

Annex I

List of the names, pharmaceutical forms, strengths of the medicinal products, routes of administration, marketing authorisation holders in the Member States

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strengths	Pharmaceutical forms	Routes of administration
Belgium	SCS Boehringer Ingelheim SA Avenue Ariane 16 B-1200 Woluwe-Saint-Lambert Belgium	fenoterol	BEROTEC 0,5MG/10 ML	0.5mg/10ml	Solution for injection	Intravenous use
Germany	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Str. 173 55216 Ingelheim Germany	fenoterol	Partusisten intrapartal	0.025mg/ml	Concentrate for solution for injection	Intravenous use
Germany	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Str. 173 55216 Ingelheim Germany	fenoterol	Partusisten	0.5mg/10ml	Concentrate for solution for infusion	Intravenous use
Germany	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Str. 173 55216 Ingelheim Germany	fenoterol	Partusisten	5mg	Tablet	Oral use
Poland	Teva Pharmaceuticals Polska Sp. z o.o. ul. Emilii Plater 53 00-113 Warszawa Poland	fenoterol	Fenoterol Teva	0.05mg/ml	Solution for injection	Intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strengths	Pharmaceutical forms	Routes of administration
Poland	GlaxoSmithKline Pharmaceuticals S.A. ul. Grunwaldzka 189 60-322 Poznań Poland	fenoterol	Fenoterol GSK	5mg	Tablet	Oral use
The Netherlands	Boehringer Ingelheim B.V. Comeniusstraat 6 1817 MS Alkmaar The Netherlands	fenoterol	Partusisten, concentraat voor oplossing voor intraveneuze infusie 50 microgram/ml	0.05mg/ml	Concentrate for solution for infusion	Intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strengths	Pharmaceutical forms	Routes of administration
Austria	Takeda Austria GmbH St.-Peter-Straße 25 A -4020 Linz Austria	hexoprenaline	Gynipral 25 µg - Konzentrat zur Infusionsbereitu ng	0.025mg/5m l	Concentrate for solution for infusion	Intravenous use
Austria	Takeda Austria GmbH St.-Peter-Straße 25 A -4020 Linz Austria	hexoprenaline	Gynipral 10 µg / 2 ml - Ampullen	0.01mg/2ml	Solution for injection/infusion	Intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strengths	Pharmaceutical forms	Routes of administration
Bulgaria	NYCOMED Austria GmbH St.-Peter-Straße 25 A -4020 Linz Austria	hexoprenaline	Gynipral	0.005mg/ml	Solution for injection	Intravenous use
Bulgaria	NYCOMED Austria GmbH St.-Peter-Straße 25 A -4020 Linz Austria	hexoprenaline	Gynipral	0.5mg	Tablet	Oral use
Czech Republic	Takeda Austria GmbH St.-Peter-Straße 25 A -4020 Linz Austria	hexoprenaline	GYNIPRAL 0,5 MG	0.5mg	Tablet	Oral use
Czech Republic	Takeda Austria GmbH St.-Peter-Straße 25 A -4020 Linz Austria	hexoprenaline	GYNIPRAL 10 MCG/2 ML	0.005mg/ml	Solution for injection/infusion	Intravenous use
Czech Republic	Takeda Austria GmbH St.-Peter-Straße 25 A -4020 Linz Austria	hexoprenaline	GYNIPRAL 25 MCG KONCENTRÁT PRO PŘÍPRAVU INFÚZE	0.025mg/5m l	Concentrate for solution for infusion	Intravenous use
Estonia	NYCOMED Austria GmbH St.-Peter-Straße 25 A -4020 Linz Austria	hexoprenaline	GYNIPRAL	0.5mg	Tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strengths	Pharmaceutical forms	Routes of administration
