhaven Germany	Valbazen 10 %	Albendazole	100 mg/ml	Oral suspension	Cattle	Oral use
Belgium	Chanelle Pharmaceuticals Manufacturing Ltd IDA Industrial Estate Dublin Road, Loughrea Co Galway H62 H771 Ireland	Albex 200 mg/ml oral suspension for cattle	Albendazole	200 mg/ml	Oral suspension	Cattle	Oral use
Bulgaria	Intervet International BV Wim de Körverstraat 35 5831 AN Boxmeer The Netherlands	Gardal 10 %	Albendazole	100 mg/ml	Oral suspension	Cattle, sheep	Oral use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Bulgaria	Asklep-Pharma Ltd., Lyulin 7, bl. 711A, shop 3, Bulgaria	Albex BG 100 mg/ml oral suspension for cattle and sheep	Albendazole	100 mg/ml	Oral suspension	Cattle, sheep	Oral use
Croatia	Mount Trade d.o.o., Indus- trijska cesta 13, 43280 Gar- ešnica Croatia	Albix 100 mg/ml, oralna sus- penzija za goveda i ovce	Albendazole	100 mg/ml	Oral suspension	Cattle, sheep	Oral use
France	Zoetis France 10 Rue Raymond David 92240 Malakoff France	Valbazen dix	Albendazole	100 mg/ml	Oral suspension	Cattle	Oral use
France	Chanelle Pharmaceuticals Manufacturing Ltd IDA Industrial Estate Dublin Road, Loughrea Co Galway H62 H771 Ireland	Albex Gold 200 mg/ml sus- pension buvable pour bovins	Albendazole	200 mg/ml	Oral suspension	Cattle	Oral use
Germany	Lilly Deutschland GmbH Ab- teilung Elanco Animal Health Werner-Reimers-Straße 2-4 61352 Bad Homburg Germany	Valbazen 10 %	Albendazole	100 mg/ml	Oral suspension	Cattle	Oral use
Germany	Chanelle Pharmaceuticals Manufacturing Ltd IDA Industrial Estate Dublin Road, Loughrea Co Galway H62 H771 Ireland	Albex Gold 200 mg/ml Oral Suspension for Cattle	Albendazole	200 mg/ml	Oral suspension	Cattle	Oral use
Greece	Provet S.A. 77, Posidonos Avenue 174 55 Alimos, Attiki Greece	Albendazole/Provet, πόσιμο εναώρημα 10 % w/v	Albendazole	100 mg/ml	Oral suspension	Calves, Sheep, Goats	Oral use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Greece	Chanelle Pharmaceuticals Manufacturing Ltd IDA Industrial Estate Dublin Road, Loughrea Co Galway H62 H771 Ireland	Albex Πόσιμο εναιώρημα 10 % w/v/	Albendazole	100 mg/ml	Oral suspension	Cattle, sheep, goats	Oral use
Ireland	Zoetis Belgium S.A. 2nd Floor, Building 10, Cher- rywood Business Park, Loughlinstown, Co Dublin, Ireland	Valbazen 100 mg/ml Total Spectrum Wormer	Albendazole	100 mg/ml	Oral suspension	Cattle, sheep	Oral use
Ireland	Chanelle Pharmaceuticals Manufacturing Ltd IDA Industrial Estate Dublin Road, Loughrea Co Galway H62 H771 Ireland	Albex Gold 200 mg/ml oral suspension for cattle	Albendazole	200 mg/ml	Oral suspension	Cattle	Oral use
Italy	Zoetis Italia S.r.l. Via Andrea Doria 41M 00192 Roma Italy	Valbazen 100 mg/ml sospen- sione per uso orale per bovini ed ovini	Albendazole	100 mg/ml	Oral suspension	Cattle, sheep	Oral use
Italy	Fatro S.p.A. Via Emilia, 285 40064 Ozzano dell'Emilia (Bologna) Italy	Sverminator 10, 100 mg/ml, sospensione orale per bovini ed ovini	Albendazole	100 mg/ml	Oral suspension	Cattle, sheep	Oral use
Italy	Chanelle Pharmaceuticals Manufacturing Ltd IDA Industrial Estate Dublin Road, Loughrea Co Galway H62 H771 Ireland	Albex Gold 200 mg/ml sos- pensione orale per bovini	Albendazole	200 mg/ml	Oral suspension	Cattle	Oral use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Luxembourg	Elanco GmbH Heinz-Lohmann-Straße 4 27472 Cuxhaven Germany	Valbazen 10 %	Albendazole	100 mg/ml	Oral suspension	Cattle	Oral use
Malta	Fatro S.p.A. Via Emilia, 285 40064 Ozzano dell'Emilia (Bologna) Italy	Sverminator 10	Albendazole	100 mg/ml	Oral suspension	Cattle, Sheep	Oral use
Poland	Chanelle Pharmaceuticals Manufacturing Ltd IDA Industrial Estate Dublin Road, Loughrea Co Galway H62 H771 Ireland	Albex Gold 200 mg/ml oral suspension for cattle	Albendazole	200 mg/ml	Oral suspension	Cattle	Oral use
Poland	ZoetisPolska Sp. z.o.o Postępu 17B, 02-676 Warsza- wa Poland	Valbazen 10 %, 10 g/100 ml zawiesina doustna dla bydla i owiec	Albendazole	100 mg/ml	Oral suspension	Cattle, sheep	Oral use
Poland	C&H Generics Limited c/o Michael McEvoy and Co Seville House New Dock Street H91CKV0 Galway Ireland	Albex 10 %	Albendazole	100 mg/ml	Oral suspension	Cattle, sheep	Oral use
Romania	Crida Pharm S.R.L., Str. Intrarea Vagonetului, Nr.2 Bl 101, Ap. 47, Sector 6, RO-061151 Bucharest, Romania	Cribendazol 10 %, 100 mg/ml	Albendazole	100 mg/ml	Oral suspension	Cattle	Oral use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
The Netherlands	Chanelle Pharmaceuticals Manufacturing Ltd IDA Industrial Estate Dublin Road, Loughrea Co Galway H62 H771 Ireland	Albex Gold 200 mg/ml, orale suspensie voor runderen	Albendazole	200 mg/ml	Oral suspension	Cattle	Oral use

