

**Summary of European Union decisions on marketing authorisations in respect of medicinal products
from 1 July 2020 to 31 July 2020***(Decisions taken pursuant to Article 34 of Directive 2001/83/EC ⁽¹⁾ or Article 38 of Directive 2001/82/EC ⁽²⁾)**(2020/C 285/02)***— 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
7.7.2020	fluorouracil and related substances (capecitabine, tegafur and flucytosine)	fluorouracil or fluorouracil and related substances (capecitabine, tegafur and flucytosine)	See Annex	See Annex	7.7.2020

⁽¹⁾ OJ L 311, 28.11.2001, p. 67.⁽²⁾ OJ L 311, 28.11.2001, p. 1.

List of nationally authorised medicinal products

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Austria	Accord Healthcare Limited	Fluorouracil Accord	Fluorouracil 50 mg/ml	Solution for injection/infusion	Intravenous use
Austria	Almirall Hermal GmbH	Actikerall	Fluorouracil 5mgg, Salicylic Acid 100 mgg	Cutaneous solution	Cutaneous use
Austria	Almirall Hermal GmbH	Verrumal	Fluorouracil 5mgg, Salicylic Acid 100 mgg	Cutaneous solution	Cutaneous use
Austria	Ebewe Pharma	5-Fluorouracil Ebewe	Fluorouracil 50 mg/ml	Concentrate for solution for injection/infusion	Intravenous use
Austria	Fairmed Healthcare GmbH	Capecitabin Fair-Med	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Austria	Fairmed Healthcare GmbH	Capecitabin Fair-Med	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Austria	G.L. Pharma GmbH	Capecel	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Austria	G.L. Pharma GmbH	Capecel	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Austria	Hikma Farmacêutica (Portugal), S.A.	Capecitabin Hikma	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Austria	Hikma Farmacêutica (Portugal), S.A.	Capecitabin Hikma	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Austria	Meda Pharma GmbH	Ancotil	Flucytosine 2,5 g/250 ml	Solution for infusion	Intravenous use
Austria	Sandoz GmbH	Capecitabin Sandoz	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Austria	Sandoz GmbH	Capecitabin Sandoz	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Austria	Stada Arzneimittel GmbH	Capecitabin Stada	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Austria	Stada Arzneimittel Gmbh	Capecitabin Stada	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Belgium	Accord Healthcare B.V.	Fluorouracil Accord Healthcare	Fluorouracil 1 000 mg/20 ml	Solution for injection/infusion	Intravenous use
Belgium	Accord Healthcare B.V.	Fluorouracil Accord Healthcare	Fluorouracil 2 500 mg/50 ml	Solution for injection/infusion	Intravenous use
Belgium	Accord Healthcare B.V.	Fluorouracil Accord Healthcare	Fluorouracil 250 mg/ml	Solution for injection/infusion	Intravenous use
Belgium	Accord Healthcare B.V.	Fluorouracil Accord Healthcare	Fluorouracil 5 000 mg/100 ml	Solution for injection/infusion	Intravenous use
Belgium	Accord Healthcare B.V.	Fluorouracil Accord Healthcare	Fluorouracil 500 mg/10 ml	Solution for injection/infusion	Intravenous use
Belgium	Actavis Group Ptc Ehf.	Capecitabine Actavis	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Belgium	Actavis Group Ptc Ehf.	Capecitabine Actavis	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Belgium	Cipla (Uk) Limited	Xelcip	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Belgium	Cipla (Uk) Limited	Xelcip	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Belgium	Eurogenerics N.V./S.A.	Capecitabine Eg	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Belgium	Eurogenerics N.V./S.A.	Capecitabine Eg	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Belgium	Fairmed Healthcare Gmbh	Capécitabine Fair-Med	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Belgium	Fairmed Healthcare Gmbh	Capécitabine Fair-Med	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Belgium	S.A. Meda Pharma N.V.	Efudix	Fluorouracil 5 g/100 g	Ointment	Cutaneous use
Belgium	Sandoz N.V.	Capecitabin Sandoz	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Belgium	Sandoz N.V.	Capecitabin Sandoz	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Belgium	Teva Pharma Belgium N.V./S.A	Fluracetyl	Fluorouracil 50 mg/ml	Solution for injection/infusion	Intraarterial use/intravenous Use
Bulgaria	Accord Healthcare Limited	Флуороурацил Акорд	Fluorouracil 50 mg/ml	Solution for injection/infusion	Intraarterial use/intravenous Use
Bulgaria	Alvogen Ipco S.Ar.L	Ксалвобин	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Bulgaria	Ebewe Pharma	5-Флуороурацил 'ебеве'	Fluorouracil 50 mg/ml	Concentrate for solution for injection/infusion	Intravenous use
Bulgaria	Egis Pharmaceuticals Plc	Колоксет	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Bulgaria	Egis Pharmaceuticals Plc	Колоксет	Capecitabine 300 mg Tablet	Film-coated tablet	Oral use
Bulgaria	Egis Pharmaceuticals Plc	Колоксет	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Bulgaria	Fairmed Healthcare GmbH	Капецитабин Феър-Мед	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Bulgaria	Fairmed Healthcare GmbH	Капецитабин Феър-Мед	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Bulgaria	Meda Pharma GmbH & Co. Kg	Ефудикс	Fluorouracil 50mgg	Cream	Cutaneous use
Croatia	Alpha-Medical D.O.O.	Капетрал	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Croatia	Alpha-Medical D.O.O.	Капетрал	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Croatia	Alvogen Malta Operations (Row) Ltd	Xalvobin	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Croatia	Jadran-Galenski Laboratorij D.D.	Капецитабин Jgl	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Croatia	Jadran-Galenski Laboratorij D.D.	Капецитабин Jgl	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Croatia	Krka-Farma D.O.O.	Cansata	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Croatia	Krka-Farma D.O.O.	Cansata	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Croatia	Mibe Pharmaceuticals D.O.O.	Verrucutan	Fluorouracil 5mgg, Salicylic Acid 100 mgg	Cutaneous solution	Cutaneous use
Croatia	Pliva Hrvatska D.O.O.	Fluorouracil Pliva	Fluorouracil 50 mg/Ml	Injection	Intravenous use
Croatia	Pliva Hrvatska D.O.O.	Fluorouracil Pliva	Fluorouracil 50 mg/Ml	Solution for injection/infusion	Intravenous use
Croatia	Sandoz D.O.O.	Fluorouracil Sandoz	Fluorouracil 50 mg/Ml	Concentrate for solution for injection/infusion	Intravenous use
Croatia	Sandoz D.O.O.	Kapecitabin Sandoz	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Cyprus	Accord Healthcare Limited	Fluorouracil Accord	Fluorouracil 50 mg/Ml	Solution for injection/infusion	Intravenous use
Cyprus	Remedica Ltd	Capecitabine Remedica	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Cyprus	Remedica Ltd	Capecitabine Remedica	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Cyprus	Remedica Ltd	Kapetral	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Cyprus	Remedica Ltd	Kapetral	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Cyprus	Sandoz Gmbh	Capecitabin Sandoz	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Cyprus	Sandoz Gmbh	Capecitabin Sandoz	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Cyprus	Zentiva, K.S.	Capecitabine Zentiva	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Cyprus	Zentiva, K.S.	Capecitabine Zentiva	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Czech Republic	Accord Healthcare Polska Sp. Z O.O.	Fluorouracil Accord	Fluorouracil 250 mg/5 ml	Solution for injection/infusion	Intravenous use
