



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 March 2021
EMA/164735/2021
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: oxymetazoline

Procedure no.: PSUSA/00002258/202008

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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
Nasin 0,25 mg/ml nässpray, lösning	not available	11669	PERRIGOSVERIGE AB	SE
respibien 0,5 mg/ml solución para pulverización nasal	not available	51.889	LABORATORIOS CINFA, S.A.	ES
Sinuzolin, 0,5 mg/ml, krople do nosa, roztwór	EE/H/0274/001	25588	NORD FARM SP. Z O.O.	PL
Sinuzolin, 0,5 mg/ml ninatilgad, lahus	EE/H/0274/001	992819	NORD FARM SP. Z O.O.	EE
PERNAZENE 0,05 POUR CENT, solution pour pulvérisation nasale	not available	34009 308 199 6 8	CILFA DEVELOPPEMENT	FR
Nasivin 0,01% 0,1 rng/rnl, krople do nosa, roztwór	not available	R/1084	P&G HEALTH GERMANY GMBH	PL

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
Африн 0,05% спрей за нос, разтвор	not available	20010699	BAYER BULGARIA EOOD	BG
Nezemer 0,5 mg/ml nässpray, lösning	not available	59019	PERRIGOSVERIGE AB	SE
Nezeril 0,25 mg/ml näsdroppar, lösning, endosbehållare	not available	8683	PERRIGOSVERIGE AB	SE
Nezeril 0,5 mg/ml nefdropar, lausn, stakskammtaílát	not available	853658	PERRIGOSVERIGE AB	IS
Sinusin 0,05 % - Nasenspray	not available	136509	P&G HEALTH GERMANY GMBH	AT
Sinex	SE-H-0196-001-MR	848614	WICK PHARMA ZWEIGNIEDERLASSUNG DER PROCTER & GAMBLE GMBH	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
Sinex 0,5 mg/ml deguna aerosols, šķīdums	SE/H/0196/001	14-0197	WICK PHARMA ZWEIGNIEDERLASSUNG DER PROCTER & GAMBLE GMBH	LV
Sinex 0,5 mg/ml nosies purškalas (tirpalas)	SE/H/0196/001	LT/1/14/3591/002	WICK PHARMA ZWEIGNIEDERLASSUNG DER PROCTER & GAMBLE GMBH	LT
WICK SinexAloe Nasenspray 0,5 mg/ml Lösung	SE/H/0196/001	1-24037	WICK PHARMA ZWEIGNIEDERLASSUNG DER PROCTER & GAMBLE GMBH	AT
Vicks Sinex Congestion Nasale 0,5 mg/ml, solution pour pulvérisation nasale	SE/H/0196/001/MR	BE225495	PROCTER & GAMBLE DISTRIBUTION COMPANY EUROPE B.V.B.A.	BE
Vicks Sinex Verstopfte Neus 0,5 mg/ml, neusspray oplossing	SE/H/0196/001	BE225495	PROCTER & GAMBLE DISTRIBUTION COMPANY EUROPE B.V.B.A.	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
Vicks Sinex Verstopfte Nase 0,5 mg/ml Nasenspray- Lösung	SE/H/0196/001	BE225495	PROCTER & GAMBLE DISTRIBUTION COMPANY EUROPE B.V.B.A.	BE
Sinex Vicks Aloe a Eukalyptus 0,5 mg/ml, nosní sprej, roztok	SE/H/0196/001	69/972/10-C	PROCTER & GAMBLE GMBH	CZ
Vicks Sinex 0,5 mg/ml nenäsumute, liuos	SE/H/0196/001	28483	WICK PHARMA ZWEIGNIEDERLASSUNG DER PROCTER & GAMBLE GMBH	FI
WICK Sinex avera Nasenspray 0,5 mg/ml Lösung	SE/H/0196/001	50661.00.00	WICK PHARMA ZWEIGNIEDERLASSUNG DER PROCTER & GAMBLE GMBH	DE
Wick Sinex Aloe Vera és Eukaliptusz 0,5 mg/ml oldatos orrspray	SE/H/0196/001	OGYI-T-21730/02	WICK PHARMA ZWEIGNIEDERLASSUNG DER PROCTER & GAMBLE GMBH	HU

