



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

10 January 2013  
EMA/8624/2013  
Patient Health Protection

## Annex I

List of the names, pharmaceutical forms, strengths of the medicinal products, routes of administration, marketing authorisation holders in the member states for Short Acting Beta Agonists (SABAs) containing medicinal products authorised in obstetric indications

INN/active substance: terbutaline, salbutamol, hexoprenaline, ritodrine, fenoterol, isoxsuprine

Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data

Procedure number: EMEA/H/A-31/1347



## Fenoterol containing medicinal products

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Belgium	SCS Boehringer Ingelheim SA Avenue Ariane 16 1200 Woluwe-Saint-Lambert Belgium	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	Partusisten intrapartal	0.025 mg/ml	Concentrate for solution for injection	Intravenous use
Germany	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Str. 173 55216 Ingelheim Germany	Partusisten	0.5 mg / 10 ml	Concentrate for solution for infusio	Intravenous use
Germany	Boehringer Ingelheim Pharma GmbH & Co. KG Binger Str. 173 55216 Ingelheim Germany	Partusisten	5 mg	Tablet	Oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Poland	Teva Pharmaceuticals Polska Sp. z o.o. ul. Emilii Plater 53 00-113 Warszawa Poland	Fenoterol Teva	50 mcg/ml	Solution for injection	Intravenous use
Poland	GlaxoSmithKline Pharmaceuticals S.A. ul. Grunwaldzka 189 60-322 Poznań Poland	Fenoterol GSK	5 mg	Tablet	Oral use
The Netherlands	Boehringer Ingelheim B.V. Comeniusstraat 6 1817 MS Alkmaar The Netherlands	Partusisten, concentraat voor oplossing voor intraveneuze infusie 50 microgram/m	50 mcg/ml	Concentrate for solution for infusion	Intravenous use

## Hexoprenaline containing medicinal products

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Austria	NYCOMED Austria GmbH St.-Peter-Straße 25 A -4020 Linz Austria	GYNIPRAL 0,5 mg - Tabletten	0.5 mg	Tablet	Oral use
Austria	NYCOMED Austria GmbH St.-Peter-Straße 25 A -4020 Linz Austria	Gynipral 25 µg - Konzentrat zur Infusionsbereitung	25 mcg/5 ml	Concentrate for solution for infusion	Intravenous use
Austria	NYCOMED Austria GmbH St.-Peter-Straße 25 A -4020 Linz Austria	Gynipral 10 µg / 2 ml - Ampullen	10 mcg/2 ml	Solution for infusion solution for injection	Intravenous use
Bulgaria	NYCOMED Austria GmbH St.-Peter-Straße 25 A -4020 Linz Austria	Gynipral	5 mcg/ml	Solution for injection	Intravenous use
Bulgaria	NYCOMED Austria GmbH St.-Peter-Straße 25 A -4020 Linz Austria	Gynipral	0.5 mg	Tablet	Oral use
Czech Republic	NYCOMED Austria GmbH St.-Peter-Straße 25 A -4020 Linz Austria	GYNIPRAL 0,5 MG	0.5 mg	Tablet	Oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Czech Republic	NYCOMED Austria GmbH St.-Peter-Straße 25 A -4020 Linz Austria	GYNIPRAL 10 MCG/2 ML	5mcg/ml	Solution for injection	Intravenous use
Czech Republic	NYCOMED Austria GmbH St.-Peter-Straße 25 A -4020 Linz Austria	GYNIPRAL 25 MCG KONCENTRÁT PRO PŘÍPRAVU INFÚZE	0.025 mg/5 ml	Concentrate for solution for infusion	Intravenous use
Estonia	Nycomed Austria GmbH St. Peter-Strasse 25 P.O. Box 122 A-4021 Linz Austria	GYNIPRAL	0.5mg	Tablet	Oral use
Lithuania	Nycomed Austria GmbH Peter Strasse 25 A-4021 Linz Austria	Gynipral	500mcg	Tablet	Oral use
Lithuania	Nycomed Austria GmbH Peter Strasse 25 A-4021 Linz Austria	Gynipral	25mcg/5ml	Concentrate for solution for injection /infusion	Intravenous use
Lithuania	Nycomed Austria GmbH Peter Strasse 25 A-4021 Linz Austria	Gynipral	10mcg/2ml	Solution for injection/infusion	Intravenous use
Romania	NYCOMED Austria GmbH St.-Peter-Straße 25 A -4020 Linz Austria	GYNIPRAL 0,5 mg	0.5 mg	Tablet	Oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Romania	NYCOMED Austria GmbH St.-Peter-Straße 25 A -4020 Linz Austria	GYNIPRAL 10 µg/2 ml	10 mcg/2 ml	Solution for injection	Parenteral use