Czech Republic	Accord Healthcare Polska Sp. Z O.O.	Fluorouracil Accord	Fluorouracil 50 mg/Ml	Solution for injection/infusion	Intravenous use
Czech Republic	Almirall Hermal Gmbh	Actikerall	Fluorouracil 5 mgg, Salicylic Acid 100 mgg	Cutaneous solution	Cutaneous use
Czech Republic	Almirall Hermal Gmbh	Verrumal	Fluorouracil 5 mgg, Salicylic Acid 100 mgg	Cutaneous solution	Cutaneous use
Czech Republic	Ebewe Pharma	5-Fluorouracil Ebewe	Fluorouracil 50 mg/Ml	Concentrate for solution for injection/infusion	Intraarterial use/intraperitoneal use/intrapleural use/intravenous Use
Czech Republic	Egis Pharmaceuticals Plc	Coloxet	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Czech Republic	Egis Pharmaceuticals Plc	Coloxet	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Czech Republic	Fairmed Healthcare Gmbh	Capecitabin Fair-Med	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Czech Republic	Fairmed Healthcare Gmbh	Capecitabin Fair-Med	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Czech Republic	Glenmark Pharmaceuticals S.R.O.	Capecitabine Glenmark	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Czech Republic	Glenmark Pharmaceuticals S.R.O.	Capecitabine Glenmark	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Czech Republic	Grindeks	Ftorafur	Tegafur 400 mg Capsule	Capsule, hard	Oral use
Czech Republic	Mylan Ireland Limited	Capecitabine Mylan	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Czech Republic	Mylan Ireland Limited	Capecitabine Mylan	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Czech Republic	Pharmagen Cz S.R.O.	Capecitabine	Capecitabine 500 mg Tablet	Coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Czech Republic	Pharmagen Cz S.R.O.	Capecitabine Pharmagen	Capecitabine 150 mg Tablet	Coated tablet	Oral use
Denmark	Accord Healthcare Limited	Fluorouracil Accord	Fluorouracil 1 000 mg/20 ml	Solution for injection/infusion	Intravenous use
Denmark	Accord Healthcare Limited	Fluorouracil Accord	Fluorouracil 2 500 mg/50 ml	Solution for injection/infusion	Intravenous use
Denmark	Accord Healthcare Limited	Fluorouracil Accord	Fluorouracil 250 mg/5 ml	Solution for injection/infusion	Intravenous use
Denmark	Accord Healthcare Limited	Fluorouracil Accord	Fluorouracil 5 000 mg/100 ml	Solution for injection/infusion	Intravenous use
Denmark	Accord Healthcare Limited	Fluorouracil Accord	Fluorouracil 500 mg/10 ml	Solution for injection/infusion	Intravenous use
Denmark	Actavis Group Ptc Ehf.	Capecitabin Actavis	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Denmark	Actavis Group Ptc Ehf.	Capecitabin Actavis	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Denmark	Almirall Hermal Gmbh	Actikerall	Fluorouracil 5mgg, Salicylic Acid 100 mgg	Cutaneous solution	Cutaneous use
Denmark	Fairmed Healthcare Gmbh	Capecitabin 'fair-Med'	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Denmark	Fairmed Healthcare Gmbh	Capecitabin 'fair-Med'	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Denmark	Fresenius Kabi Ab	Capecitabine Fresenius Kabi	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Denmark	Fresenius Kabi Ab	Capecitabine Fresenius Kabi	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Denmark	Orion Corporation	Capecitabine Orion	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Denmark	Orion Corporation	Capecitabine Orion	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Denmark	Pfizer Aps	Fluorouracil 'pfizer'	Fluorouracil 50 mg/Ml	Solution for injection	Intravenous use
Denmark	Pfizer Aps	Flurablastin	Fluorouracil 50 mg/Ml	Solution for injection	Intravenous use
Denmark	Sandoz A/S	Capecitabine Sandoz	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Denmark	Sandoz A/S	Capecitabine Sandoz	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Denmark	Stada Arzneimittel Ag	Capecitabin Stada	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Denmark	Stada Arzneimittel Ag	Capecitabin Stada	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Denmark	Teva B.V	Fluorouracil Teva	Fluorouracil 50 mg/Ml	Solution for injection/infusion	Intravenous use
Estonia	Accord Healthcare B.V.	Fluorouracil Accord	Fluorouracil 1 000 mg/20 ml	Solution for injection/infusion	Intravenous use
Estonia	Accord Healthcare B.V.	Fluorouracil Accord	Fluorouracil 2 500 mg/50 ml	Solution for injection/infusion	Intravenous use
Estonia	Accord Healthcare B.V.	Fluorouracil Accord	Fluorouracil 250 mg/5 ml	Solution for injection/infusion	Intravenous use
Estonia	Accord Healthcare B.V.	Fluorouracil Accord	Fluorouracil 5 000 mg/100 ml	Solution for injection/infusion	Intravenous use
Estonia	Accord Healthcare B.V.	Fluorouracil Accord	Fluorouracil 500 mg/10 ml	Solution for injection/infusion	Intravenous use
Estonia	Almirall Hermal GmbH	Actikerall	Fluorouracil 5 mgg, Salicylic Acid 100 mgg	Cutaneous solution	Cutaneous use
Estonia	Norameda Uab	Capecitabine Norameda	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Estonia	Norameda Uab	Capecitabine Norameda	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Estonia	Sandoz Pharmaceuticals D.D.	5-Fluorouracil Ebewe	Fluorouracil 500 mg/Ml	Concentrate for solution for injection/infusion	Intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Estonia	Sandoz Pharmaceuticals D.D.	Capecitabine Sandoz	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Estonia	Sandoz Pharmaceuticals D.D.	Capecitabine Sandoz	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Estonia	Zentiva, K.S.	Capecitabine Zentiva	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Estonia	Zentiva, K.S.	Capecitabine Zentiva	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Finland	Accord Healthcare B.V.	Fluorouracil Accord	Fluorouracil 1 000 mg/20 ml	Solution for injection/infusion	Intravenous use
Finland	Accord Healthcare B.V.	Fluorouracil Accord	Fluorouracil 2 500 mg/50 ml	Solution for injection/infusion	Intravenous use
Finland	Accord Healthcare B.V.	Fluorouracil Accord	Fluorouracil 250 mg/5 ml	Solution for injection/infusion	Intravenous use
Finland	Accord Healthcare B.V.	Fluorouracil Accord	Fluorouracil 5 000 mg/100 ml	Solution for injection/infusion	Intravenous use
Finland	Accord Healthcare B.V.	Fluorouracil Accord	Fluorouracil 500 mg/10 ml	Solution for injection/infusion	Intravenous use
Finland	Actavis Group Ptc Ehf.	Capecitabin Actavis	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Finland	Almirall Hermal GmbH	Actikerall	Fluorouracil 5 mgg, Salicylic Acid 100 mgg	Cutaneous solution	Cutaneous use
Finland	Fairmed Healthcare GmbH	Capecitabin Fair-Med	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Finland	Fairmed Healthcare GmbH	Capecitabin Fair-Med	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Finland	Orion Oyj	Capecitabine Orion	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Finland	Orion Oyj	Capecitabine Orion	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
France	Accord Healthcare France Sas	Fluorouracile Accord	Fluorouracil 1 000 mg/20 ml	Concentrate for solution for infusion	Intraarterial use/intravenous Use
France	Accord Healthcare France Sas	Fluorouracile Accord	Fluorouracil 2 500 mg/50 ml	Concentrate for solution for infusion	Intraarterial use/intravenous Use
France	Accord Healthcare France Sas	Fluorouracile Accord	Fluorouracil 250 mg/5 ml	Concentrate for solution for infusion	Intraarterial use/intravenous Use