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
Vicks Sinex Aloë, 0,5 mg/ml, neusspray oplossing	SE/H/0196/001	RVG 25847	PROCTER & GAMBLE NEDERLAND B.V.	NL
Vicks Sinex Aloes i Eukaliptus, 0,5 mg/ml, aerozol do nosa, roztwór	SE/H/0196/001	17702	WICK PHARMA ZWEIGNIEDERLASSUNG DER PROCTER & GAMBLE GMBH	PL
Sinexsensi, 0,5 mg/ml, solução para pulverização nasal	SE/H/0196/001	3632783	LABORATORIOS VICKS, S.L.	PT
SinexSensi 0,5 mg/ml, solución para pulverización nasal	SE/H/0196/001	69.328	LABORATORIOS VICKS, S.L.	ES
Vicks Sinex, 0,5 mg/ml, nässpray, lösning	SE/H/0196/001	13104	WICK PHARMA ZWEIGNIEDERLASSUNG DER PROCTER & GAMBLE GMBH	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
Vicks Sinex 0,5 mg/ml, διάλυμα ρινικού εκνεφώματος	SE/H/0196/001	61190/2-8-2016	PROCTER & GAMBLE HELLAS EPE	GR
Викс Синекс Алое и Евкалипт 0,5 mg/ml спрей за нос, разтвор	SE/H/0196/001	20140218	WICK PHARMA ZWEIGNIEDERLASSUNG DER PROCTER & GAMBLE GMBH	BG
Rino Calyptol 0,5 mg/ml spray nasale, soluzione	not available	028742031	LABORATORIO FARMACEUTICOS.I.T. S.R.L.	IT
Afrin, 500 mikrogramów/ml, aerozol do nosa, roztwór	not available	R/1212	BAYER SP.Z.O.O	PL
Respir 0,5 mg/ml solución para pulverización nasal	not available	41.111	BAYER HISPANIA SL	ES
Nasivin Soft 0,025%	not available	69/0271/05-S	P&G HEALTH GERMANY GMBH	SK

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
Nezeril 0,5 mg/ml nässpray, lösning	not available	73802	PERRIGOSVERIGE AB	SE
Nasivin Baby; 0,1 mg/ml, krople do nosa, roztwór	not available	9095	P&G HEALTH GERMANY GMBH	PL
Nasivin Kinder sanft 0,025 % - Spray	not available	1-22717	P&G HEALTH GERMANY GMBH	AT
Nasivin Classic 0,05 % - Spray	not available	12.194	P&G HEALTH GERMANY GMBH	AT
Nasivin Kinder 0,025 % - Nasentropfen	not available	15.056	P&G HEALTH GERMANY GMBH	AT
Nezeril 0,25 mg/ml nässpray, lösning	not available	10470	PERRIGOSVERIGE 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
Nezemax 0,5 mg/ml nässpray, lösning	not available	58417	PERRIGOSVERIGE AB	SE
Afrin 0,5 mg/ml oldatos orrspray	not available	OGYI-T-1733/01	BAYER HUNGARIA KFT	HU
Afrin 0,5 mg/ml oldatos orrspray	not available	OGYI-T-1733/02	BAYER HUNGARIA KFT	HU
RONAL 22 µg/dose Εκνέφωμα ρινικό σταθερών δόσεων	not available	40254/07/14-05-2008	P&G HEALTH GERMANY GMBH	GR
Nasivin 0,025 %	not available	69/0304/19-S	P&G HEALTH GERMANY GMBH	SK
NASIVIN 0,5 mg/ml nosní kapky, roztok	not available	69/041/91-C/C	P&G HEALTH GERMANY GMBH	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
Nezeril 0,5 mg/ml nefúði, lausn	not available	870219	PERRIGOSVERIGE AB	IS
Bisolspray Nebulicina Adulto 0,5 mg/ml solução para pulverização nasal	not available	3574589	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
Nasivin Classic; 0,5 mg/ml, aerosol do nosa, roztwór	not available	9189	P&G HEALTH GERMANY GMBH	PL
Nasivin Nasenspray ohne Konservierungsstoffe Erwachsene und Schulkinder 0,5 mg/ml Nasenspray, Lösung	not available	3494.00.01	P&G HEALTH GERMANY GMBH	DE
Sinuben 0,05 % - Nasenspray	not available	136508	P&G HEALTH GERMANY GMBH	AT