Lithuania	NYCOMED Austria GmbH St.-Peter-Straße 25 A -4020 Linz Austria	hexoprenaline	Gynipral	0.5mg	Tablet	Oral use
Lithuania	NYCOMED Austria GmbH St.-Peter-Straße 25 A -4020 Linz Austria	hexoprenaline	Gynipral	0.025mg/5ml	Concentrate for solution for injection /infusion	Intravenous use
Lithuania	NYCOMED Austria GmbH St.-Peter-Straße 25 A -4020 Linz Austria	hexoprenaline	Gynipral	0.01mg/2ml	Solution for injection/infusion	Intravenous use
Romania	NYCOMED Austria GmbH St.-Peter-Straße 25 A -4020 Linz Austria	hexoprenaline	GYNIPRAL 0,5 mg,	0.5mg	Tablet	Oral use
Romania	NYCOMED Austria GmbH St.-Peter-Straße 25 A -4020 Linz Austria	hexoprenaline	GYNIPRAL 10 µg/2 ml	0.01mg/2ml	Solution for injection	Parenteral use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strengths	Pharmaceutical forms	Routes of administration
Italy	Istituto Luso Farmaco d'Italia SpA Via W. Tobagi 8 20068 Peschiera Borromeo (MI) Italy	isoxsuprine	VASOSUPRINA ILFI	10mg/2ml	Solution for injection	Intramuscular use, intravenous use
Italy	Istituto Luso Farmaco d'Italia SpA Via W. Tobagi 8 20068 Peschiera Borromeo (MI) Italy	isoxsuprine	VASOSUPRINA RETARD	30mg	Modified-release tablet	Oral use
Portugal	Tecnifar - Indústria Técnica Farmacêutica, S.A. Rua Tierno Galvan Amoreiras Torre 3 - 12, 1099-036 Portugal	isoxsuprine	Dilum Retard	30mg	Prolonged-release tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strengths	Pharmaceutical forms	Routes of administration
Belgium	EUMEDICA N.V. Av. Winston Churchill 67 B-1180 Bruxelles Belgium	ritodrine	PRE-PAR 10 MG	10mg	Tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strengths	Pharmaceutical forms	Routes of administration
Belgium	EUMEDICA N.V. Av. Winston Churchill 67 B-1180 Bruxelles Belgium	ritodrine	PRE-PAR 50MG/5ML	50mg/5ml	Solution for injection	Intravenous use
Greece	Galenica SA 4, Eleftherias Street Kifisia 14564 Greece	ritodrine	YUTOPAR	10mg	Tablet	Oral use
Greece	Galenica SA 4, Eleftherias Street Kifisia 14564 Greece	ritodrine	YUTOPAR	50mg/5ml	Solution for Injection	Intravenous use; Intramuscular use
Italy	Istituto Luso Farmaco d'Italia SpA Via W. Tobagi 8 20068 Peschiera Borromeo (MI) Italy	ritodrine	MIOLENE	10mg/2ml	Solution for Injection	Intramuscular use
Italy	Istituto Luso Farmaco d'Italia SpA Via W. Tobagi 8 20068 Peschiera Borromeo (MI) Italy	ritodrine	MIOLENE	10mg	Tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strengths	Pharmaceutical forms	Routes of administration
Italy	Istituto Luso Farmaco d'Italia SpA Via W. Tobagi 8 20068 Peschiera Borromeo (MI) Italy	ritodrine	MIOLENE	50mg/5ml	Solution for infusion	Intravenous use
Luxembourg	Eumedica S.A. Av. Winston Churchill 67 B-1180 Bruxelles Belgium	ritodrine	Pre-Par comprimés	10mg	Tablet	Intravenous use
Luxembourg	Eumedica S.A. Av. Winston Churchill 67 B-1180 Bruxelles Belgium	ritodrine	Pre-Par solution injectable	50mg/5ml	Solution for injection/infusion	Intravenous use
Spain	Laboratorio Reig Jofre SA. Gran Capita 10 Sant Joan Despi Barcelona 08970 Spain	ritodrine	PRE-PAR AMPOLLAS	10mg/ml	Solution for injection	Intravenous use; Intramuscular use
Spain	Laboratorio Reig Jofre SA. Gran Capita 10 Sant Joan Despi Barcelona 08970 Spain	ritodrine	PRE-PAR 10 mg COMPRIMIDOS	10mg	Tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strengths	Pharmaceutical forms	Routes of administration