France	Accord Healthcare France Sas	Fluorouracile Accord	Fluorouracil 5 000 mg/100 ml	Concentrate for solution for infusion	Intraarterial use/intravenous Use
France	Accord Healthcare France Sas	Fluorouracile Accord	Fluorouracil 500 mg/10 ml	Concentrate for solution for infusion	Intraarterial use/intravenous Use
France	Arrow Generiques	Capecitabine Arrow	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
France	Arrow Generiques	Capecitabine Arrow	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
France	Biogaran	Capecitabine Biogaran	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
France	Biogaran	Capecitabine Biogaran	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
France	Cristers	Capecitabine Cristers	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
France	Cristers	Capecitabine Cristers	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
France	Dr Reddy's Laboratories (Uk) Ltd.	Capecitabine Reddy	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
France	Eg Labo Laboratoires Eurogenerics	Capecitabine Eg	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
France	Eg Labo Laboratoires Eurogenerics	Capecitabine Eg	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
France	Fairmed Healthcare Gmbh	Capecitabine Fair-Med	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
France	Fairmed Healthcare Gmbh	Capecitabine Fair-Med	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
France	Meda Pharma Sas	Efudix	Fluorouracil 5 g/100 g	Cream	Cutaneous use
France	Meda Pharma Sas	Ancotil	Flucytosine 1 g/100 ml	Solution for infusion	Intravenous use
France	Meda Pharma Sas	Ancotil	Flucytosine 500 mg Tablet	Tablet	Oral use
France	Mylan S.A.S	Capecitabine Mylan	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
France	Mylan S.A.S	Capecitabine Mylan	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
France	Pfizer Holding France	Fluorouracile Pfizer	Fluorouracil 10 g/200 ml	Concentrate for solution for infusion	Intraarterial use/intravenous Use
France	Pfizer Holding France	Fluorouracile Pfizer	Fluorouracil 1 g/20 ml	Concentrate for solution for infusion	Intraarterial use/intravenous Use
France	Pfizer Holding France	Fluorouracile Pfizer	Fluorouracil 250 mg/5 ml	Concentrate for solution for infusion	Intraarterial use/intravenous Use
France	Pfizer Holding France	Fluorouracile Pfizer	Fluorouracil 500 mg/10 ml	Concentrate for solution for infusion	Intraarterial use/intravenous Use
France	Pfizer Holding France	Fluorouracile Pfizer	Fluorouracil 5 g/100 ml	Concentrate for solution for infusion	Intraarterial use/intravenous Use
France	Sandoz	Capecitabine Sandoz	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
France	Sandoz	Capecitabine Sandoz	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
France	Teva Santé	Fluorouracile Teva	Fluorouracil 1 000 mg/20 ml	Injection	Intravenous use
France	Teva Santé	Fluorouracile Teva	Fluorouracil 250 mg/5ml	Injection	Intravenous use
France	Teva Santé	Fluorouracile Teva	Fluorouracil 5 000 mg/100 ml	Injection	Intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
France	Teva Santé	Fluorouracile Teva	Fluorouracil 500 mg/10 ml	Solution for injection	Intravenous use
France	Zentiva France	Capecitabine Zentiva	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
France	Zentiva France	Capecitabine Zentiva	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Germany	Accord Healthcare B.V.	Fluorouracil Accord	Fluorouracil 50 mg/Ml	Solution for injection/infusion	Intravenous use
Germany	Aliud Pharma Gmbh	Capecitabin Al	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Germany	Aliud Pharma Gmbh	Capecitabin Al	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Germany	Almirall Hermal Gmbh	Actikerall	Fluorouracil 5 mgg, Salicylic Acid 100 mgg	Cutaneous solution	Cutaneous use
Germany	Almirall Hermal Gmbh	Verrumal	Fluorouracil 0,5 g/100 g, Salicylic Acid 10 g/100 g	Cutaneous solution	Cutaneous use
Germany	Amneal Pharma Europe Limited	Fluorouracil Amneal	Fluorouracil 50 mg/Ml	Solution for injection	Intravenous use
Germany	Aqvida Gmbh	5-Fu Liv Pharma	Fluorouracil 50 mg/Ml	Solution for injection	Intravenous use
Germany	Bendalis Gmbh	Benda-5 Fu	Fluorouracil 50 mg/Ml	Solution for injection	Intravenous use
Germany	Betapharm Arzneimittel Gmbh	Capecitabin Beta	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Germany	Betapharm Arzneimittel Gmbh	Capecitabin Beta	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Germany	Bhardwaj Gmbh	Fluorouracil Bhardwaj	Fluorouracil 50 mg/Ml	Solution for injection	Intravenous use
Germany	Dermapharm Ag	Verrucutan	Fluorouracil 5mgg, Salicylic Acid 100 mgg	Cutaneous solution	Cutaneous use
Germany	Fairmed Healthcare Gmbh	Capecitabin Fair-Med	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Germany	Fairmed Healthcare Gmbh	Capecitabin Fair-Med	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Germany	Hexal Ag	Fluorouracil Hexal	Fluorouracil 50 mg/ml	Solution for injection/infusion	Intravenous use
Germany	Hexal Ag	Capecitabin Hexal	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Germany	Hexal Ag	Capecitabin Hexal	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Germany	Hikma Farmacêutica (Portugal), S.A.	5-Fluorouracil Hikma Farmacêutica (Portugal)	Fluorouracil 50 mg/ml	Solution for injection	Intravenous use
Germany	Hikma Farmacêutica (Portugal), S.A.	Ribofluor	Fluorouracil 50 mg/ml	Solution for injection	Intravenous use
Germany	Hikma Farmacêutica (Portugal), S.A.	Capecitabin Ribose-pharm	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Germany	Hikma Farmacêutica (Portugal), S.A.	Capecitabin Ribose-pharm	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Germany	Meda Pharma Gmbh & Co. Kg	Efudix	Fluorouracil 50mgg	Cream	Cutaneous use
Germany	Meda Pharma Gmbh & Co. Kg	Ancotil	Flucytosine 2,5 g/250 ml	Solution for infusion	Intravenous use
Germany	Medac Gesellschaft Für Klinische Spezialpräparate Mbh (Wedel)	5-Fu Medac	Fluorouracil 50 mg/ml	Solution for injection	Intravenous use
Germany	Onkovis Gmbh	5-Fu Onkovis	Fluorouracil 50 mg/ml	Solution for injection	Intravenous use
Germany	Onkovis Gmbh	Capecitabin Onkovis	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Germany	Onkovis Gmbh	Capecitabin Onkovis	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Germany	Pharma Resources Gmbh	Fluorouracil Phares	Fluorouracil 50 mg/ml	Solution for injection	Intravenous use
Germany	Stadapharm Gmbh	5 Fu	Fluorouracil 50 mg/ml	Solution for injection	Intravenous use
Germany	Stadapharm Gmbh	Capecitabin Cell Pharm	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Germany	Stadapharm Gmbh	Capecitabin Cell Pharm	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Germany	Temmler Pharma Gmbh	Fluorouracil Temmler	Fluorouracil 50 mg/ml	Solution for injection	Intravenous use
Germany	Teva Gmbh	Fluorouracil Gry	Fluorouracil 250 mg/5 ml	Solution for injection	Intravenous use
Germany	Tillomed Pharma Gmbh	Fluorouracil Tillomed	Fluorouracil 50 mg/ml	Solution for injection	Intravenous use
Germany	Vitane Pharma Gmbh	Fluorouracil Vitane	Fluorouracil 50 mg/ml	Solution for injection	Intravenous use
Germany	Wave Pharma Limited	Capecitabin Waverley	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Germany	Wave Pharma Limited	Capecitabin Waverly	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Germany	Zentiva Pharma Gmbh	Capecitabin Zentiva	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Germany	Zentiva Pharma Gmbh	Capecitabin Zentiva	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Greece	Anabiosis Pc	Fluorouracil Anabiosis	Fluorouracil 50 mg/ml	Solution for injection/infusion	Intravenous use