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
Nasivin® Nasenspray Erwachsene und Schulkinder 0,5 mg/ml Nasenspray, Lösung	not available	6462346.00.00	P&G HEALTH GERMANY GMBH	DE
Nezequr 0,5 mg/ml nässpray, lösning	not available	59020	PERRIGO SVERIGE AB	SE
ATURGYL 0,05 POUR CENT, SOLUTION POUR PULVERISATION NASALE	not available	34009 300 845 6 4	SANOFI-AVENTIS FRANCE	FR
Zolinol 0,25 mg/ml gotas nasais, solução	not available	5788401	LABORATÓRIO EDOL - PRODUTOS FARMACÊUTICOS, S.A.	PT
Nasivin Classic sanft 0,05 % - Spray	not available	1-22694	P&G HEALTH GERMANY GMBH	AT
NASIVIN 0,5 mg/ml Nosní sprej, roztok	not available	69/042/91-S/C	P&G HEALTH GERMANY GMBH	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
Nasivin Nasentropfen Erwachsene und Schulkinder 0,5 mg/ml Nasentropfen, Lösung	not available	6108938.00.01	P&G HEALTH GERMANY GMBH	DE
Nasivin Nasenspray ohne Konservierungsstoffe Kleinkinder 0,25 mg/ml Nasenspray, Lösung	not available	6109145.00.00	P&G HEALTH GERMANY GMBH	DE
Bisolspray Nebulicina Adulto 0,5 mg/ml solução para pulverização nasal	not available	3574589	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
NASIVIN pro kojence 0,1 mg/ml nosní kapky, roztok	not available	69/041/91-A/C	P&G HEALTH GERMANY GMBH	CZ
NEO BOROCILLINA NASALE 0,05% spray nasale, soluzione	not available	042188019	ALFASIGMA S.P.A.	IT
Nasivin Soft 0,05%	not available	69/0272/05-S	P&G HEALTH GERMANY GMBH	SK

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
Назопас 0,25 mg/ml капки за нос, разтвор	HR/H/0133/001	20190019	ALKALOID-INT D.O.O.	BG
Назопас 0,5 mg/ml капки за нос, разтвор	HR/H/0133/002	20190020	ALKALOID-INT D.O.O.	BG
Nazopass 0,25 mg/ml kapi za nos, otopina	HR/H/0133/001	HR-H-937341551	ALKALOID-INT D.O.O.	HR
Nazopass 0,5 mg/ml kapi za nos, otopina	HR/H/0133/002	HR-H-834473112	ALKALOID-INT D.O.O.	HR
Nazopass 0,25 mg/ml kapljice za nos, raztopina	HR/H/0133/001	H/19/02573/001	ALKALOID-INT D.O.O.	SI

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
Nazopass 0,5 mg/ml kapljice za nos, raztopina	HR/H/0133/002	H/19/02573/002	ALKALOID-INT D.O.O.	SI
Nasiben sanft 0,05 % - Nasenspray	not available	136507	P&G HEALTH GERMANY GMBH	AT
Nasivin Classic 0,05 % - Nasentropfen	not available	12193	P&G HEALTH GERMANY GMBH	AT
Nasiben Baby sanft 0,01 % - Dosiertropfer	not available	1-27063	P&G HEALTH GERMANY GMBH	AT
Nezeril 0,25 mg/ml nefúđi, lausn	not available	870218	PERRIGOSVERIGE AB	IS