## Isoxsuprine containing medicinal products

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

## Ritodrine containing medicinal products

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

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



## Salbutamol containing medicinal products

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Belgium	GlaxoSmithKline Pharmaceuticals S.A./N.V. Site Apollo, 2-4-6 B-1300 wavre Belgium	VENTOLIN POUR PERFUSION I.V.	5.00 mg	Solution for injection - Ampoule	Intravenous use
Belgium	GlaxoSmithKline Pharmaceuticals S.A./N.V. Site Apollo, 2-4-6 B-1300 wavre Belgium	VENTOLIN I.M.-S.C	0.50 mg	Solution for injection - Ampoule	Intramuscular use, Subcutaneous use
Belgium	GlaxoSmithKline Pharmaceuticals S.A./N.V. Site Apollo, 2-4-6 B-1300 wavre Belgium	VENTOLIN 4MG	4.00 mg	Oral solution - Bottle	Oral use
Belgium	GlaxoSmithKline Pharmaceuticals S.A./N.V. Site Apollo, 2-4-6 B-1300 wavre Belgium	VENTOLIN 2 MG	2.00 mg	Oral solution - Bottle	Oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Cyprus	Remedica Ltd Aharnon Street Industrial Estate 3508 Lemesos Cyprus	SALBUTAMOL tablets 4 mg	4 mg	Tablet	Oral use
Denmark	GlaxoSmithKline Pharma A/S Nykær 68 DK-2605 Brøndby Denmark	Ventoline	0,5 mg/ml	Solution for injection	Intramuscular use, Subcutaneous use
Denmark	GlaxoSmithKline Pharma A/S Nykær 68 DK-2605 Brøndby Denmark	Ventoline	1 mg/ml	Concentrate for infusion	Intravenous use
France	GLAXOSMITHKLINE 100, route de Versailles 78163 Marly-le-Roi Cedex France	SALBUMOL 0,5 mg/1 ml, solution for injection	0.5 mg/1 ml	Solution for injection	Intravenous use, Intramuscular use, Subcutaneous use
France	GLAXOSMITHKLINE 100, route de Versailles 78163 Marly-le-Roi Cedex France	SALBUMOL 1 mg, suppository	1 mg	Suppository	Rectal use
France	GLAXOSMITHKLINE 100, route de Versailles 78163 Marly-le-Roi Cedex France	SALBUMOL 2 mg tablet	2 mg	Tablet	Oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
France	GLAXOSMITHKLINE 100, route de Versailles 78163 Marly-le-Roi Cedex France	SALBUMOL FORT 5 mg / 5 ml solution for infusion	5 mg/5 ml	Solution for infusion	Intravenous use
France	MYLAN SAS 117, allée des Parcs 69800 Saint-Priest France	SALBUTAMOL MYLAN 5 mg/5 ml, solution for infusion	5 mg/5 ml	Solution for infusion	Intravenous use
France	Laboratoire Renaudin Z A. Errobi Itxassou 64250 Cambo les Bains France	SALBUTAMOL RENAUDIN 5 mg/5 ml, Solution for infusion	5 mg/5 ml	Solution for infusion	Intravenous use
Ireland	GlaxoSmithKline (Ireland) Limited Stonemasons Way Rathfarnham Dublin 16 Ireland	Ventolin 500 micrograms/ml Solution for Injection	500 mcg/ml	Solution for Injection	Subcutaneous, intramuscular, intravenous
Ireland	GlaxoSmithKline (Ireland) Limited Stonemasons Way Rathfarnham Dublin 16 Ireland	Ventolin 1mg/ml Concentrate for Solution for Intravenous Infusion	1mg/ml	Solution for Intravenous Infusion	Intravenous use
