

## **Annex I**

**List of the names, pharmaceutical forms, strengths of the medicinal products, routes of administration and marketing authorisation holders in the member states**

<b>Member State (in EEA)</b>	<b>Marketing authorisation holder</b>	<b>Product name</b>	<b>Strength</b>	<b>Pharmaceutical form</b>	<b>Route of administration</b>
Austria	Forest Pharma B.V. Newtonlaan 115 3584 BH Utrecht The Netherlands	Colistin Forest - Trockenstechampullen mit Lösungsmittel	1000000 I.U.	powder and solvent for suspension for injection, nebuliser solution	intramuscular use, intravenous use, inhalation use
Austria	Profile Pharma Limited Chichester Business Park City Fields Way Tangmere, Chichester West Sussex PO20 2FT United Kingdom	Tadim 1 Million I.E. Pulver zur Herstellung einer Infusionslösung	1000000 I.U.	powder for solution for infusion	intravenous use
Austria	Xellia Pharmaceuticals ApS Dalslandsgade 11 DK-2300 Copenhagen S Denmark	Colistin Xellia 1 Million I.E. Pulver zur Herstellung einer Injektions-/Infusionslösung	1000000 I.U.	powder for solution for injection/infusion	intravenous use
Austria	Profile Pharma Limited Chichester Business Park City Fields Way Tangmere, Chichester West Sussex PO20 2FT United Kingdom	Tadim 1 Million I.E. Pulver zur Herstellung einer Lösung für einen Vernebler	1000000 I.U.	powder for nebuliser solution	inhalation use
Austria	PARI Pharma GmbH Moosstrasse 3 82319 Starnberg Germany	ColiFin 1 Mio. I.E. Pulver zur Herstellung einer Lösung für einen Vernebler	1000000 I.U.	powder for nebuliser solution	inhalation use

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Austria	PARI Pharma GmbH Moosstrasse 3 82319 Starnberg Germany	ColiFin 2 Mio. I.E. Pulver zur Herstellung einer Lösung für einen Vernebler	2000000 I.U.	powder for nebuliser solution	inhalation use
Belgium	Forest Laboratories UK Ltd. Riverbridge House Anchor Boulevard Crossways Business Park Dartford Kent DA2 6SL United Kingdom	Colistineb 1000000 IE	1000000 I.U.	powder for solution for injection/infusion	intravenous use, inhalation use
Belgium	Forest Laboratories UK Ltd. Riverbridge House Anchor Boulevard Crossways Business Park Dartford Kent DA2 6SL United Kingdom	Colistineb 2000000 IE	2000000 I.U.	powder for solution for injection/infusion	intravenous use, inhalation use
Bulgaria	Alvogen IPCo.S.ar. I. 5 Rue Heienhaff Senningerberg L-1736 Luxembourg	Colistin Alvogen	1000000 I.U.	powder for solution for injection/infusion	intravenous use

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Bulgaria	Alvogen IPCo.S.ar. I. 5 Rue Heienhaff Senningerberg L-1736 Luxembourg	Colistin Alvogen	2000000 I.U.	powder for solution for injection/infusion	intravenous use
Croatia	Altamedics d.o.o. Karlovačka cesta 24a, Zagreb 10020 Croatia	Colixin 1 milijun IU prašak za otopinu za injekciju	1000000 I.U.	powder for solution for injection	intravenous use
Czech Republic	Forest Laboratories UK Limited Riverbridge House Anchor Boulevard Crossways Business Park Dartford Kent DA2 6SL United Kingdom	Colomycin injekce 1000000 IU	1000000 I.U.	powder for solution for injection/infusion or nebuliser solution	intravenous use, inhalation use
Denmark	Profile Pharma Limited Chichester Business Park City Fields Way Tangmere, Chichester West Sussex PO20 2FT United Kingdom	Promixin	1000000 I.U.	nebuliser solution	inhalation use

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Denmark	Profile Pharma Limited Chichester Business Park City Fields Way Tangmere, Chichester West Sussex PO20 2FT United Kingdom	Promixin	1000000 I.U.	powder for solution for infusion	intravenous use
Denmark	Xellia Pharmaceuticals ApS Dalslandsgade 11 DK-2300 Copenhagen S Denmark	Colistimethatnatrium "Xellia"	1000000 I.U.	powder for solution for injection/infusion	intravenous use
France	Sanofi-Aventis France 1-13 boulevard R. Rolland 75014 Paris France	COLIMYCINE 1 MUI, poudre et solvant pour inhalation par nébuliseur	1000000 I.U.	powder and solvent for nebuliser solution	inhalation use
France	Sanofi-Aventis France 1-13 boulevard R. Rolland 75014 Paris France	COLIMYCINE 1.000.000 U.I., poudre et solvant pour solution injectable	1000000 I.U.	powder and solvent for solution for injection	intravenous use

