11 October 2017
EMA/784453/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance(s): ipratropium / salbutamol

Procedure No.: PSUSA/00001781/201701

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Brometo de ipratrópio + Salbutamol Cipla, 0,525 mg/2,5 ml + 3 mg/2,5 ml, solução para inalação por nebulização	not available	5678156	CIPLA (EU) LIMITED	PT
Brometo de ipratrópio + Salbutamol Cipla, 0,525 mg/2,5 ml + 3 mg/2,5 ml, solução para inalação por nebulização	not available	5678164	CIPLA (EU) LIMITED	PT
Ipratropiumbromid/Salbutamol Cipla 0,5 mg/2,5mg per 2,5 ml, lösning för nebulisator	NL/H/3022/001	49853	CIPLA EUROPE NV	SE
Ipratropijev bromid/salbutamol Cipla 0,5 mg/2,5 mg u 2,5 ml, otopina za atomizator	NL/H/3022/001	HR-H-807555647	CIPLA EUROPE NV	HR
Ipratropiumbromide/Salbutamol Cipla 0,5/2,5 mg per 2,5 ml, verneveloplossing	NL/H/3022/001	RVG 114132	CIPLA EUROPE NV	NL
Ipratropiumbromide/Salbutamol Cipla 0,5 mg/2,5 ml + 2,5 mg/2,5 ml, verneveloplossing	NL/H/3022/001	BE468142	CIPLA EUROPE NV	BE
Ipratropium bromide/Salbutamol Cipla 0.5 mg/2.5 mg per 2.5 ml Nebuliser solution	NL/H/3022/001	16500/5-3-2015	CIPLA EUROPE NV	GR
Ipratropio bromuro/Salbutamolo Cipla 0,5 mg/2,5 mg in 2,5 ml soluzione per nebulizzatore	NL/H/3022/001	043052012	CIPLA EUROPE NV	IT
Ipratropio bromuro/Salbutamolo Cipla 0,5 mg/2,5 mg in 2,5 ml soluzione per nebulizzatore	NL/H/3022/001	043052024	CIPLA EUROPE NV	IT
Ipratropio bromuro/Salbutamolo Cipla 0,5 mg/2,5 mg in 2,5 ml soluzione per nebulizzatore	NL/H/3022/001	043052036	CIPLA EUROPE NV	IT
Ipratropio bromuro/Salbutamolo Cipla 0,5 mg/2,5 mg in 2,5 ml soluzione per nebulizzatore	NL/H/3022/001	043052048	CIPLA EUROPE NV	IT
Ipratropio bromuro/Salbutamolo Cipla 0,5 mg/2,5 mg in 2,5 ml soluzione per nebulizzatore	NL/H/3022/001	043052051	CIPLA EUROPE NV	IT

