



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

07 July 2016
EMA/478258/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance(s): salmeterol

Procedure No.: PSUSA/00002681/201510



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
Sereflo CFC-free Inhaler 25 micrograms per actuation pressurised inhalation, suspension	not available	PL 36390/0074	CIPLA (EU) LIMITED	UK
Salmeterol Sandoz 25 microgramos/inhalación suspensión para inhalación en envase a presión	UK/H/5548/001	79349	SANDOZ FARMACÉUTICA, S.A.	ES
Salmeterol CFC-free 25 micrograms per actuation pressurised inhalation, suspension	UK/H/5548/001	PL 04416/1411	SANDOZ LTD	UK
SALMETEROLO SANDOZ	UK/H/5548/001	043541010	SANDOZ S.P.A.	IT
SALMETEROLO SANDOZ	UK/H/5548/001	043541022	SANDOZ S.P.A.	IT
SALMETEROLO SANDOZ	UK/H/5548/001	043541034	SANDOZ S.P.A.	IT
SALMETEROLO SANDOZ	UK/H/5548/001	043541046	SANDOZ S.P.A.	IT
SALMETEROLO SANDOZ	UK/H/5548/001	043541059	SANDOZ S.P.A.	IT
Dilamax Inalador 25 microgramas/dose suspensão pressurizada para inalação	not available	2259588	BIALFAR - PRODUTOS FARMACÊUTICOS, S.A.	PT
Dilamax Diskus 50 microgramas/dose pó para inalação	not available	2338481	BIALFAR - PRODUTOS FARMACÊUTICOS, S.A.	PT
ARIAL 25 mcg/erogazione Sospensione pressurizzata per inalazione	not available	027891136	DOMPÉ FARMACEUTICI S.P.A.	IT
ARIAL 50 mcg Polvere per inalazione	not available	027891124	DOMPÉ FARMACEUTICI S.P.A.	IT
SALMETEDUR 25 mcg/erogazione Sospensione pressurizzata per inalazione	not available	027892138	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	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
Salmeterol 50 mcg polvere per inalazione	not available	027892126	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
SALMETEDUR 25 mcg/erogazione Sospensione pressurizzata per inalazione	not available	027892138	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
Salmeterol 50 mcg polvere per inalazione	not available	027892126	A. MENARINI - INDUSTRIE FARMACEUTICHE RIUNITE - S.R.L.	IT
Neuvent TM CFC-free Inhaler 25 micrograms per actuation pressurised inhalation, suspension	UK/H/3624/001	PL20417/0058	FANNIN LTD	UK
Salmeterol Neolab 25micrograms per metered dose pressurised inhalation suspension	UK/H/3624/001	PA 1585/3/1	FANNIN LTD	IE
Pulveril, 25 mikrogramów/dawkę, aerozol inhalacyjny, zawiesina	UK/H/3624/001	18281	SANDOZ GMBH	PL
Salmeterol HEXAL 25 Mikrogramm/Dosis Druckgasinhalation, Suspension	UK/H/3624/001	79516.00.00	HEXAL AG	DE
Pulveril	UK/H/3624/001	18281	SANDOZ GMBH	PL
Vertine [®] CFC-free Inhaler 25 micrograms per actuation pressurised inhalation, suspension	UK/H/3625/001	PL 00289/1667	TEVA UK LIMITED	UK
Serevent Diskus 50 mikrograma/dozi, prašak inhalata	not available	UP/I-530-09/10-02/195	GLAXOSMITHKLINE D.O.O.	HR
Serevent Inhaler 25 mikrograma/dozi, stlačeni inhalat, suspenzija	not available	UP/I-530-09/10-02/196	GLAXOSMITHKLINE D.O.O.	HR

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
Serevent® 25 microgramos, suspensión para inhalación en envase a presión	not available	59.490	GLAXOSMITHKLINE S.A.	ES
Inspir Accuhaler 50 microgramos/inhalación, polvo para inhalación	not available	59.526	GLAXOSMITHKLINE S.A.	ES
Inspir 25 microgramos/inhalación, suspensión para inhalación en envase a presión	not available	59.527	GLAXOSMITHKLINE S.A.	ES
Betamcan® Accuhaler® 50 microgramos/inhalación, polvo para inhalación	not available	59.675	GLAXOSMITHKLINE S.A.	ES
Betamcan® 25 microgramos/inhalación, suspensión para inhalación en envase a presión	not available	59.676	GLAXOSMITHKLINE S.A.	ES
Beglan Accuhaler 50 microgramos, polvo para inhalación	not available	59.522	GLAXO S.A.	ES
Beglan 25 microgramos, suspensión para inhalación en envase a presión	not available	59.523	GLAXO S.A.	ES
Serevent Diskus, 50 micrograms per metered dose, inhalation powder, pre-dispensed	not available	AA192/01901	GLAXOSMITHKLINE (IRELAND) LIMITED	MT
Serevent Diskus 50 mikrog/dos inhalationspulver, avdelad dos	not available	11624	GLAXOSMITHKLINE OY	FI
Serevent Diskus 50 microgram/dosis – Inhalatiepoeder, voorverdeeld	not available	BE182664	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE