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France	Profile Pharma Limited Chichester Business Park City Fields Way Tangmere, Chichester West Sussex PO20 2FT United Kingdom	TADIM 1 million d'unités internationales (UI) poudre pour solution pour inhalation par nébuliseur	1000000 I.U.	powder for nebuliser solution	inhalation use
Germany	Forest Laboratories Nederland B.V. Newtonlaan 115 3584 BH Utrecht The Netherlands	Colistin CF	1000000 I.U.	powder and solvent for nebuliser solution	inhalation use
Germany	InfectoPharm Arzneimittel und Consilium GmbH Von-Humboldt-Straße 1 64646 Heppenheim Germany	Colistimethat-Natrium Infectopharm I.E. Pulver zur Herstellung einer Injektions- oder Infusionslösung	1000000 I.U.	powder for solution for injection/infusion	intravenous use
Germany	InfectoPharm Arzneimittel und Consilium GmbH Von-Humboldt-Straße 1 64646 Heppenheim Germany	Colistimethat-Natrium Infectopharm I.E. Pulver zur Herstellung einer Injektions- oder Infusionslösung	1000000 I.U.	powder for solution for injection/infusion	intravenous use

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Germany	Profile Pharma Limited Bicentennial Building Southern Gate Chichester PO19 8EZ United Kingdom	Promixin 1 MI.E. Pulver zur Herstellung einer Lösung für einen Vernebler	1000000 I.U.	powder for nebuliser solution	inhalation use
Germany	Profile Pharma Limited Bicentennial Building Southern Gate Chichester PO19 8EZ United Kingdom	Promixin 1 MI.E. Pulver zur Herstellung einer Lösung für einer Infusionslösung	1000000 I.U.	powder for solution for infusion	intravenous use
Greece	NORMA HELLAS AE 54 Menandrou str 10431 Athens Greece	COLISTIN/NORMA	1000000 I.U.	powder for solution for injection	intramuscular use
Greece	NORMA HELLAS AE 54 Menandrou str 10431 Athens Greece	COLISTIN/NORMA	1000000 I.U.	powder and solvent for nebuliser solution	inhalation use
Greece	NORMA HELLAS AE 54 Menandrou str 10431 Athens Greece	COLISTIN/NORMA	1000000 I.U.	powder for solution for infusion	intravenous use

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Greece	NORMA HELLAS AE 54 Menandrou str 10431 Athens Greece	COLISTIN/NORMA	2000000 I.U.	powder for solution for infusion	intravenous use
Greece	ALLERTEC HELLAS AE 74 Karamanli str. 55134, Kalamaria, Thessaloniki Greece	TADIM	1000000 I.U.	powder and solvent for nebuliser solution	inhalation use
Hungary	Forest Laboratories UK Limited Riverbridge House Anchor Boulevard Crossways Business Park Dartford, Kent DA2 6SL United Kingdom	COLOMYCIN	1000000 I.U.	powder for solution for injection/infusion, powder for nebuliser solution	intravenous use, inhalation use
Hungary	Forest Laboratories UK Limited Riverbridge House Anchor Boulevard Crossways Business Park Dartford, Kent DA2 6SL United Kingdom	COLOMYCIN	2000000 I.U.	powder for solution for injection/infusion, powder for nebuliser solution	intravenous use, inhalation use



Member State (in EEA)	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Iceland	Alvogen IPCo S.à.r.l., 5 Rue Heienhaff, L-1736 Senningerberg Luxembourg	Colistimethate Alvogen	1000000 I.U.	powder for solution for injection or infusion	intravenous use
Iceland	Alvogen IPCo S.à.r.l., 5 Rue Heienhaff, L-1736 Senningerberg Luxembourg	Colistimethate Alvogen	2000000 I.U.	powder for solution for injection or infusion	intravenous use
Ireland	Forest Laboratories UK Limited Riverbridge House Anchor Boulevard Crossways Business Park Dartford, Kent DA2 6SL United Kingdom	Colomycin Injection 1 million International Units. Powder for solution for injection, infusion or inhalation	1000000 I.U.	powder for solution for injection, infusion or inhalation	intravenous use, inhalation use
Ireland	Forest Laboratories UK Limited Riverbridge House Anchor Boulevard Crossways Business Park Dartford, Kent DA2 6SL United Kingdom	Colomycin Injection 2 million International Units. Powder for solution for injection, infusion or inhalation	2000000 I.U.	powder for solution for injection, infusion or inhalation	intravenous use, inhalation use