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Ipratropio bromuro/Salbutamolo Cipla 0,5 mg/2,5 mg in 2,5 ml soluzione per nebulizzatore	NL/H/3022/001	043052063	CIPLA EUROPE NV	IT
Bromure d'ipratropium/Salbutamol Cipla 0,5 mg/2,5 ml + 2,5 mg/2,5 ml solution pour inhalation par nébuliseur	NL/H/3022/001	2014120360	CIPLA EUROPE NV	LU
Zerseos 0.5 mg/2.5 mg per 2.5 ml Nebuliser solution	NL/H/3022/001	PL 36390/0161	CIPLA (EU) LIMITED	UK
Ipratropiu/Salbutamol Cipla 0,5 mg/2,5 mg soluţie de inhalat prin nebulizator	NL/H/3022/001	7213/2014/01	CIPLA EUROPE NV	RO
Ipratropiu/Salbutamol Cipla 0,5 mg/2,5 mg soluţie de inhalat prin nebulizator	NL/H/3022/001	7213/2014/02	CIPLA EUROPE NV	RO
Ipratropiu/Salbutamol Cipla 0,5 mg/2,5 mg soluţie de inhalat prin nebulizator	NL/H/3022/001	7213/2014/03	CIPLA EUROPE NV	RO
Ipratropiu/Salbutamol Cipla 0,5 mg/2,5 mg soluţie de inhalat prin nebulizator	NL/H/3022/001	7213/2014/04	CIPLA EUROPE NV	RO
Ipratropiu/Salbutamol Cipla 0,5 mg/2,5 mg soluţie de inhalat prin nebulizator	NL/H/3022/001	7213/2014/05	CIPLA EUROPE NV	RO
Ipratropiu/Salbutamol Cipla 0,5 mg/2,5 mg soluţie de inhalat prin nebulizator	NL/H/3022/001	7213/2014/06	CIPLA EUROPE NV	RO
Ipratropiumbromid/salbutamol "Cipla", inhalationsvæske til nebulisator, opløsning, enkeltdosisbeholder	NL/H/3022/001	52977	CIPLA EUROPE NV	DK
Ipratropiumbromidi/Salbutamoli Cipla 0,5 mg/2,5 mg per 2,5 ml sumutinliuos	NL/H/3022/001	31749	CIPLA EUROPE NV	FI
Ipratropiumbromidi/Salbutamoli Cipla 0,5 mg/2,5mg per 2,5 ml lösning för nebulisator	NL/H/3022/001	31749	CIPLA EUROPE NV	FI
Ipratropiumbromid/Salbutamol Cipla 0,5 mg/2,5 mg pro 2,5 ml Lösung für einen Vernebler	NL/H/3022/001	135901	CIPLA EUROPE NV	AT
Ипратропиев бромид / салбутамол Сипла 0,5 mg/2,5 mg на 2,5 ml разтвор за небулизатор	NL/H/3022/001	20140386	CIPLA EUROPE NV	BG
BREVA 0,375% + mg 0,075% Soluzione da	not available	024154066	VALEAS S.P.A.	IT

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
nebulizzare o soluzione orale				
BREVA® Aerosol dosato	not available	024154054	VALEAS S.P.A.	IT
COMBIPRASAL 0.5 mg / 2.5 mg per 2.5 ml nebuliser solution	NL/H/2736/001	PA1815/001/001	PHARMA STULLN GMBH	IE
IPRASA 0,5 mg / 2,5 mg per 2,5 ml, verneveloplossing	NL/H/2736/001	RVG112344	PHARMA STULLN GMBH	NL
COMBIPRASAL 0,5 mg / 2,5 mg Lösung für einen Vernebler	NL/H/2736/001	88376.00.00	PENTA ARZNEIMITTEL GMBH	DE
COMBIPRASAL 0.5 mg / 2.5 mg nebuliser solution	NL/H/2736/001	PL 20905/0001	PHARMA STULLN GMBH	UK
Ipramol Steri-Neb 0.5mg / 2.5mg per 2.5ml Nebuliser Solution.	IE/H/0163/001	PA 282/79/1	NORTON HEALTHCARE LTD T/A IVAX PHARMACEUTICALS UK	IE
Ipramol 0,5 mg/2,5 mg in 2,5 ml soluzione per nebulizzatore	IE/H/0163/001	039021023	TEVA ITALIA S.R.L.	IT
Ipramol 0,5 mg/2,5 mg in 2,5 ml soluzione per nebulizzatore	IE/H/0163/001	039021062	TEVA ITALIA S.R.L.	IT
Ipramol 0,5 mg/2,5 mg in 2,5 ml soluzione per nebulizzatore	IE/H/0163/001	039021047	TEVA ITALIA S.R.L.	IT
Ipramol 0,5 mg/2,5 mg in 2,5 ml soluzione per nebulizzatore	IE/H/0163/001	039021050	TEVA ITALIA S.R.L.	IT
Ipramol 0,5 mg/2,5 mg in 2,5 ml soluzione per nebulizzatore	IE/H/0163/001	039021035	TEVA ITALIA S.R.L.	IT
Ipramol 0,5 mg/2,5 mg in 2,5 ml soluzione per nebulizzatore	IE/H/0163/001	039021011	TEVA ITALIA S.R.L.	IT
Ipramol 0,5 mg/2,5 mg in 2,5 ml soluzione per nebulizzatore	IE/H/0163/001	039021086	TEVA ITALIA S.R.L.	IT
Ipramol 0,5 mg/2,5 mg in 2,5 ml soluzione per nebulizzatore	IE/H/0163/001	039021074	TEVA ITALIA S.R.L.	IT
Ipramol 0,5 mg/2,5 mg in 2,5 ml soluzione per nebulizzatore	IE/H/0163/001	039021098	TEVA ITALIA S.R.L.	IT
Ipramol 0,5 mg / 2,5 mg per 2,5 ml, sumutinliuos	IE/H/0163/001	21614	TEVA SWEDEN AB	FI
Ipramol 0,5 mg / 2,5 mg per 2,5 ml, lösning för nebulisator	IE/H/0163/001	22979	TEVA SWEDEN AB	SE