Lithuania	Warszawskie Zakłady Farmaceutyczne Polfa S.A. ul. Karolkowa 22/24 01-207 Warszawa Poland	SALBUTAMOL WZF Polfa	2 mg	Tablet	Oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Lithuania	Warszawskie Zakłady Farmaceutyczne Polfa S.A. ul. Karolkowa 22/24 01-207 Warszawa Poland	SALBUTAMOL WZF Polfa	4 mg	Tablet	Oral use
Luxembourg	GlaxoSmithKline Pharmaceuticals S.A./N.V. Site Apollo, 2-4-6 B-1300 wavre Belgium	Ventolin comprimés	2 mg	Tablet	Oral use
Luxembourg	GlaxoSmithKline Pharmaceuticals S.A./N.V. Site Apollo, 2-4-6 B-1300 wavre Belgium	Ventolin comprimés	4 mg	Tablet	Oral use
Luxembourg	GlaxoSmithKline Pharmaceuticals S.A./N.V. Site Apollo, 2-4-6 B-1300 wavre Belgium	Ventolin solution injectable	0.5 mg /ml	Solution for injection	Intravenous use
Luxembourg	GlaxoSmithKline Pharmaceuticals S.A./N.V. Site Apollo, 2-4-6 B-1300 wavre Belgium	Ventolin solution à diluer pour perfusion	5 mg/5 ml	Solution for injection	Intravenous use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Poland	Warszawskie Zakłady Farmaceutyczne Polfa S.A. ul. Karolkowa 22/24 01-207 Warszawa Poland	Salbutamol WZF	0.5 mg/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 WZF	2 mg	Tablet	Oral use
Poland	Warszawskie Zakłady Farmaceutyczne Polfa S.A. ul. Karolkowa 22/24 01-207 Warszawa Poland	Salbutamol WZF	4 mg	Tablet	Oral use
Portugal	Glaxo Wellcome Farmacêutica, Lda. Rua Dr. António Loureiro Borges, 3 - Arquiparque - Miraflores 1495-131 Algés Lisboa Portugal	ventilan	4 mg	Tablet	Oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Portugal	Glaxo Wellcome Farmacêutica, Lda. Rua Dr. António Loureiro Borges, 3 - Arquiparque - Miraflores 1495-131 Algés Lisboa Portugal	ventilan	5 mg/5 ml	Solution for infusion	Intravenous use
Portugal	Glaxo Wellcome Farmacêutica, Lda. Rua Dr. António Loureiro Borges, 3 - Arquiparque - Miraflores 1495-131 Algés Lisboa Portugal	ventilan	0.5 mg/1 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	VENTOLIN®, soluție injectabilă, 0,5 mg/ml	0.5 mg/ml	Solution for injection	Parenteral use
Slovenia	GSK d.o.o. Cvetkova ulica 29 1000 Ljubljana Slovenija	Ventolin 2 mg tablete	2 mg	Tablet	Oral use
United Kingdom	Actavis UK Limited Whiddon Valley Barnstaple North Devon EX32 8NS United Kingdom	Salbutamol Tablets BP 2mg	2 mg	Tablet	Oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
United Kingdom	Actavis UK Limited Whiddon Valley Barnstaple North Devon EX32 8NS United Kingdom	Salbutamol Tablets BP 4mg	4 mg	Tablet	Oral use
United Kingdom	Teva UK Limited Bampton Road Hampden Park Eastbourne East Sussex BN22 9AG United Kingdom	Asmaven 2 / Salbutamol Tablets BP 2mg	2 mg	Tablet	Oral use
United Kingdom	Teva UK Limited Bampton Road Hampden Park Eastbourne East Sussex BN22 9AG United Kingdom	Asmaven 4 / Salbutamol Tablets BP 4mg	4 mg	Tablet	Oral use
United Kingdom	Glaxo Wellcome UK Limited Stockley Park West Uxbridge Middlesex UB11 1BT United Kingdom	Ventolin Solution for Intravenous Infusion	1 mg/ml	Solution for injection	Intravenous use, Subcutaneous use