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Ireland	Profile Pharma Limited Chichester Business Park City Fields Way Tangmere, Chichester West Sussex PO20 2FT United Kingdom	Promixin, 1 million International Units (IU), Powder for Nebuliser Solution	1000000 I.U.	powder for nebuliser solution	inhalation use
Italy	UCB Pharma S.p.A.Via Gadames 5720151 - Milano (MI) Italy	COLIMICINA	1000000 I.U.	powder and solvent for solution for injection	intramuscular use
Italy	PARI Pharma GmbH Moosstrasse 3 82319 Starnberg Germany	COLFINAIR	1000000 I.U.	powder for nebuliser solution	inhalation use
Italy	PARI Pharma GmbH Moosstrasse 3 82319 Starnberg Germany	COLFINAIR	2000000 I.U.	powder for nebuliser solution	Inhalation use

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Italy	Profile Pharma Limited Chichester Business Park City Fields Way Tangmere, Chichester West Sussex PO20 2FT United Kingdom	PROMIXIN	1000000 I.U.	powder for nebuliser solution	Inhalation use
Luxembourg	Profile Pharma Limited Chichester Business Park City Fields Way Tangmere, Chichester West Sussex PO20 2FT United Kingdom	Tadim	1000000 I.U.	powder for nebuliser solution	inhalation use
Malta	Forest Laboratories UK Limited Riverbridge House Anchor Boulevard Crossways Business Park Dartford, Kent DA2 6SL United Kingdom	Colomycin Injection 1million International Units powder for solution for injection, infusion or inhalation	1000000 I.U.	powder for solution for injection/infusion/ inhalation	intravenous use, inhalation use
Norway	Xellia Pharmaceuticals ApS Dalslandsgade 11 DK-2300 Copenhagen S Denmark	Colistimethate Xellia	1000000 I.U.	powder for solution for infusion	intravenous use

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Norway	Profile Pharma Limited Chichester Business Park City Fields Way Tangmere, Chichester West Sussex PO20 2FT United Kingdom	Promixin	1000000 I.U.	powder for nebuliser solution	nasal use
Norway	Profile Pharma Limited Chichester Business Park City Fields Way Tangmere, Chichester West Sussex PO20 2FT United Kingdom	Promixin	1000000 I.U.	powder for solution for infusion	intravenous use
Poland	Tarchomińskie Zakłady Farmaceutyczne "Polfa" S.A. 2, A. Fleminga Str. 03-176 Warsaw Poland	Colistin TZF	1000000 I.U.	powder for solution for injection, injection or inhalation	intramuscular use, intravenous use, inhalation use
Poland	Profile Pharma Limited Chichester Business Park City Fields Way Tangmere, Chichester West Sussex PO20 2FT United Kingdom	Promixin	1000000 I.U.	powder for nebuliser solution	inhalation use

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Portugal	Generis Farmacêutica, S.A. Rua João de Deus 19 2700-487 Amadora Portugal	Colistina Generis	1000000 I.U.	powder for solution for injection or for nebuliser solution	intravenous use, inhalation use
Portugal	Pharmis Biofarmacêutica, Lda. Praceta do Farol, lote 101 Cascais 2750-341 Portugal	Colixin	2000000 I.U.	powder for solution for injection or for nebuliser solution	intravenous use, inhalation use
Portugal	Pharmis Biofarmacêutica, Lda. Praceta do Farol, lote 101 Cascais 2750-341 Portugal	Colixin	1000000 I.U.	powder for solution for injection or for nebuliser solution	intravenous use, inhalation use
Portugal	Profile Pharma Limited Chichester Business Park City Fields Way Tangmere, Chichester West Sussex PO20 2FT United Kingdom	Promixin	1000000 I.U.	powder for nebuliser solution	inhalation use
Romania	S.C. ANTIBIOTICE S.A., Str. Valea Lupului nr.1 707410 Iași România	COLISTINĂ ANTIBIOTICE 1000000 UI,	1000000 I.U.	powder for solution for injection/infusion	intravenous use

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Romania	Xellia Pharmaceuticals ApS Dalslandsgade 11 DK-2300 Copenhagen S Denmark	Colistimetat sodic Xellia 1 milion unități internaționale (U.I.)	1000000 I.U.	powder for solution for injection/infusion	intravenous use
Slovak Republic	sanofi-aventis Slovakia s.r.o. Einsteinova 24 851 01 Bratislava Slovak Republic	Colimycine	1000000 I.U.	powder for solution for injection	intravenous use, intramuscular use
Slovak Republic	Forest Laboratories UK Limited Riverbridge House Anchor Boulevard Crossways Business Park Dartford, Kent DA2 6SL United Kingdom	KOLOMYCÍN INJEKCIA 1 milión IU	1000000 I.U.	powder for solution for injection/infusion/ inhalation	intravenous use, inhalation use
Slovak Republic	Forest Laboratories UK Limited Riverbridge House Anchor Boulevard Crossways Business Park Dartford, Kent DA2 6SL United Kingdom	KOLOMYCÍN INJEKCIA 2 milión IU	2000000 I.U.	powder for solution for injection/infusion/ inhalation	intravenous use, inhalation use