Greece	Anabiosis Pc	Zerectum	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Greece	Anabiosis Pc	Zerectum	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Greece	Ariti Sa	Capibine	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Greece	Ariti Sa	Capibine	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Greece	Medicus A.E	Uraciflor	Fluorouracil 250 mg/5 ml	Solution for injection	Intraarticular use/intra-peritoneal use/intravenous use
Greece	Medicus A.E	Uraciflor	Fluorouracil 500 mg/10 ml	Solution for injection	Intraarticular use/intra-peritoneal use/intravenous use
Greece	Mylan S.A.S	Capecitabine Mylan	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Greece	Mylan S.A.S	Capecitabine Mylan	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Greece	Olvos Science S.A.	Verruca Hermal	Fluorouracil 4,74 mg/ML, Salicylic Acid 94,8 mg/ML	Cutaneous solution	Cutaneous use
Greece	Opus-Materia Ltd	Fluorouracil Opus	Fluorouracil 50 mg/ML	Solution for injection/infusion	Intravenous use
Greece	Pharmazac Sa	Preveloda	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Greece	Pharmazac Sa	Preveloda	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Greece	Sandoz Gmbh	Capecitabine Sandoz	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Greece	Sandoz Gmbh	Capecitabine Sandoz	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Greece	Verisfield (Uk) Ltd	Actiker	Fluorouracil 5 mgg, Salicylic Acid 100 mgg	Cutaneous solution	Cutaneous use
Greece	Vocate Φαρμακευτική Αε	Xelazor	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Greece	Vocate Φαρμακευτική Αε	Xelazor	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Greece	Zentiva, K.S.	Capecitabine Zentiva	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Greece	Zentiva, K.S.	Capecitabine Zentiva	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Hungary	Accord Healthcare Polska Sp. Z O.O.	Fluorouracil Accord	Fluorouracil 50 mg/ML	Solution for injection/infusion	Intravenous use
Hungary	Almirall Hermal Gmbh	Verrumal	Fluorouracil 0,005 gg, Salicylic Acid 0,1 gg	Cutaneous solution	Cutaneous use
Hungary	Alvogen Ipco S.Ar.L	Xalvobin	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Hungary	Alvogen Ipco S.Ar.L	Xalvobin	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Hungary	Egis Pharmaceuticals Plc	Coloxet	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Hungary	Egis Pharmaceuticals Plc	Coloxet	Capecitabine 300 mg Tablet	Film-coated tablet	Oral use
Hungary	Egis Pharmaceuticals Plc	Coloxet	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Hungary	Fresenius Kabi Oncology Plc.	Capecitabine Fresenius Kabi	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Hungary	Fresenius Kabi Oncology Plc.	Capecitabine Fresenius Kabi	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Hungary	Grindeks	Ftorafur	Tegafur 400 mg Capsule	Capsule, hard	Oral use
Hungary	Mylan Epd Kft.	Efudix	Fluorouracil 50 mgg	Ointment	Cutaneous use
Hungary	Sandoz Hungária Kft	5-Fluorouracil Ebewe	Fluorouracil 50 mg/ml	Concentrate for solution for injection/infusion	Intravenous use
Hungary	Sandoz Hungária Kft	Capecitabin Sandoz	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Hungary	Sandoz Hungária Kft	Capecitabin Sandoz	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Hungary	Teva Gyógyszergyár Zrt	Fluorouracil Teva	Fluorouracil 50 mg/ml	Injection	Intravenous use
Hungary	Teva Gyógyszergyár Zrt	Fluorouracil Teva	Fluorouracil 50 mg/ml	Solution for injection	Intravenous use
Hungary	Zentiva, K.S.	Capecitabine Zentiva	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Hungary	Zentiva, K.S.	Capecitabine Zentiva	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Iceland	Accord Healthcare B.V.	Flúoróúracíl Accord	Fluorouracil 1 000 mg/20 ml	Solution for injection/infusion	Intravenous use
Iceland	Accord Healthcare B.V.	Flúoróúracíl Accord	Fluorouracil 2 500 mg/50 ml	Solution for injection/infusion	Intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Iceland	Accord Healthcare B.V.	Flúoróúracíl Accord	Fluorouracil 250 mg/5 ml	Solution for injection/infusion	Intravenous use
Iceland	Accord Healthcare B.V.	Flúoróúracíl Accord	Fluorouracil 5 000 mg/100 ml	Solution for injection/infusion	Intravenous use
Iceland	Accord Healthcare B.V.	Flúoróúracíl Accord	Fluorouracil 500 mg/10 ml	Solution for injection/infusion	Intravenous use
Iceland	Actavis Group Ptc Ehf.	Capecitabin Actavis	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Iceland	Actavis Group Ptc Ehf.	Capecitabin Actavis	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Iceland	Almirall Hermal GmbH	Actikerall	Fluorouracil 5mgg, Salicylic Acid 100 mgg	Cutaneous solution	Cutaneous use
Iceland	Fresenius Kabi Ab	Capecitabine Fresenius Kabi	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Iceland	Fresenius Kabi Ab	Capecitabine Fresenius Kabi	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Iceland	Pfizer Aps	Flurablastin	Fluorouracil 50 mg/ml	Solution for injection	Intravenous use
Ireland	Accord Healthcare Limited	Fluorouracil Accord Healthcare	Fluorouracil 1 000 mg/20 ml	Solution for injection/infusion	Intravenous use
Ireland	Accord Healthcare Limited	Fluorouracil Accord Healthcare	Fluorouracil 2 500 mg/50 ml	Solution for injection/infusion	Intravenous use
Ireland	Accord Healthcare Limited	Fluorouracil Accord Healthcare	Fluorouracil 250 mg/5 ml	Solution for injection/infusion	Intravenous use
Ireland	Accord Healthcare Limited	Fluorouracil Accord Healthcare	Fluorouracil 5 000 mg/100 ml	Solution for injection/infusion	Intravenous use
Ireland	Accord Healthcare Limited	Fluorouracil Accord Healthcare	Fluorouracil 500 mg/10 ml	Solution for injection/infusion	Intravenous use
Ireland	Fresenius Kabi Oncology Plc.	Capecitabine Fresenius Kabi Oncology	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Ireland	Fresenius Kabi Oncology Plc.	Capecitabine Fresenius Kabi Oncology	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Ireland	Mylan Ire Healthcare Limited	Efudix	Fluorouracil 5 % w/W	Cream	Cutaneous use
Ireland	Mylan Ire Healthcare Limited	Ancotil	Flucytosine 2,5 g/250 ml	Solution for infusion	Intraperitoneal use/intravenous use
Ireland	Pfizer Healthcare Ireland	Fluorouracil Pfizer Healthcare Ireland	Fluorouracil 25 mg/ml	Solution for injection/infusion	Intraarterial use/intravenous Use
Ireland	Rowex Ltd	Capecitabine Sandoz	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Ireland	Rowex Ltd	Capecitabine Sandoz	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Italy	Accord Healthcare Limited	Fluorouracile Ahcl	Fluorouracil 500 mg/50 ml	Solution for injection/infusion	Intravenous use
Italy	Accord Healthcare Limited	Fluorouracile Ahcl	Fluorouracil 50 mg/ml	Solution for injection/infusion	Intravenous use
Italy	Almirall Hermal GmbH	Actikerall	Fluorouracil 5mgg, Salicylic Acid 100 mgg	Cutaneous solution	Cutaneous use
Italy	Dr Reddy's Laboratories (Uk) Ltd.	Capecitabina Dr Reddy's	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Italy	Fairmed Healthcare GmbH	Capecitabina Fair-Med	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Italy	Fairmed Healthcare GmbH	Capecitabina Fair-Med	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Italy	Hikma Farmacêutica (Portugal), S.A.	Fluorouracile Hikma	Fluorouracil 50 mg/ml	Solution for injection/infusion	Intravenous use