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
Nasivin Dosiertropfer ohne Konservierungsstoffe Baby 0,1 mg/ml Nasentropfen, Lösung	not available	6109145.01.00	P&G HEALTH GERMANY GMBH	DE
Nezeril 0,5 mg/ml näsdroppar, lösning, endosbehållare	not available	8684	PERRIGOSVERIGE AB	SE
Nasivin Soft 0,01%	not available	69/0270/05-S	P&G HEALTH GERMANY GMBH	SK
Nasivin 0,01 %	not available	69/0305/19-S	P&G HEALTH GERMANY GMBH	SK
Nasivin 0,05%	not available	69/0042/91-S	P&G HEALTH GERMANY GMBH	SK
Nebulicina 0,5 mg/ml solución para pulverización nasal	not available	48.818	SANOFI-AVENTIS, S.A.	ES

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
Nasin 0,5 mg/ml nässpray, lösning	not available	11670	PERRIGOSVERIGE AB	SE
Nasivin Kids; 0,25 mg/ml, aerosol do nosa, roztwór	not available	9096	P&G HEALTH GERMANY GMBH	PL
Nasivin® Spray für Erwachsene und Schulkinder	not available	6108938.00.00	P&G HEALTH GERMANY GMBH	DE
Nasiben sanft 0,025% - Nasenspray für Kleinkinder	not available	136506	P&G HEALTH GERMANY GMBH	AT
Nasivin 0,05 %	not available	69/0041/91-S	P&G HEALTH GERMANY GMBH	SK
Nezeril 0,25 mg/ml nefdropar, lausn, stakskammtaílát.	not available	853657	PERRIGOSVERIGE AB	IS

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
Nasex 0,5 mg/ml Solução para inalação por nebulização	not available	9167205	JOHNSON & JOHNSON LDA	PT
Nasex 0,5 mg/ml Gotas nasais, solução	not available	9188219	JOHNSON & JOHNSON LDA	PT
Nezebi 0,5 mg/ml nässpray, lösning	not available	59018	PERRIGOSVERIGE AB	SE
Nesivine 0,01% baby sine conservans, neusdruppels, oplossing	not available	BE272806	P&G HEALTH BELGIUM B.V.B.A.	BE
Nesivine 0,025% pediatrie sine conservans, neusspray, oplossing	not available	BE272797	P&G HEALTH BELGIUM B.V.B.A.	BE
Nesivine 0,05% sine conservans, neusspray, oplossing	not available	BE272815	P&G HEALTH BELGIUM B.V.B.A.	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
Nesivine 0,01% baby sine conservans, solution nasale en gouttes	not available	BE272806	P&G HEALTH BELGIUM B.V.B.A.	BE
Nesivine 0,025 % pédiatrie sine conservans, solution nasale en gouttes	not available	BE272797	P&G HEALTH BELGIUM B.V.B.A.	BE
Nesivine 0,05% sine conservans, solution pour pulvérisation nasale	not available	BE272815	P&G HEALTH BELGIUM B.V.B.A.	BE
Nesivine 0,01% Baby Sine Conservans, Nasentropfen, Lösung	not available	BE272806	P&G HEALTH BELGIUM B.V.B.A.	BE
Nesivine 0,05% Sine Conservans, Nasenspray, Lösung	not available	BE272815	P&G HEALTH BELGIUM B.V.B.A.	BE
Nesivine 0,025% Pädiatrie Sine Conservans, Nasenspray, Lösung	not available	BE272797	P&G HEALTH BELGIUM B.V.B.A.	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
NASIVIN pro děti 0,25 mg/ml nosní kapky, roztok	not available	69/041/91-B/C	P&G HEALTH GERMANY GMBH	CZ
Nezepro 0,5 mg/ml nässpray, lösning	not available	58416	PERRIGO SVERIGE AB	SE