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Spain	GES GENÉRICOS ESPAÑOLES LABORATORIO, S.A. Cólquide, 6 - Portal 2, 1º-Oficina F 28230 Las Rozas (Madrid) Spain	Colistimetato de sodio GES 1 MUI polvo para solución inyectable/para inhalación por nebulizador	1000000 I.U.	powder for solution for injection, powder for nebuliser solution	intravenous use, inhalation use
Spain	Profile Pharma Limited Chichester Business Park City Fields Way Tangmere, Chichester West Sussex PO20 2FT United Kingdom	Promixin 1 millón de Unidades Internacionales (UI) polvo para solución para inhalación por nebulizador	1000000 I.U.	powder for nebuliser solution	inhalation use
Spain	Pharmis Biofarmacêutica, Lda. Praceta do Farol, lote 101 Cascais 2750-341 Portugal	Colixin 1 MUI polvo para solución inyectable o para solución para inhalación por nebulizador	1000000 I.U.	powder for solution for injection, powder for nebuliser solution	intravenous use, inhalation use
Sweden	Profile Pharma Limited Bicentennial Building Southern Gate Chichester West Sussex PO19 8EZ United Kingdom	Tadim	1000000 I.U.	powder for nebuliser solution	inhalation use

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Sweden	Profile Pharma Limited Bicentennial Building Southern Gate Chichester West Sussex PO19 8EZ United Kingdom	Tadim	1000000 I.U.	powder for solution for infusion	intravenous use
Sweden	Xellia Pharmaceuticals ApS Dalslandsgade 11 DK-2300 Copenhagen S Denmark	Colistin Xellia	1000000 I.U.	powder for solution for injection/infusion	intravenous use
The Netherlands	Forest Pharma B.V. Newtonlaan 115 3584 BH Utrecht The Netherlands	Colistin, poeder voor verneveloplossing met oplosmiddel 1.000.000 IE	1000000 I.U.	powder for nebuliser solution	inhalation use
United Kingdom	Forest Laboratories UK Limited Riverbridge House Anchor Boulevard Crossways Business Park Dartford, Kent DA2 6SL United Kingdom	Colomycin Injection 2 million international units powder for soln for inj, infusion or inhalation	2000000 I.U.	powder for solution for injection	intravenous use



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United Kingdom	Forest Laboratories UK Limited Riverbridge House Anchor Boulevard Crossways Business Park Dartford, Kent DA2 6SL United Kingdom	Colomycin Injection 1 million international units powder for soln for inj, infusion or inhalation	1000000 I.U.	powder for solution for injection, infusion or inhalation	intramuscular use, intravenous use, inhalation use
United Kingdom	Xellia Pharmaceuticals ApS Dalslandsgade 11 DK-2300 Copenhagen S Denmark	Colistimethate sodium 1 million international units powder for solution for injection or infusion	1000000 I.U.	powder for solution for injection/infusion	intravenous use
United Kingdom	Beacon Pharmaceuticals Limited, Tunbridge Wells, Kent TN1 1YG United Kingdom	Colistimethate sodium 1 million I.U. powder for solution for injection	1000000 I.U.	powder for solution for injection	intravenous use, inhalation use
United Kingdom	Profile Pharma Limited Chichester Business Park City Fields Way Tangmere, Chichester West Sussex PO20 2FT United Kingdom	Promixin 1 million international units (IU) powder for nebuliser solution	1000000 I.U.	powder for nebuliser solution	inhalation use

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United Kingdom	Profile Pharma Limited Chichester Business Park City Fields Way Tangmere, Chichester West Sussex PO20 2FT United Kingdom	Promixin 1 million international units (IU) powder for solution for infusion	1000000 I.U.	powder for solution for injection	intramuscular use, intravenous use
United Kingdom	PARI Pharma GmbH Moosstrasse 3 82319 Starnberg Germany	Colifin 1 MIU powder for nebuliser solutions	1000000 I.U.	powder for nebuliser solution	inhalation use
United Kingdom	PARI Pharma GmbH Moosstrasse 3 82319 Starnberg Germany	Colifin 2 MIU powder for nebuliser solutions	2000000 I.U.	powder for nebuliser solution	inhalation use