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
Ipramol Steri-Neb 0,5/2,5mg ανά 2,5ml Διάλυμα για Εισπνοή με Εκνεφωτή	IE/H/0163/001	55924/29-7-2009	TEVA PHARMA B.V.	GR
Nebu-Iprasal 0,5 mg/2,5 mg/2,5 ml verneveloplossing	IE/H/0163/001	BE315551	TEVA PHARMA BELGIUM N.V./S.A	BE
Ipramol Steri-Neb 0.5mg / 2.5mg per 2.5ml Nebuliser Solution.	IE/H/0163/001	PL00530/0961	NORTON HEALTHCARE LTD T/A IVAX PHARMACEUTICALS UK	UK
Ipramol Teva® 0,5 mg+2,5 mg/2,5 ml Steri-Neb® Lösung für einen Vernebler	IE/H/0163/001	69306.00.00	TEVA GMBH	DE
Ipramol 0,5 mg/2,5 mg in 2,5 ml soluzione per nebulizzatore	IE/H/0163/001	039021100	TEVA ITALIA S.R.L.	IT
Ipramol Steri-Neb	IE/H/0163/001	41308	TEVA DENMARK A/S	DK
Ipramol 0,5 mg/2,5ml + 2,5 mg/2,5ml	IE/H/0163/001	5071410	TEVA PHARMA – PRODUTOS FARMACÊUTICOS LDA	PT
NEBU-IPRASAL 0,5 mg/2,5 mg/2,5 ml LÖSUNG FÜR EINEN VERNEBLER	IE/H/0163/001	BE315551	TEVA PHARMA BELGIUM N.V./S.A	BE
Nebu-Iprasal 0,5 mg / 2,5 mg / 2,5 ml verneveloplossing	IE/H/0163/001	BE315551	TEVA PHARMA BELGIUM N.V./S.A	BE
Ipramol 0,5 mg/2,5ml + 2,5 mg/2,5ml	IE/H/0163/001	5071428	TEVA PHARMA – PRODUTOS FARMACÊUTICOS LDA	PT
Ipramol Steri-Neb 0,5 mg / 2,5 mg per 2,5 ml, verneveloplossing	IE/H/0163/001	RVG 33224	TEVA NEDERLAND B.V.	NL
Ipramol 0,5 mg/2,5 mg per 2,5 ml, lösning för nebulisator	IE/H/0163/001	21614	TEVA SWEDEN AB	FI
Zerseos 0,5 mg/2,5 mg per 2,5 ml, verneveloplossing	NL/H/3597/001	RVG 118115	CIPLA (EU) LIMITED	NL
Zerseos 0.5 mg/2.5 mg per 2.5 ml nebuliser solution	NL/H/3597/001	PA 1809/022/001	CIPLA (EU) LIMITED	IE
Salipra 0,5 mg/2,5 mg lösning för nebulisator	not available	50553	ALTERNOVA A/S	SE
Combivent, inhalationsvæske til nebulisator, opløsning, enkeltdosisbeholder	not available	17745	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	DK
Combivent® UDVs® 500 micrograms/2.5 mg per 2.5 ml Nebuliser solution	not available	PA 7/52/2	BOEHRINGER INGELHEIM LTD.	IE
Atrodual lösning för nebulisator i endosbehållare	not available	12394	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	FI