List of nationally authorised medicinal products

Member State (EEA)	Marketing Authorisation Holder	Product name	INN/Active substance + Strength (per unit)	Pharmaceutical form	Route of administration
Croatia	Alvogen Pharma Trading Europe Eood	Ulipristalacetat Alvogen	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use
Czech Republic	Aristo Pharma Gmbh (Art 57)	Ulimyo	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use
Czech Republic	Zentiva, K.S.	Stillupra	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use
France	Accord Healthcare France Sas	Ulipristal Acetate Accord	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use
France	Eg Labo Laboratoires Eurogenerics	Ulipristal Acetate Eg	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use
France	Helm Ag	Ulipristal Acetate Helm	Ulipristal Acetate 5 mg Tablet	Film-Coated Tablet	Oral Use
France	Zentiva France	Ulipristal Acetate Zentiva	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use
Germany	Accord Healthcare B.V.	Ulipristal Accord	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use
Germany	Aliud Pharma Gmbh	Ulipristal Al	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use
Germany	Aristo Pharma Gmbh (Art 57)	Ulimyo	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use
Germany	Cipla Europe Nv	Ulipristal Cipla	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use
Germany	Cyndeia Pharma S.L	Ulipristal Cyndeia	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use

Member State (EEA)	Marketing Authorisation Holder	Product name	INN/Active substance + Strength (per unit)	Pharmaceutical form	Route of administration
Germany	Heumann Pharma Gmbh & Co. Generica Kg	Ulipristal Heumann	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use
Germany	Zentiva Pharma Gmbh	Ulipristal Zentiva	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use
Greece	Faran S.A.	Boled	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use
Hungary	Alvogen Pharma Trading Europe Eood	Uliprisztál-Acetát Alvogen	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use
Hungary	Aristo Pharma Gmbh (Art 57)	Ulimyo	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use
Iceland	Alvogen Pharma Trading Europe Eood	Ulipristal Asetat Alvogen	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use
Malta	G.L. Pharma Gmbh	Ulipristal G.L.	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use
Netherlands	Helm Ag	Ulipristal Helm	Ulipristal Acetate 5 mg Tablet	Film-Coated Tablet	Oral Use
Netherlands	Sandoz B.V.	Elyoma	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use
Poland	Alvogen Pharma Trading Europe Eood	Ulipristal Alvogen	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use
Poland	Aristo Pharma Gmbh (Art 57)	Ulimyo	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use
Portugal	Cicum Farma Unipessoal Lda.	Ulipristal Cicum	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use
Portugal	G.L. Pharma Gmbh	Ulipristal G.L.	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use

Member State (EEA)	Marketing Authorisation Holder	Product name	INN/Active substance + Strength (per unit)	Pharmaceutical form	Route of administration
Portugal	Sumar Pharma Ehf	Karevonol	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use
Portugal	Sumar Pharma Ehf	Selavona	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use
Portugal	Sumar Pharma Ehf	Ulipristal Sumar	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use
Portugal	Sumar Pharma Ehf	Varinam	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use
Portugal	Zentiva Portugal, Lda	Stillupra	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use
Portugal	Zentiva Portugal, Lda	Ulipristal Zentiva	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use
Slovakia	Aristo Pharma Gmbh (Art 57)	Ulimyo	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use
Slovakia	Zentiva, K.S.	Stillupra	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use
Spain	Adamed Laboratorios, S.L.U.	Missitel	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use
Spain	Cipla Europe Nv	Ulipristal Cipla	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use
Spain	Cyndeia Pharma S.L	Ulipristal Cyndeia	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use
Spain	Helm Ag	Ulipristal Acetate Helm	Ulipristal Acetate 5 mg Tablet	Film-Coated Tablet	Oral Use
United Kingdom	Accord Healthcare Limited	Ulipristal Acetate Accord Healthcare	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use
United Kingdom	Cipla (Eu) Limited	Ulipristal Acetate Cipla	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use

Member State (EEA)	Marketing Authorisation Holder	Product name	INN/Active substance + Strength (per unit)	Pharmaceutical form	Route of administration
United Kingdom	Creo Pharma Ltd	Ulipristal Acetate Creo Pharma	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use
United Kingdom	Helm Ag	Ulipristal Helm	Ulipristal Acetate 5 mg Tablet	Film-Coated Tablet	Oral Use
United Kingdom	Mercury Pharmaceuticals Ltd.	Ulipristal Acetate Mercury Pharmaceu- ticals	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use
United Kingdom	Zentiva Pharma Uk Limited	Ulipristal Acetate Zentiva	Ulipristal Acetate 5 mg Tablet	Tablet	Oral Use