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
Serevent Diskus 50 Microgramm/dosis Einzeldosiertes Pulver zur Inhalation	not available	BE182664	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Serevent Diskus 50 microgram/dosis – Inhalatiepoeder, voorverdeeld	not available	2003 10 7734	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Serevent Diskus 50 Microgramm/dosis Einzeldosiertes Pulver zur Inhalation	not available	2003 10 7734	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Serevent Evohaler 25 microgram per dosis, aërosol, suspensie.	UK/H/0880/001	BE289177	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Serevent Evohaler 25 Mikrogramm/Dosis (Sprühstoß) Druckgasinhalation, Suspension	UK/H/0880/001	BE289177	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Serevent Evohaler 25 microgram per dosis, aërosol, suspensie	UK/H/0880/001	0260/11 11 1328	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Serevent Evohaler 25 Mikrogramm/Dosis (Sprühstoß) Druckgasinhalation, Suspension	UK/H/0880/001	0260/11 11 1328	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Ultrabeta Diskus 50 microgramas/dose pó para inalação	not available	8795237	GLAXOSMITHKLINE - PRODUTOS FARMACEUTICOS, LIMITADA	PT
Ultrabeta Diskus 50 microgramas/dose pó para inalação	not available	8795245	GLAXOSMITHKLINE - PRODUTOS FARMACEUTICOS, LIMITADA	PT
Ultrabeta 25 microgramas/dose suspensão pressurizada para inalação	not available	8795104	GLAXOSMITHKLINE - PRODUTOS FARMACEUTICOS, LIMITADA	PT

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
Serevent Diskus, 50 micrograms per metered dose, inhalation powder, pre-dispensed	not available	PA 1077/47/3	GLAXOSMITHKLINE (IRELAND) LIMITED	IE
SEREVENT 25 mcg/erogazione Sospensione pressurizzata per inalazione	not available	027890110	GLAXOSMITHKLINE S.P.A.	IT
Salmeterol Inhalator Baggerman 25 microgram/dosis, aërosol, suspensie	not available	RVG 103065	BAGGERMAN FARMANET NV	NL
Serevent Evohaler 25 Mikrogramm/Sprühstoß - Dosieraerosol	UK/H/0880/001	1-26720	GLAXOSMITHKLINE PHARMA GMBH.	AT
Serevent Evohaler 25 mikrogramm/agad túlnyomásos inhalációs szuszpenzió	UK/H/0880/001	OGYI-T-20251/01	GLAXOSMITHKLINE KFT.	HU
Serevent 25 míkrog/skammt innúðalyf, dreifa.	UK/H/0880/001	IS/1/06/031/01	GLAXOSMITHKLINE PHARMA A/S	IS
Serevent Evohaler 25 micrograms per actuation pressurised inhalation suspension	UK/H/0880/001	PA 1077/47/5	GLAXOSMITHKLINE (IRELAND) LIMITED	IE
Serevent 25 mikrogramai/išpurškime suslegtoji ikvepiamoji suspensija	UK/H/0880/001	LT/1/06/0598/001	GLAXOSMITHKLINE LIETUVA UAB	LT
Serevent Evohaler 25 microgrammes par dose, suspension pour inhalation en flacon pressurisé.	UK/H/880/001	0260/11 11 1328	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU

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
Serevent Evohaler 25 micrograms per actuation pressurised inhalation suspension.	UK/H/0880/001	MA 192/01002	GLAXOSMITHKLINE (IRELAND) LIMITED	MT
Serevent 25 Inhalator CFK-vrij, aërosol, suspensie 25 microgram/dosis	UK/H/0880/001	RVG 33735	GLAXOSMITHKLINE B.V.	NL
Serevent 25 mikrogram/dose inhalasjonsaerosol, suspensjon	UK/H/880/001	06-3997	GLAXOSMITHKLINE AS	NO
Serevent, 25 mikrogramów/dawkę inhalacyjną, aerozol inhalacyjny, zawiesina	UK/H/0880/001	12486	GLAXOSMITHKLINE EXPORT LTD	PL
SereventInhaler N 25 mikrogramov/davka	UK/H/0880/001	14/0402/06-S	GLAXOSMITHKLINE SLOVAKIA S.R.O.	SK
Serevent 25 mikrogramov/vpih inhalacijska suspenzija pod tlakom	UK/H/0880/001	H/06/01406/001	GLAXOSMITHKLINE D.O.O.	SI
Serevent Evohaler 25 mikrogram/dos inhalationsspray, suspension	UK/H/0880/001	23548	GLAXOSMITHKLINE AB	SE
Serevent Evohaler 25 micrograms per actuation pressurised inhalation suspension.	UK/H/0880/001	PL 10949/0369	GLAXO WELLCOME LTD	UK
Serevent Evohaler 25 microgrammes par dose, suspension pour inhalation en flacon pressurisé.	UK/H/0880/001	BE289177	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Serevent	UK/H/0880/001	39110	GLAXOSMITHKLINE PHARMA A/S	DK
Serevent, 25 mikrogrammi/annuses inhalatsiooniaerosool, suspensioon.	UK/H/0880/001	518806	GLAXOSMITHKLINE EXPORT LTD	EE