Belgium	GlaxoSmithKline Pharmaceuticals S.A./N.V. Site Apollo, 2-4-6 B-1300 Wavre Belgium	salbutamol	VENTOLIN POUR PERFUSION I.V.	5mg	Solution for injection	Intravenous use
Belgium	GlaxoSmithKline Pharmaceuticals S.A./N.V. Site Apollo, 2-4-6 B-1300 Wavre Belgium	salbutamol	VENTOLIN I.M.-S.C.	0.5mg	Solution for injection	Intramuscular use, Subcutaneous use
Belgium	GlaxoSmithKline Pharmaceuticals S.A./N.V. Site Apollo, 2-4-6 B-1300 Wavre Belgium	salbutamol	VENTOLIN 4MG	4mg	Oral solution	Oral use
Belgium	GlaxoSmithKline Pharmaceuticals S.A./N.V. Site Apollo, 2-4-6 B-1300 Wavre Belgium	salbutamol	VENTOLIN 2 MG	2mg	Oral solution	Oral use
Cyprus	Remedica Ltd Aharnon Street Industrial Estate 3508 Lemesos Cyprus	salbutamol	SALBUTAMOL tablets 4 mg	4mg	Tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strengths	Pharmaceutical forms	Routes of administration
Denmark	GlaxoSmithKline Pharma A/S Nykær 68 DK-2605 Brøndby Denmark	salbutamol	Ventoline	0.5mg/ml	Solution for injection	Intramuscular use, Subcutaneous use
Denmark	GlaxoSmithKline Pharma A/S Nykær 68 DK-2605 Brøndby Denmark	salbutamol	Ventoline	1mg/ml	Concentrate for infusion	Intravenous use
France	Laboratoire GlaxoSmithKline 100, route de Versailles 78163 Marly-le-Roi Cedex France	salbutamol	SALBUMOL 0,5 mg/1 ml, solution for injection	0.5mg/ml	Solution for injection	Intravenous use, Intramuscular use, Subcutaneous use
France	Laboratoire GlaxoSmithKline 100, route de Versailles 78163 Marly-le-Roi Cedex France	salbutamol	SALBUMOL 1 mg, suppository	1mg	Suppository	Rectal use
France	Laboratoire GlaxoSmithKline 100, route de Versailles 78163 Marly-le-Roi Cedex France	salbutamol	SALBUMOL 2 mg tablet	2mg	Tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strengths	Pharmaceutical forms	Routes of administration
France	Laboratoire GlaxoSmithKline 100, route de Versailles 78163 Marly-le-Roi Cedex France	salbutamol	SALBUMOL FORT 5 mg / 5 ml solution for infusion	5mg/5ml	Solution for infusion	Intravenous use
France	MYLAN SAS 117, allée des Parcs 69800 Saint-Priest France	salbutamol	SALBUTAMOL MYLAN 5 mg/5 ml, solution for infusion	5mg/5ml	Solution for infusion	Intravenous use
France	Laboratoire Renaudin Z A. Errobi Itxassou 64250 Cambo les Bains France	salbutamol	SALBUTAMOL RENAUDIN 5 mg/5 ml, Solution for infusion	5mg/5ml	Solution for infusion	Intravenous use
Ireland	GlaxoSmithKline (Ireland) Limited Stonemasons Way Rathfarnham Dublin 16 Ireland	salbutamol	Ventolin 500 micrograms/ml Solution for Injection	0.5mg/ml	Solution for Injection	Subcutaneous, intramuscular, intravenous
Ireland	GlaxoSmithKline (Ireland) Limited Stonemasons Way Rathfarnham Dublin 16 Ireland	salbutamol	Ventolin 1mg/ml Concentrate for Solution for Intravenous Infusion	1mg/ml	Concentrate for solution for intravenous infusion	Intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strengths	Pharmaceutical forms	Routes of administration
Lithuania	Warszawskie Zakłady Farmaceutyczne Polfa S.A. ul. Karolkowa 22/24 01-207 Warszawa Poland	salbutamol	SALBUTAMOL WZF Polfa	2mg	Tablet	Oral use