Italy	Hikma Farmacêutica (Portugal), S.A.	Capecitabina Hikma	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Italy	Hikma Farmacêutica (Portugal), S.A.	Capecitabina Hikma	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Italy	Meda Pharma S.P.A.	Ancotil	Flucytosine 2,5 g/250 ml	Solution for infusion	Intravenous use
Italy	Mylan S.P.A.	Capecitabina Mylan	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Italy	Mylan S.P.A.	Capecitabina Mylan	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Italy	Teva Italia S.R.L.	Fl	Fluorouracil 50 mg/Ml	Injection	Intramuscular use/intravenous use
Italy	Teva Italia S.R.L.	Fluorouracil Teva	Fluorouracil 50 mg/Ml	Injection	Intramuscular use/intravenous use
Italy	Zentiva Italia Srl	Capecitabina Zentiva	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Italy	Zentiva Italia Srl	Capecitabina Zentiva	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Latvia	Accord Healthcare B.V.	Fluorouracil Accord	Fluorouracil 50 mg/Ml	Solution for injection/infusion	Intravenous use
Latvia	Almirall Hermal GmbH	Actikerall	Fluorouracil 5 mg, Salicylic Acid 100 mg	Cutaneous solution	Cutaneous use
Latvia	Grindeks	Ftorafur	Tegafur 400 mg Capsule	Capsule, hard	Oral use
Latvia	Norameda Uab	Capecitabine Norameda	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Latvia	Norameda Uab	Capecitabine Norameda	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Latvia	Sandoz Pharmaceuticals D.D.	Fluorouracil Ebewe	Fluorouracil 50 mg/Ml	Concentrate for solution for injection/infusion	Intraarterial use/intravenous Use
Latvia	Sandoz Pharmaceuticals D.D.	Fluorouracil Ebewe	Fluorouracil 50 mg/Ml Fluorouracil 50 ml/Ml	Concentrate for solution for injection/infusion	Intravenous use
Latvia	Sandoz Pharmaceuticals D.D.	Capecitabine Sandoz	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Latvia	Zentiva, K.S.	Capecitabine Zentiva	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Latvia	Zentiva, K.S.	Capecitabine Zentiva	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Lithuania	Accord Healthcare B.V.	Fluorouracil Accord	Fluorouracil 50 mg/ml	Solution for injection/infusion	Intravenous use
Lithuania	Grindeks	Ftorafur	Tegafur 400 mg Capsule	Capsule, hard	Oral use
Lithuania	Norameda Uab	Capecitabine Norameda	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Lithuania	Norameda Uab	Capecitabine Norameda	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Lithuania	Zentiva, K.S.	Capecitabine Zentiva	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Lithuania	Zentiva, K.S.	Capecitabine Zentiva	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Luxembourg	Almirall Hermal GmbH	Actikerall	Fluorouracil 5 mg/g, Salicylic Acid 100 mg/g	Cutaneous solution	Cutaneous use
Luxembourg	Almirall Hermal GmbH	Verrumal	Fluorouracil 0,5 g/100 g, Salicylic Acid 10 g/100 g	Cutaneous solution	Cutaneous use
Luxembourg	Eurogenerics N.V./S.A.	Capecitabine Eg	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Luxembourg	Eurogenerics N.V./S.A.	Capecitabine Eg	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Luxembourg	S.A. Meda Pharma N.V.	Efudix	Fluorouracil 5 g/100 g	Ointment	Cutaneous use
Luxembourg	Teva Pharma Belgium N.V./S.A	Fluracetyl	Fluorouracil 50 mg/ml	Injection	Intravenous use
Malta	1 A Pharma GmbH	Capecitabine Sandoz	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Malta	1 A Pharma GmbH	Capecitabine Sandoz	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Malta	Accord Healthcare Limited	Fluorouracil Accord Healthcare	Fluorouracil 1 000 mg/20 ml	Solution for injection/infusion	Intravenous use
Malta	Accord Healthcare Limited	Fluorouracil Accord Healthcare	Fluorouracil 2 500 mg/50 ml	Solution for injection/infusion	Intravenous use
Malta	Accord Healthcare Limited	Fluorouracil Accord Healthcare	Fluorouracil 250 mg/5 ml	Solution for injection/infusion	Intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Malta	Accord Healthcare Limited	Fluorouracil Accord Healthcare	Fluorouracil 5 000 mg/100 ml	Solution for injection/infusion	Intravenous use
Malta	Accord Healthcare Limited	Fluorouracil Accord Healthcare	Fluorouracil 500 mg/10 ml	Solution for injection/infusion	Intravenous use
Malta	Fresenius Kabi Oncology Plc.	Capecitabine Fresenius Kabi Oncology	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Malta	Fresenius Kabi Oncology Plc.	Capecitabine Fresenius Kabi Oncology	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Malta	Hospira Uk Ltd	Fluorouracil Hospira Uk	Fluorouracil 1 g/20 ml	Solution for injection	Intraarterial use/intravenous Use
Malta	Hospira Uk Ltd	Fluorouracil Hospira Uk	Fluorouracil 2,5 g/50 ml	Solution for injection	Intraarterial use/intravenous Use
Malta	Hospira Uk Ltd	Fluorouracil Hospira Uk	Fluorouracil 500 mg/10 ml	Solution for injection	Intraarterial use/intravenous Use
Malta	Hospira Uk Ltd	Fluorouracil Hospira Uk	Fluorouracil 5 g/100 ml	Solution for injection	Intraarterial use/intravenous Use
Malta	Meda Pharmaceuticals Limited	Efudix	Fluorouracil 5 % w/W	Cream	Cutaneous use
Netherlands	Accord Healthcare B.V.	Fluorouracil Accord	Fluorouracil 50 mg/Ml	Solution for injection/infusion	Intravenous use
Netherlands	Centrafarm B.V.	Capecitabine Cf	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Netherlands	Centrafarm B.V.	Capecitabine Cf	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Netherlands	Egis Pharmaceuticals Plc	Coloxet	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Netherlands	Egis Pharmaceuticals Plc	Coloxet	Capecitabine 300 mg Tablet	Film-coated tablet	Oral use
Netherlands	Egis Pharmaceuticals Plc	Coloxet	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Netherlands	Fairmed Healthcare Gmbh	Capecitabine Fair-Med	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Netherlands	Fairmed Healthcare Gmbh	Capecitabine Fair-Med	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Netherlands	Fresenius Kabi Nederland B.V.	Capecitabine Fresenius Kabi	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Netherlands	Fresenius Kabi Nederland B.V.	Capecitabine Fresenius Kabi	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Netherlands	Intas Pharmaceuticals Limited	Capecitabine Astron	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Netherlands	Intas Pharmaceuticals Limited	Capecitabine Astron	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Netherlands	Mylan B.V.	Capecitabine Mylan	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Netherlands	Mylan B.V.	Capecitabine Mylan	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Netherlands	Mylan Healthcare B.V.	Efudix	Fluorouracil 50 mgg	Cream	Cutaneous use
Netherlands	Mylan Healthcare B.V.	Ancotil	Flucytosine 10 mg/Ml	Solution for infusion	Intravenous use
Netherlands	Sandoz B.V.	5-Fluorouracil Sandoz	Fluorouracil 50 mg/Ml	Concentrate for solution for injection/infusion	Intravenous use
Netherlands	Sandoz B.V.	Capecitabine Sandoz	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Netherlands	Sandoz B.V.	Capecitabine Sandoz	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Norway	Accord Healthcare B.V.	Fluorouracil Accord	Fluorouracil 1 000 mg/20 ml	Solution for injection/infusion	Intravenous use