Product Name (in authorisation country)	MRP/DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
ipratropiumbromid/salbutamol				
Combivent 0,5 mg/2,5 ml + 2,5 mg/2,5 ml Lösung für einen Vernebler	not available	632/01/09/7766	SCS BOEHRINGER INGELHEIM COMM.V.	LU
Combivent 0,5 mg/2,5 ml + 2,5 mg/2,5 ml Lösung für einen Vernebler	not available	BE187056	SCS BOEHRINGER INGELHEIM COMM.V.	BE
Atrodual sumutinliuos kerta-annossäiliössä	not available	12394	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	FI
Combivent 0,5 mg/2,5 ml + 2,5 mg/2,5 ml Solution pour inhalation par nébuliseur	not available	632/01/09/7766	SCS BOEHRINGER INGELHEIM COMM.V.	LU
Combivent Unidose 0,52 mg/2,5 ml + 3 mg/2,5 ml	not available	3218682	BOEHRINGER INGELHEIM, UNIPESSOAL, LDA.	PT
Combivent Unidose 0,52 mg/2,5 ml + 3 mg/2,5 ml	not available	3218781	BOEHRINGER INGELHEIM, UNIPESSOAL, LDA.	PT
Combivent Unidose 0,52 mg/2,5 ml + 3 mg/2,5 ml	not available	3218880	BOEHRINGER INGELHEIM, UNIPESSOAL, LDA.	PT
Combivent Unit Dose, verneveloplossing	not available	RVG 20233	BOEHRINGER INGELHEIM B.V.	NL
Berovent® διάλυμα για εισπνοή με εκνεφωτή	not available	19532	BOEHRINGER INGELHEIM ELLAS AE	CY
Berovent® διάλυμα για εισπνοή με εκνεφωτή	not available	37256/10	BOEHRINGER INGELHEIM ELLAS AE	GR
Combivent® UDVs®	not available	PL 00015/0197	BOEHRINGER INGELHEIM LTD.	UK
Combivent 0,5 mg/2,5 mg lösning för nebulisator, endosbehållare	not available	13095	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	SE
Combivent 0,5 mg/2,5 ml + 2,5 mg/2,5 ml Solution pour inhalation par nébuliseur	not available	BE187056	SCS BOEHRINGER INGELHEIM COMM.V.	BE
Combivent 0,5 mg/2,5 ml + 2,5 mg/2,5 ml Verneveloplossing	not available	BE187056	SCS BOEHRINGER INGELHEIM COMM.V.	BE
Combivent® Lösung für einen Vernebler in Einzeldosisbehältnissen	not available	1-21541	BOEHRINGER INGELHEIM RCV GMBH & CO KG	AT
COMBIPRASAL 0.5 mg/2.5 mg solución para inhalación por nebulizador	not available	73561	LABORATORIO ALDO-UNIÓN, S.L.	ES
Ipratropium/Salbutamol "Sandoz"	NL/H/2221/001	48234	SANDOZ A/S	DK
Ipratropiumbromide/Salbutamol Sandoz 0,5 mg/2,5 mg per 2,5 ml Unit Dose,	NL/H/3022/001	RVG 100362	SANDOZ B.V.	NL

Product Name (in authorisation country)	MRP / DCP Authorisation number	National Authorisation Number	MAH of product in the member state	Member State where product is authorised
verneveloplossing				
Ipratropiumbromide/Salbutamol Sandoz 0,5/2,5 mg per 2,5 ml, verneveloplossing	NL/H/2221/001	RVG 109136	SANDOZ B.V.	NL
Copralineb 0.5 mg/2.5 mg per 2.5 ml Nebuliser Solution	NL/H/2221/001	PL 04416/1296	SANDOZ LTD	UK
Ipratropium/Salbutamol Sandoz 0,5 mg/2,5 mg lösning för nebulisator	NL/H/2221/001	45656	SANDOZ A/S	SE