Lithuania	Warszawskie Zakłady Farmaceutyczne Polfa S.A. ul. Karolkowa 22/24 01-207 Warszawa Poland	salbutamol	SALBUTAMOL WZF Polfa	4mg	Tablet	Oral use
Luxembourg	GlaxoSmithKline Pharmaceuticals S.A./N.V. Site Apollo, 2-4-6 B-1300 wavre Belgium	salbutamol	Ventolin comprimés	2mg	Tablet	Oral use
Luxembourg	GlaxoSmithKline Pharmaceuticals S.A./N.V. Site Apollo, 2-4-6 B-1300 wavre Belgium	salbutamol	Ventolin comprimés	4mg	Tablet	Oral use
Luxembourg	GlaxoSmithKline Pharmaceuticals S.A./N.V. Site Apollo, 2-4-6 B-1300 wavre Belgium	salbutamol	Ventolin solution injectable	0.5mg/ml	Solution for injection	Intravenous use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strengths	Pharmaceutical forms	Routes of administration
Luxembourg	GlaxoSmithKline Pharmaceuticals S.A./N.V. Site Apollo, 2-4-6 B-1300 wavre Belgium	salbutamol	Ventolin solution à diluer pour perfusion	5mg/5ml	Solution for injection	Intravenous use
Poland	Warszawskie Zakłady Farmaceutyczne Polfa S.A. ul. Karolkowa 22/24 01-207 Warszawa Poland	salbutamol	Salbutamol WZF	0.5mg/ml	Solution for Injection	Intravenous use, Intramuscular use, Subcutaneous use
Poland	Warszawskie Zakłady Farmaceutyczne Polfa S.A. ul. Karolkowa 22/24 01-207 Warszawa Poland	salbutamol	Salbutamol WZF	2mg	Tablet	Oral use
Poland	Warszawskie Zakłady Farmaceutyczne Polfa S.A. ul. Karolkowa 22/24 01-207 Warszawa Poland	salbutamol	Salbutamol WZF	4mg	Tablet	Oral use
Portugal	Glaxo Wellcome Farmacêutica, Lda. Rua Dr. António Loureiro Borges, 3 - Arquiparque - Miraflores 1495-131 Algés, Lisbon Portugal	salbutamol	ventilan	4mg	Tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strengths	Pharmaceutical forms	Routes of administration
Portugal	Glaxo Wellcome Farmacêutica, Lda. Rua Dr. António Loureiro Borges, 3 - Arquiparque - Miraflores 1495-131 Algés, Lisbon Portugal	salbutamol	ventilan	5mg/5ml	Solution for infusion	Intravenous use
Portugal	Glaxo Wellcome Farmacêutica, Lda. Rua Dr. António Loureiro Borges, 3 - Arquiparque - Miraflores 1495-131 Algés, Lisbon Portugal	salbutamol	ventilan	0.5mg/ml	Solution for Injection	Intravenous use, Subcutaneous use Intramuscular use
Romania	GLAXO WELLCOME UK Limited Glaxo Wellcome House Berkeley Avenue Greenford Middlesex UB6 0NN United Kingdom	salbutamol	VENTOLIN®, soluție injectabilă, 0,5 mg/ml	0.5mg/ml	Solution for injection	Parenteral use
Slovak Republic	Warszawskie Zakłady Farmaceutyczne Polfa S.A. ul. Karolkowa 22/24 01-207 Warszawa Poland	salbutamol	Salbutamol WZF Polfa 2 mg	2mg	Tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strengths	Pharmaceutical forms	Routes of administration
Slovak Republic	Warszawskie Zakłady Farmaceutyczne Polfa S.A. ul. Karolkowa 22/24 01-207 Warszawa Poland	salbutamol	Salbutamol WZF Polfa 4 mg	4mg	Tablet	Oral use
Slovenia	GSK d.o.o. Cvetkova ulica 29 1000 Ljubljana Slovenija	salbutamol	Ventolin 2 mg tablete	2mg	Tablet	Oral use
United Kingdom	Actavis UK Limited Whiddon Valley Barnstaple North Devon EX32 8NS United Kingdom	salbutamol	Salbutamol Tablets BP 2mg	2mg	Tablet	Oral use
United Kingdom	Actavis UK Limited Whiddon Valley Barnstaple North Devon EX32 8NS United Kingdom	salbutamol	Salbutamol Tablets BP 4mg	4mg	Tablet	Oral use