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
Serevent Accuhaler	not available	10949/0214	GLAXO WELLCOME LTD	UK
Serevent 25 microgramas/dose suspensão pressurizada para inalação	not available	8786319	GLAXO WELLCOME FARMACÊUTICA, LDA	PT
Serevent Diskus 50 microgrammes/dose – Poudre pour inhalation en récipient unidose	not available	BE182664	GLAXOSMITHKLINE PHARMACEUTICALS SA	BE
Serevent® Diskus® 50 µg/Dosis, einzeldosiertes Pulver zur Inhalation	not available	25243.00.01	GLAXOSMITHKLINE GMBH & CO. KG	DE
Serevent Diskus 50 mcg, 50 mikrogrammi/annuses inhalatsioonipulber	not available	108195	GLAXO WELLCOME LTD	EE
СЕРЕВЕНТ Инхалер 25 микрограма/дозирано впръскване, суспензия под налягане за инхалация	not available	20020425	GLAXOSMITHKLINE EOOD	BG
SEREVENT	not available	21237/2-4-08	GLAXOSMITHKLINE AEBE	GR
SEREVENT Rotadisks/Diskus	not available	67556/08/13-2-09	GLAXOSMITHKLINE AEBE	GR
Serevent™ 25 mikrogrami aerosols inhalacijām, zem spiediena, suspensija	not available	99-0388	GLAXOSMITHKLINE LATVIA SIA	LV
Serevent™ Diskus™ 50 mikrogrami pulveris inhalācijām	not available	99-1049	GLAXOSMITHKLINE LATVIA SIA	LV
Serevent Diskus Dávkovaný prášek k inhalaci	not available	14/029/02-C	GLAXO GROUP LIMITED	CZ

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
Serevent Diskus 50 mikrogramu/dozeje dozuoti ikvepiamieji milteliai	not available	LT/1/95/1430/001	GLAXOSMITHKLINE LIETUVA UAB	LT
Sereventâ Dosier-Aerosol 25 µg/Dosis, Druckgasinhalation, Suspension	not available	25243.00.00	GLAXOSMITHKLINE GMBH & CO. KG	DE
Serevent Diskus 50 mikrog/annos inhalaatiojauhe, annosteltu	not available	11624	GLAXOSMITHKLINE OY	FI
Salmeterol GSK 25 µg Dosier-Aerosol 25 µg/Dosis, Druckgasinhalation, Suspension	not available	65254.00.00	GLAXOSMITHKLINE GMBH & CO. KG	DE
Serevent 50 Diskus, inhalatiepoeder 50 microgram/dosis, voorverdeeld	not available	RVG 18150	GLAXOSMITHKLINE B.V.	NL
Serevent Diskus 50 microgrammes/dose – Poudre pour inhalation en récipient unidose	not available	2003 10 7734	GLAXOSMITHKLINE PHARMACEUTICALS SA	LU
Serevent® Diskus® 50 microgramas/dose pó para inalação	not available	8786459	GLAXO WELLCOME FARMACÊUTICA, LDA	PT
Serevent Diskus 50 mikrogram/dos inhalationspulver, avdelad dos	not available	12363	GLAXOSMITHKLINE AB	SE
Serevent Dysk, 50 µg/dawke inhalacyjna, proszek do inhalacji	not available	4378	GLAXOSMITHKLINE EXPORT LTD	PL
Serevent, inhalationspulver afdelt i Diskos	not available	15968	GLAXOSMITHKLINE PHARMA A/S	DK
SEREVENT 25 microgrammes par dose, suspension pour inhalation en flacon pressurisé	not available	NL17083	LABORATOIRE GLAXOSMITHKLINE	FR

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SEREVENT DISKUS 50 microgrammes/dose, poudre pour inhalation	not available	NL20762	LABORATOIRE GLAXOSMITHKLINE	FR
Serevent Diskus 50 mikrogramm/adag adagolt inhalációs por	not available	OGYI-T-5766/01	GLAXOSMITHKLINE KFT.	HU
SEREVENT 50 mcg Polvere per inalazione	not available	027890146	GLAXOSMITHKLINE S.P.A.	IT
Serevent Diskus	not available	14/0195/98-S	GLAXOSMITHKLINE SLOVAKIA S.R.O.	SK
Serevent Diskus, 50 míkrog/skammt innöndunarduft	not available	940050	GLAXOSMITHKLINE PHARMA A/S	IS
Serevent 50 mikrog/dose inhalasjonspulver	not available	8049	GLAXOSMITHKLINE AS	NO
Serevent® Accuhaler® 50 microgramos, polvo para inhalación	not available	59.489	GLAXOSMITHKLINE S.A.	ES
Serevent Evohaler 25 micrograms per actuation pressurised inhalation suspension.	not available	20043	GLAXO GROUP LIMITED	CY
Serevent Diskus	not available	16824	GLAXO GROUP LIMITED	CY