



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 March 2022
EMA/164850/2022
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: budesonide / salmeterol

Procedure no.: PSUSA/00010511/202107



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
Zephirus 240 microgram/20 microgram, inhalatiepoeder in harde capsules	NL/H/3241/002	BE479377	LABORATOIRES SMB S.A.	BE
Zephirus 120 microgram/20 microgram, inhalatiepoeder in harde capsules	NL/H/3241/001	BE479360	LABORATOIRES SMB S.A.	BE
Zephirus 120 microgrammes/20 microgrammes, poudre pour inhalation en gélules	NL/H/3241/001	BE479360	LABORATOIRES SMB S.A.	BE
Zephirus 120 Mikrogramm/20 Mikrogramm, Hartkapseln mit Pulver zur Inhalation	NL/H/3241/001	BE479360	LABORATOIRES SMB S.A.	BE
Zephirus 240 microgrammes/20 microgrammes, poudre pour inhalation en gélules	NL/H/3241/002	BE479377	LABORATOIRES SMB S.A.	BE
Zephirus 240 Mikrogramm/20 Mikrogramm, Hartkapseln mit Pulver zur Inhalation	NL/H/3241/002	BE479377	LABORATOIRES SMB S.A.	BE
Busalair 240+20 mikrogram, inhalationspulver, hård	NL/H/3250/002	54379	LABORATOIRES SMB S.A.	DK

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kapsel				
Busalair, inhalationspulver, hård kapsel	NL/H/3250/001	54378	LABORATOIRES SMB S.A.	DK
Desoterol 120 μικρογραμμάρια/20 μικρογραμμάρια, Κόνις για εισπνοή, σκληρό καψάκιο	NL/H/3250/001	79420/01-09-2021	RAFARM SA.	GR
Desoterol 240 μικρογραμμάρια/20 μικρογραμμάρια, Κόνις για εισπνοή, σκληρό καψάκιο	NL/H/3250/002	79421/01-09-2021	RAFARM SA.	GR
ReviX Axahaler 120 mikrogramm/20 mikrogramm inhalációs por kemény kapszulában	NL/H/3250/001	OGYI-T-22986/01	SAGER PHARMA KFT.	HU
ReviX Axahaler 120 mikrogramm/20 mikrogramm inhalációs por kemény kapszulában	NL/H/3250/001	OGYI-T-22986/02	SAGER PHARMA KFT.	HU
ReviX Axahaler 120 mikrogramm/20 mikrogramm inhalációs por kemény kapszulában	NL/H/3250/001	OGYI-T-22986/03	SAGER PHARMA KFT.	HU

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ReviX Axahaler 240 mikrogramm/20 mikrogramm inhalációs por kemény kapszulában	NL/H/3250/002	OGYI-T-22986/04	SAGER PHARMA KFT.	HU
ReviX Axahaler 240 mikrogramm/20 mikrogramm inhalációs por kemény kapszulában	NL/H/3250/002	OGYI-T-22986/05	SAGER PHARMA KFT.	HU
ReviX Axahaler 240 mikrogramm/20 mikrogramm inhalációs por kemény kapszulában	NL/H/3250/002	OGYI-T-22986/06	SAGER PHARMA KFT.	HU
Zephirus 120 microgrammes/20 microgrammes, poudre pour inhalation en gélules	NL/H/3241/001	2016040104	LABORATOIRES SMB S.A.	LU
Zephirus 120 Mikrogramm/20 Mikrogramm, Hartkapseln mit Pulver zur Inhalation	NL/H/3241/001	2016040104	LABORATOIRES SMB S.A.	LU
Zephirus 240 microgrammes/20 microgrammes, poudre pour inhalation en gélules	NL/H/3241/002	2016040105	LABORATOIRES SMB S.A.	LU
Zephirus 240 Mikrogramm/20 Mikrogramm, Hartkapseln	NL/H/3241/002	2016040105	LABORATOIRES SMB S.A.	LU

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mit Pulver zur Inhalation				
Busalair 120 microgram/20 microgram, inhalatiepoeder in harde capsules	NL/H/3250/001	RVG 115690	LABORATOIRES SMB S.A.	NL
Busalair 240 microgram/20 microgram, inhalatiepoeder in harde capsules	NL/H/3250/002	RVG 115691	LABORATOIRES SMB S.A.	NL
Zephirus 120 microgram/20 microgram, inhalatiepoeder in harde capsules	NL/H/3241/001	RVG 115687	LABORATOIRES SMB S.A.	NL
Zephirus 240 microgram/20 microgram, inhalatiepoeder in harde capsules	NL/H/3241/002	RVG 115688	LABORATOIRES SMB S.A.	NL
Duastmin, 120 mikrogramów + 20 mikrogramów, proszek do inhalacji w kapsułce twardej	NL/H/3250/001	23867	LABORATOIRES SMB S.A.	PL
Duastmin, 240 mikrogramów + 20 mikrogramów, proszek do	NL/H/3250/002	23868	LABORATOIRES SMB S.A.	PL

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inhalacji w kapsułce twardej				
Busalair 240 mikrogram/20 mikrogram, inhalationspulver, hård kapsel	NL/H/3250/002	51354	LABORATOIRES SMB S.A.	SE
Busalair, 120 mikrogram/20 mikrogram inhalationspulver, hård kapsel	NL/H/3250/001	51353	LABORATOIRES SMB S.A.	SE