United Kingdom	Teva UK Limited Bampton Road Hampden Park Eastbourne East Sussex BN22 9AG United Kingdom	salbutamol	Asmaven 2 / Salbutamol Tablets BP 2mg	2mg	Tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strengths	Pharmaceutical forms	Routes of administration
United Kingdom	Teva UK Limited Bampton Road Hampden Park Eastbourne East Sussex BN22 9AG United Kingdom	salbutamol	Asmaven 4 / Salbutamol Tablets BP 4mg	4mg	Tablet	Oral use
United Kingdom	Glaxo Wellcome UK Limited Stockley Park West Uxbridge Middlesex UB11 1BT United Kingdom	salbutamol	Ventolin Solution for Intravenous Infusion	1mg/ml	Solution for injection	Intravenous use, Subcutaneous use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strengths	Pharmaceutical forms	Routes of administration
Austria	AstraZeneca Österreich GmbH Schwarzenbergplatz 7 A-1037 Vienna Austria	terbutaline	Bricanyl 0,5 mg - Ampullen	0.5mg/ml	Solution for injection	Subcutaneous use, Intravenous use
Cyprus	Medochemie Ltd 1-10 Constantinoupoleos Street 3505 Lemesos Cyprus	terbutaline	ATALINE tablets 2.5 mg	2.5mg	Tablet	Oral use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strengths	Pharmaceutical forms	Routes of administration
Cyprus	Medochemie Ltd 1-10 Constantinoupoleos Street 3505 Lemesos Cyprus	terbutaline	ATALINE syrup 1.5 mg/5ml	1.5mg/5ml	Syrup	Oral use
France	AstraZeneca 1, place Renault 92844 Rueil Malmaison Cedex France	terbutaline	BRICANYL 0.5 mg/1 ml Solution for injection	0.5mg/ml	Solution for injection	Intravenous use, Subcutaneous use
Hungary	AstraZeneca Kft. Bocskai út 134-146. Budapest 1113 Hungary	terbutaline	Bricanyl 0,5 mg/ml oldatos injekció	0.5mg/ml	Solution for injection or infusion	Intravenous use
Ireland	AstraZeneca UK Limited 600 Capability Green Luton, LU1 3LU United Kingdom	terbutaline	Bricanyl 500 micrograms/ml solution for injection or infusion	0.5mg/ml	Solution for injection or infusion	Subcutaneous, intramuscular, intravenous
Norway	AstraZeneca AS Innspurten 15 0663 Oslo Norway	terbutaline	Bricanyl	0.5mg/ml	Solution for injection	Parenteral use
Norway	AstraZeneca AS Innspurten 15 0663 Oslo Norway	terbutaline	Bricanyl	0.3mg/ml	Oral solution	Oral use

Member State (in EEA)	Marketing authorisation holder	INN	Invented name	Strengths	Pharmaceutical forms	Routes of administration
Norway	AstraZeneca AS Innspurten 15 0663 Oslo Norway	terbutaline	Bricanyl	5mg	Film- coated tablet	Oral use
Norway	AstraZeneca AS Innspurten 15 0663 Oslo Norway	terbutaline	Bricanyl Depot	7.5mg	Prolonged- release tablet	Oral use
Sweden	AstraZeneca AB SE - 151 85 Södertälje Sweden	terbutaline	Bricanyl®	0.5mg/ml	Solution for injection Concentrate for solution for injection	Intravenous use
Sweden	AstraZeneca AB SE - 151 85 Södertälje Sweden	terbutaline	Bricanyl®	0.3mg/ml	Oral solution	Oral use
United Kingdom	AstraZeneca UK Limited 600 Capability Green Luton, LU1 3LU United Kingdom	terbutaline	Bricanyl Injection	0.5mg/ml	Solution for injection	Intravenous use, Intramuscular use, Subcutaneous use
United Kingdom	AstraZeneca UK Limited 600 Capability Green Luton, LU1 3LU United Kingdom	terbutaline	Bricanyl Tablets 5mg	5mg	Tablet	Oral use
United Kingdom	AstraZeneca UK Limited 600 Capability Green Luton, LU1 3LU United Kingdom	terbutaline	Bricanyl Syrup	0.3mg/ml	Oral solution	Oral use