## Terbutaline containing medicinal products

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Austria	AstraZeneca Österreich GmbH Schwarzenbergplatz 7 A-1037 Vienna Austria	Bricanyl 0,5 mg - Ampullen	0.5 mg/ml	Solution for injection	Subcutaneous use, Intravenous use Cyprus
Cyprus	Medochemie Ltd 1-10 Constantinoupoleos Street 3505 Lemesos Cyprus	ATALINE tablets 2.5 mg	2.5 mg	Tablet	Oral use
Cyprus	Medochemie Ltd 1-10 Constantinoupoleos Street 3505 Lemesos Cyprus	ATALINE syrup 1.5 mg/5ml	1.5 mg/5ml	Syrup	Oral use
France	AstraZeneca 1, place Renault 92844 Rueil Malmaison Cedex France	BRICANYL 0.5 mg/1 ml Solution for injection	0,5 mg/1 ml	Solution for injection	Intravenous use, Subcutaneous use



Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Hungary	AstraZeneca Kereskedelmi és Szolgáltató Kft. Bocskai út 134-146. Budapest 1113 Hungary	Bricanyl 0,5 mg/ml oldatos injekció	0.5 mg/ml	Solution for injection or infusion	Intravenous use
Ireland	AstraZeneca UK Limited 600 Capability Green Luton, LU1 3LU United Kingdom	Bricanyl 500 micrograms/ml solution for injection or infusion	500 mcg/ml	Solution for injection or infusion	Subcutaneous, intramuscular, intravenous
Norway	AstraZeneca AS Innspurten 15 Box 6050 Etterstad 0601 Oslo Norway	Bricanyl	0.5 mg/ml	Solution for injection	Parenteral use
Norway	AstraZeneca AS Innspurten 15 Box 6050 Etterstad 0601 Oslo Norway	Bricanyl	0.3 mg/ml	Oral solution	Oral use
Norway	AstraZeneca AS Innspurten 15 Box 6050 Etterstad 0601 Oslo Norway	Bricanyl	5 mg	Film- coated tablet	Oral use
Norway	AstraZeneca AS Innspurten 15 Box 6050 Etterstad 0601 Oslo Norway	Bricanyl Depot	7.5 mg	Prolonged- release tablet	Oral use

Member State in EEA	Marketing authorisation holder	Product name	Strength	Pharmaceutical form	Route of administration
Norway	AstraZeneca Plc 2 Kingdom Street Paddington London, W2 6BD United Kingdom	Respirol	5 mg	Tablet	Oral use
Norway	AstraZeneca Plc 2 Kingdom Street Paddington London, W2 6BD United Kingdom	Respirol Retard	7.5 mg	Prolonged- release tablet	Oral use
Sweden	AstraZeneca AB 151 85 Södertälje Sweden	Bricanyl®	0.5 mg/ml	Solution for injection/Concentrate for solution for injection	Intravenous useSweden
Sweden	AstraZeneca UK Limited 600 Capability Green Luton LU1 3LU United Kingdom	Bricanyl®	0.3 mg/ml	Oral solution	Oral use
United Kingdom	AstraZeneca UK Limited 600 Capability Green Luton LU1 3LU United Kingdom	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	Bricanyl Tablets 5mg	5 mg	Tablet	Oral use