Norway	Accord Healthcare B.V.	Fluorouracil Accord	Fluorouracil 50 mg/Ml	Solution for injection/infusion	Intravenous use
Norway	Actavis Group Ptc Ehf.	Capecitabine Actavis	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Norway	Actavis Group Ptc Ehf.	Capecitabine Actavis	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Norway	Almirall Hermal Gmbh	Actikerall	Fluorouracil 5mgg, Salicylic Acid 100 mgg	Cutaneous solution	Cutaneous use
Norway	Fresenius Kabi Oncology Plc.	Capecitabine Fresenius Kabi	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Norway	Fresenius Kabi Oncology Plc.	Capecitabine Fresenius Kabi	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Norway	Teva B.V	Fluorouracil Teva	Fluorouracil 50 mg/ml	Solution for injection/infusion	Intravenous use
Poland	Accord Healthcare Limited	Fluorouracil Accord	Fluorouracil 5 000 mg/100 ml	Solution for injection/infusion	Intravenous use
Poland	Accord Healthcare Limited	Fluorouracil Accord	Fluorouracil 50 mg/ml	Solution for injection/infusion	Intravenous use
Poland	Almirall Hermal Gmbh	Actikerall	Fluorouracil 5 mgg, Salicylic Acid 100 mgg	Cutaneous solution	Cutaneous use
Poland	Almirall Hermal Gmbh	Verrumal	Fluorouracil 5 mgg, Salicylic Acid 100 mgg	Cutaneous solution	Cutaneous use
Poland	Alvogen Ipco S.Ar.L	Xalvobin	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Poland	Alvogen Ipco S.Ar.L	Xalvobin	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Poland	Ebewe Pharma	5-Fluorouracil Ebewe	Fluorouracil 50 mg/ml	Concentrate for solution for injection/infusion	Intraarterial use/intravenous Use
Poland	Egis Pharmaceuticals Plc	Coloxet	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Poland	Egis Pharmaceuticals Plc	Coloxet	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Poland	Fairmed Healthcare Gmbh	Capecitabine Fair-Med	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Poland	Fairmed Healthcare Gmbh	Capecitabine Fair-Med	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Poland	Fresenius Kabi Oncology Plc.	Capecitabine Fresenius Kabi	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Poland	Fresenius Kabi Oncology Plc.	Capecitabine Fresenius Kabi	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Poland	Glenmark Pharmaceuticals S.R.O.	Capecitabine Glenmark	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Poland	Glenmark Pharmaceuticals S.R.O.	Capecitabine Glenmark	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Poland	Medac Gesellschaft Für Klinische Spezialpräparate Mbh (Wedel)	Fluorouracil Medac	Fluorouracil 50 mg/Ml	Solution for injection	Intraarterial use/intravenous Use
Poland	Mylan Healthcare Sp. Z.O.O.	Efudix	Fluorouracil 50mgg	Cream	Cutaneous use
Poland	Mylan S.A.S	Capecitalox	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Poland	Mylan S.A.S	Capecitalox	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Poland	Pharmaswiss Česká Republika S.R.O.	Ancotil	Flucytosine 10 mg/Ml	Solution for infusion	Intravenous use
Poland	Przedsiębiorstwo Farmaceutyczne Lek-Am Sp. Z O.O.	Capecitabine Lek-Am	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Poland	Sun-Farm Sp. Z.O.O.	Verrucutan	Fluorouracil 5 mgg, Salicylic Acid 100 mgg	Cutaneous solution	Cutaneous use
Poland	Zentiva, K.S.	Capecitabine Zentiva	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Poland	Zentiva, K.S.	Capecitabine Zentiva	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Portugal	Accord Healthcare Limited	Fluorouracilo Accord	Fluorouracil 50 mg/Ml	Solution for injection/infusion	Intravenous use
Portugal	Almirall Hermal GmbH	Actikerall	Fluorouracil 5 mgg, Salicylic Acid 100 mgg	Cutaneous solution	Cutaneous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Portugal	Almirall Hermal GmbH	Verrumal	Fluorouracil 5 mg/ml, Salicylic Acid 100 mg/ml	Cutaneous solution	Cutaneous use
Portugal	Anabiosis Pc	Fluorouracilo Anabiosis	Fluorouracil 50 mg/ml	Solution for injection/infusion	Intravenous use
Portugal	Anabiosis Pc	Zerectum	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Portugal	Anabiosis Pc	Zerectum	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Portugal	Farmoz — Sociedade Técnico Med- icinal, S.A.	Capecitabina Farmoz	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Portugal	Farmoz — Sociedade Técnico Med- icinal, S.A.	Capecitabina Farmoz	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Portugal	Fresenius Kabi Pharma Portugal, Lda.	Capecitabina Fresenius Kabi	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Portugal	Fresenius Kabi Pharma Portugal, Lda.	Capecitabina Fresenius Kabi	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Portugal	Generis Farmacêutica, S.A.	Capecitabina Aurovitas	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Portugal	Generis Farmacêutica, S.A.	Capecitabina Aurovitas	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Portugal	Hikma Farmacêutica (Portugal), S.A.	Fluorouracilo Hikma	Fluorouracil 50 mg/ml	Solution for injection/infusion	Intravenous use
Portugal	Hikma Farmacêutica (Portugal), S.A.	Capecitabina Hikma	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Portugal	Hikma Farmacêutica (Portugal), S.A.	Capecitabina Hikma	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Portugal	Laboratório Medinfar — Produtos Farmacêuticos, S.A.	Verrucare	Fluorouracil 5 mg/ml, Salicylic Acid 100 mg/ml	Cutaneous solution	Cutaneous use
Portugal	Laboratórios Normon, S.A.	Capecitabina Normon	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Portugal	Laboratórios Normon, S.A.	Capecitabina Normon	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Portugal	Laboratórios Pfizer, Lda.	Cinkef-U	Fluorouracil 1 g/20 ml	Solution for injection	Intraarterial use/intravenous Use
Portugal	Laboratórios Pfizer, Lda.	Cinkef-U	Fluorouracil 2,5 g/50 ml	Solution for injection	Intraarterial use/intravenous Use
Portugal	Laboratórios Pfizer, Lda.	Cinkef-U	Fluorouracil 500 mg/10 ml	Solution for injection	Intraarterial use/intravenous Use
Portugal	Laboratórios Pfizer, Lda.	Cinkef-U	Fluorouracil 5 g/100 ml	Solution for injection	Intraarterial use/intravenous Use
Portugal	Labosuan I+d S.L.	Capecitabina Labosuan	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Portugal	Labosuan I+d S.L.	Capecitabina Labosuan	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Portugal	Opus-Materia Ltd	Fluorouracil Opus	Fluorouracil 50 mg/Ml	Solution for injection/infusion	Intravenous use
Portugal	Pharmacare Premium Limited	Capecitabina Bluelife	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Portugal	Pharmacare Premium Limited	Capecitabina Bluelife	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Portugal	Sandoz Farmacêutica Lda.	Capecitabina Sandoz	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Portugal	Sandoz Farmacêutica Lda.	Capecitabina Sandoz	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Portugal	Stada Lda.	Capecitabina Stada	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Portugal	Stada Lda.	Capecitabina Stada	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Portugal	Teva B.V	Fluorouracilo Refta	Fluorouracil 50 mg/Ml	Solution for injection/infusion	Intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Portugal	Teva Pharma — Produtos Farmacêuticos Lda	Fluorouracilo Teva	Fluorouracil 50 mg/Ml	Solution for injection	Intraarterial use/intravenous Use
Portugal	Teva Pharma — Produtos Farmacêuticos Lda	Fluorouracilo Teva	Fluorouracil 50 mg/Ml	Injection	Intravenous use
Portugal	Vocate Φαρμακευτική Αε	Xelazor	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Portugal	Vocate Φαρμακευτική Αε	Xelazor	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Portugal	Zentiva Portugal, Lda	Capecitabina Zentiva	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Portugal	Zentiva Portugal, Lda	Capecitabina Zentiva	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Romania	Accord Healthcare Polska Sp. Z O.O.	Fluorouracil Accord	Fluorouracil 250 mg/5ml	Solution for injection/infusion	Intravenous use
Romania	Accord Healthcare Polska Sp. Z O.O.	Fluorouracil Accord	Fluorouracil 50 mg/Ml	Solution for injection/infusion	Intravenous use
Romania	Alvogen Ipco S.Ar.L	Xalvobin	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Romania	Alvogen Ipco S.Ar.L	Xalvobin	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Romania	Dr Reddy's Laboratories Romania Srl	Capecitabină Dr Reddy's	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Romania	Ebewe Pharma	5-Fluorouracil	Fluorouracil 50 mg/Ml	Concentrate for solution for injection/infusion	Intraarterial use/intraperitoneal use/intravenous use
Romania	Fairmed Healthcare GmbH	Capecitabină Fair-Med	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Romania	Fairmed Healthcare GmbH	Capecitabină Fair-Med	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Romania	Glenmark Pharmaceuticals S.R.O.	Capecitabină Glenmark	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Romania	Neola Pharma Srl	Arxeda	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Romania	Neola Pharma Srl	Arxeda	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Romania	S.C. Fresenius Kabi România S.R.L.	Capecitabina Fresenius Kabi	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Romania	S.C. Fresenius Kabi România S.R.L.	Capecitabina Fresenius Kabi	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Romania	Terapia S.A.	Cerex	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Slovakia	Accord Healthcare Polska Sp. Z O.O.	Fluorouracil Accord	Fluorouracil 50 mg/Ml	Solution for injection/infusion	Intravenous use
Slovakia	Almirall Hermal GmbH	Actikerall	Fluorouracil 5 mgg, Salicylic Acid 100 mgg	Cutaneous solution	Cutaneous use
Slovakia	Almirall Hermal GmbH	Verrumal	Fluorouracil 5 mgg, Salicylic Acid 100 mgg	Cutaneous solution	Cutaneous use
Slovakia	Ebewe Pharma	5-Fluorouracil Ebewe	Fluorouracil 50 mg/Ml	Concentrate for solution for injection/infusion	Intraarterial use/intraperitoneal use/intravenous use
Slovakia	Egis Pharmaceuticals Plc	Coloxet	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Slovakia	Egis Pharmaceuticals Plc	Coloxet	Capecitabine 300 mg Tablet	Film-coated tablet	Oral use
Slovakia	Egis Pharmaceuticals Plc	Coloxet	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Slovakia	Glenmark Pharmaceuticals S.R.O.	Capecitabine Glenmark	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Slovakia	Mylan Ire Healthcare Limited	Efudix	Fluorouracil 50 mgg	Ointment	Cutaneous use
Slovakia	Mylan Ireland Limited	Capecitalox	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Slovakia	Pharmagen Cz S.R.O.	Capecitabine Pharmagen	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Slovakia	Pharmagen Cz S.R.O.	Capecitabine Pharmagen	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Slovakia	Pharmevid S.R.O.	Capecitabine Pharma-center	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Slovakia	Sandoz Pharmaceuticals D.D.	5-Fluorouracil Ebewe	Fluorouracil 50 mg/ml	Concentrate for solution for injection/infusion	Intraarterial use/intraperitoneal use/intrapleural use/intravenous Use
Slovakia	Stada Arzneimittel Ag	Capecitabine Stada	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Slovenia	Accord Healthcare Limited	Fluorouracil Accord	Fluorouracil 1 000 mg/20 ml	Solution for injection/infusion	Intravenous use
Slovenia	Accord Healthcare Limited	Fluorouracil Accord	Fluorouracil 2 500 mg/50 ml	Solution for injection/infusion	Intravenous use
Slovenia	Accord Healthcare Limited	Fluorouracil Accord	Fluorouracil 250 mg/5 ml	Solution for injection/infusion	Intravenous use
Slovenia	Accord Healthcare Limited	Fluorouracil Accord	Fluorouracil 5 000 mg/100 ml	Solution for injection/infusion	Intravenous use
Slovenia	Accord Healthcare Limited	Fluorouracil Accord	Fluorouracil 500 mg/10 ml	Solution for injection/infusion	Intravenous use
Slovenia	Ebewe Pharma	5-Fluorouracil Ebewe	Fluorouracil 50 mg/ml	Concentrate for solution for injection/infusion	Intravenous use
Slovenia	Fresenius Kabi Oncology Plc.	Kapecitabin Fresenius Kabi	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Slovenia	Sandoz Pharmaceuticals D.D.	Kapecitabin Sandoz	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Slovenia	Sandoz Pharmaceuticals D.D.	Kapecitabin Sandoz	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Spain	Accord Healthcare S.L.U.	Fluorouracilo Accord	Fluorouracil 1 000 mg/20 ml	Solution for injection/infusion	Intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Spain	Accord Healthcare S.L.U.	Fluorouracilo Accord	Fluorouracil 250 mg/5ml	Solution for injection/infusion	Intravenous use
Spain	Accord Healthcare S.L.U.	Fluorouracilo Accord	Fluorouracil 5 000 mg/100 ml	Solution for injection/infusion	Intravenous use
Spain	Accord Healthcare S.L.U.	Fluorouracilo Accord	Fluorouracil 500 mg/10ml	Solution for injection/infusion	Intravenous use
Spain	Almirall Hermal GmbH	Actikerall	Fluorouracil 5 mgg, Salicylic Acid 100 mgg	Cutaneous solution	Cutaneous use
Spain	Aurovitas Spain, s.A.U.	Capecitabina Aurovitas Spain	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Spain	Aurovitas Spain, s.A.U.	Capecitabina Aurovitas Spain	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Spain	Cipla (Uk) Limited	Xelcip	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Spain	Cipla (Uk) Limited	Xelcip	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Spain	Fairmed Healthcare GmbH	Capecitabina Fair-Med	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Spain	Fairmed Healthcare GmbH	Capecitabina Fair-Med	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Spain	Fresenius Kabi Oncology Plc.	Capecitabina Fresenius Kabi	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Spain	Fresenius Kabi Oncology Plc.	Capecitabina Fresenius Kabi	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Spain	Kern Pharma, S.L.	Capecitabina Kern Pharma	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Spain	Kern Pharma, S.L.	Capecitabina Kern Pharma	Capecitabine 300 mg Tablet	Film-coated tablet	Oral use
Spain	Kern Pharma, S.L.	Capecitabina Kern Pharma	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Spain	Laboratorios Normon, S.A.	Capecitabina Normon	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Spain	Laboratorios Normon, S.A.	Capecitabina Normon	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Spain	Mylan Pharmaceuticals S.L.	Utefos	Tegafur 400 mg Capsule	Capsule, hard	Oral use
Spain	Reddy Pharma Iberia, S.A.	Capecitabina Dr Reddys	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Spain	Sandoz Farmacéutica, S.A.	Capecitabina Sandoz	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Spain	Sandoz Farmacéutica, S.A.	Capecitabina Sandoz	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Spain	Zaphyr Pharmaceuticals Ireland Limited	Zapetine	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Spain	Zaphyr Pharmaceuticals Ireland Limited	Zapetine	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Sweden	Accord Healthcare Limited	Fluorouracil Accord	Fluorouracil 1 000 mg/20 ml	Solution for injection/infusion	Intravenous use
Sweden	Accord Healthcare Limited	Fluorouracil Accord	Fluorouracil 2 500 mg/50 ml	Solution for injection/infusion	Intravenous use
Sweden	Accord Healthcare Limited	Fluorouracil Accord	Fluorouracil 250 mg/5 ml	Solution for injection/infusion	Intravenous use
Sweden	Accord Healthcare Limited	Fluorouracil Accord	Fluorouracil 5 000 mg/100 ml	Solution for injection/infusion	Intravenous use
Sweden	Accord Healthcare Limited	Fluorouracil Accord	Fluorouracil 500 mg/10 ml	Solution for injection/infusion	Intravenous use
Sweden	Almirall Hermal GmbH	Actikerall	Fluorouracil 5 mgg, Salicylic Acid 100 mgg	Cutaneous solution	Cutaneous use
Sweden	Alvogen Ipco S.Ar.L	Xalvobin	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Sweden	Alvogen Ipco S.Ar.L	Xalvobin	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
Sweden	Fairmed Healthcare Gmbh	Capecitabine Fair-Med	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Sweden	Fairmed Healthcare Gmbh	Capecitabine Fair-Med	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Sweden	Fresenius Kabi Oncology Plc.	Capecitabin Fresenius Kabi	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Sweden	Fresenius Kabi Oncology Plc.	Capecitabin Fresenius Kabi	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Sweden	Meda Ab	Ancotil	Flucytosine 10 mg/Ml	Solution for infusion	Intravenous use
Sweden	Mylan Ab	Capecitalox	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Sweden	Mylan Ab	Capecitalox	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Sweden	Orion Corporation	Capecitabine Orion	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Sweden	Orion Corporation	Capecitabine Orion	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Sweden	Sandoz A/S	Capecitabine Sandoz	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Sweden	Stada Arzneimittel Ag	Capecitabin Stada	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
Sweden	Stada Arzneimittel Ag	Capecitabin Stada	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
Sweden	Teva Sweden Ab	Fluorouracil Teva	Fluorouracil 50 mg/Ml	Injection	Intravenous use
United Kingdom	Accord Healthcare Limited	Fluorouracil Accord	Fluorouracil 50 mg/Ml	Solution for injection/infusion	Intravenous use
United Kingdom	Accord Healthcare Limited	Fluorouracil Accord Healthcare	Fluorouracil 50 mg/Ml	Solution for injection/infusion	Intravenous use
United Kingdom	Actavis Uk Ltd.	Capecitabine Accord-Uk	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
United Kingdom	Actavis Uk Ltd.	Capecitabine Accord-Uk	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
United Kingdom	Almirall Hermal Gmbh	Actikerall	Fluorouracil 5 mgg, Salicylic Acid 100 mgg	Cutaneous solution	Cutaneous use
United Kingdom	Cipla (Eu) Limited	Xelcip	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
United Kingdom	Cipla (Eu) Limited	Xelcip	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
United Kingdom	Dr Reddy's Laboratories (Uk) Ltd.	Capecitabine Dr Reddy's	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
United Kingdom	Dr Reddy's Laboratories (Uk) Ltd.	Capecitabine Dr Reddy's	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
United Kingdom	Fairmed Healthcare Gmbh	Capecitabine Fair-Med	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
United Kingdom	Fairmed Healthcare Gmbh	Capecitabine Fair-Med	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
United Kingdom	Fresenius Kabi Oncology Plc.	Capecitabine Fresenius Kabi Oncology	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
United Kingdom	Fresenius Kabi Oncology Plc.	Capecitabine Fresenius Kabi Oncology	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
United Kingdom	Generics [uk] Limited	Capecitabine Mylan	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
United Kingdom	Generics [uk] Limited	Capecitabine Mylan	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
United Kingdom	Glenmark Pharmaceuticals Europe Limited	Capecitabine Glenmark Pharmaceuticals Europe	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
United Kingdom	Glenmark Pharmaceuticals Europe Limited	Capecitabine Glenmark Pharmaceuticals Europe	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
United Kingdom	Hikma Farmacêutica (Portugal), S.A.	Fluorouracil Hikma Farmacêutica Portugal	Fluorouracil 50 mg/Ml	Solution for injection/infusion	Intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
United Kingdom	Hospira Uk Ltd	Fluorouracil Hospira Uk	Fluorouracil 1 g/20 ml	Solution for injection	Intraarterial use/intravenous Use
United Kingdom	Hospira Uk Ltd	Fluorouracil Hospira Uk	Fluorouracil 2,5 g/100 ml	Solution for injection	Intraarterial use/intravenous Use
United Kingdom	Hospira Uk Ltd	Fluorouracil Hospira Uk	Fluorouracil 2,5 g/50 ml	Solution for injection	Intraarterial use/intravenous Use
United Kingdom	Hospira Uk Ltd	Fluorouracil Hospira Uk	Fluorouracil 250 mg/10 ml	Solution for injection	Intraarterial use/intravenous Use
United Kingdom	Hospira Uk Ltd	Fluorouracil Hospira Uk	Fluorouracil 250 mg/5 ml	Solution for injection	Intraarterial use/intravenous Use
United Kingdom	Hospira Uk Ltd	Fluorouracil Hospira Uk	Fluorouracil 500 mg/10 ml	Solution for injection	Intraarterial use/intravenous Use
United Kingdom	Hospira Uk Ltd	Fluorouracil Hospira Uk	Fluorouracil 500 mg/20 ml	Solution for injection	Intraarterial use/intravenous Use
United Kingdom	Hospira Uk Ltd	Fluorouracil Hospira Uk	Fluorouracil 5 g/100 ml	Solution for injection	Intraarterial use/intravenous Use
United Kingdom	Medac Gesellschaft Für Klinische Spezialpräparate MbH (Wedel)	Fluorouracil Medac	Fluorouracil 25 mg/Ml	Solution for injection	Intraarterial use/intravenous Use
United Kingdom	Medac Gesellschaft Für Klinische Spezialpräparate MbH (Wedel)	Fluorouracil Medac	Fluorouracil 50 mg/Ml	Solution for injection	Intraarterial use/intravenous Use
United Kingdom	Morningside Healthcare Ltd	Capecitabine Morning-side Healthcare	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
United Kingdom	Morningside Healthcare Ltd	Capecitabine Morning-side Healthcare	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
United Kingdom	Mylan Products Limited	Efudix	Fluorouracil 5 % w/W	Cream	Cutaneous use
United Kingdom	Mylan Products Limited	Ancotil	Flucytosine 2,5 g Bottle	Solution for infusion	Intraperitoneal use/intravenous use

Member State EU/EEA	Marketing authorisation holder	Invented name	INN + Strength	Pharmaceutical form	Route of administration
United Kingdom	Sandoz Ltd	Capecitabine Sandoz	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
United Kingdom	Sandoz Ltd	Capecitabine Sandoz	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
United Kingdom	Wave Pharma Limited	Capecitabine Reliance	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
United Kingdom	Wave Pharma Limited	Capecitabine Reliance	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use
United Kingdom	Zentiva Pharma Uk Limited	Capecitabine Zentiva	Capecitabine 150 mg Tablet	Film-coated tablet	Oral use
United Kingdom	Zentiva Pharma Uk Limited	Capecitabine Zentiva	Capecitabine 500 mg Tablet	Film-coated tablet	Oral use