



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 January 2021
EMA/36692/2021
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: dexpanthenol xylometazoline

Procedure no.: PSUSA/00010030/202005

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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
nasic® pur Nasenspray für Kinder	not available	1-27711	CASELLA-MED GMBH & CO. KG	AT
Otrivin plus Dexpanthenol 1 mg/ml + 50 mg/ml, Nasenspray, Lösung	PT/H/1800/001	138424	GSK-GEBRO CONSUMER HEALTHCARE GMBH	AT
nasic® pur Nasenspray	not available	1-27710	CASELLA-MED GMBH & CO. KG	AT
nasic – Nasenspray 10 mg/ 500 mg	not available	1-27713	CASELLA-MED GMBH & CO. KG	AT
ratioSoft plus Dexpanthenol 0,5 mg/50 mg/ml Nasenspray	DE/H/3870/001	136035	TEVA B.V	AT
ratioSoft plus Dexpanthenol 1,0 mg/50 mg/ml Nasenspray	DE/H/3870/002	136036	TEVA B.V	AT
nasic - Nasenspray für Kinder 5 mg/500 mg	not available	1-27712	CASELLA-MED GMBH & CO. KG	AT
Nasic kids 5%/0,05%, nasal spray solution Назик кидс 5%,/0,05%, спрей за нос разтвор	not available	20060661	CASELLA-MED GMBH & CO. KG	BG

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
Отривин Плюс 1 mg/ml + 50 mg/ml спрей за нос, разтвор	PT/H/1800/001	20180220	GLAXOSMITHKLINE DUNGARVAN LIMITED	BG
Септаназал за възрастни 1 mg/50 mg в 1 ml спрей за нос, разтвор	CZ/H/0170/001	20130294	KRKA, D.D., NOVO MESTO	BG
Септаназал за деца 0,5 mg/50 mg в 1 ml спрей за нос, разтвор	CZ/H/0170/002	20130295	KRKA, D.D., NOVO MESTO	BG
Назик 5%/0,1%, спрей за нос разтвор За възрастни и деца над 6 години	not available	20060662	CASELLA-MED GMBH & CO. KG	BG
OLYNTH PLUS 1 mg/ml + 50 mg/ml nosní sprej, roztok	LV/H/0148/002/DC	69/1001/16-C	MCNEIL HEALTHCARE (IRELAND) LIMITED	CZ
Хълметазолин/дехпантенол Krka 0,5 mg/ml + 50 mg/ml nosní sprej, roztok	CZ/H/0643/001	69/380/16-C	KRKA, D.D., NOVO MESTO	CZ
Хълметазолин/дехпантенол Krka 1 mg/ml + 50 mg/ml nosní sprej, roztok	CZ/H/0643/002	69/381/16-C	KRKA, D.D., NOVO MESTO	CZ
OLYNTH PLUS 0,5 mg/ml + 50 mg/ml nosní sprej, roztok	LV/H/0148/001/DC	69/1000/16-C	MCNEIL HEALTHCARE (IRELAND) 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
Septanazal pro dospělé 1 mg/ml + 50 mg/ml nosní sprej, roztok	CZ/H/0170/002	69/401/13-C	KRKA, D.D., NOVO MESTO	CZ
Septanazal pro děti 0,5 mg/ml + 50 mg/ml nosní sprej, roztok	CZ/H/0170/001	69/402/13-C	KRKA, D.D., NOVO MESTO	CZ
Sinodex 0,5 mg/ml + 50 mg/ml nosní sprej, roztok	DE/H/3870/001	69/395/14-C	TEVA PHARMACEUTICALS CR, S.R.O.	CZ
Sinodex 1,0 mg/ml + 50 mg/ml nosní sprej, roztok	DE/H/3870/002	69/396/14-C	TEVA PHARMACEUTICALS CR, S.R.O.	CZ
nasic® Xylometazolinhydrochlorid 0,1 % + Dexpanthenol 5 %, Nasenspray, Lösung Für Erwachsene und Schulkinder	not available	18396.00.00	CASELLA-MED GMBH & CO. KG	DE
nasic® für Kinder Xylometazolinhydrochlorid 0,05 % + Dexpanthenol 5 %, Nasenspray, Lösung Für Kinder zwischen 2 und 6 Jahren	not available	18397.00.00	CASELLA-MED GMBH & CO. KG	DE

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Olynth Plus 0,1 % / 5 %*Nasenspray, Lösung	LV/H/0148/002/DC	99110.00.00	JOHNSON & JOHNSON GMBH	DE
nasic für Kinder Xylometazolinhydrochlorid 0,5 mg/ml + Dexpanthenol 50 mg/ml, Nasenspray, Lösung Für Kinder zwischen 2 und 6 Jahren	not available	88152.00.00	CASELLA-MED GMBH & CO. KG	DE
nasic für Kinder Xylometazolinhydrochlorid 0,5 mg/ml + Dexpanthenol 50 mg/ml, Nasenspray, Lösung Für Kinder zwischen 2 und 6 Jahren	not available	88154.00.00	CASELLA-MED GMBH & CO. KG	DE
nasic Xylometazolinhydrochlorid 1 mg/ml + Dexpanthenol 50 mg/ml, Nasenspray, Lösung Für Erwachsene und Schulkinder	not available	88128.00.00	CASELLA-MED GMBH & CO. KG	DE
RhinoDuo Nasenspray, Lösung	DE/H/3871/002	90015.00.00	RATIOPHARM GMBH	DE

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
RhinoDuo Nasenspray Kinder, Lösung	DE/H/3871/001	90014.00.00	RATIOPHARM GMBH	DE
nasic® O.K. Xylometazolinhydrochlorid 0,1 % + Dexpanthenol 5 %, Nasenspray, Lösung Für Erwachsene und Kinder ab 6 Jahren	not available	56888.00.00	CASELLA-MED GMBH & CO. KG	DE
nasic neo Xylometazolinhydrochlorid 1 mg/ml + Dexpanthenol 50 mg/ml, Nasenspray, Lösung Für Erwachsene und Kinder ab 6 Jahren	not available	95190.00.00	CASELLA-MED GMBH & CO. KG	DE
nasic® für Kinder O.K. Xylometazolinhydrochlorid 0,05 % + Dexpanthenol 5 %, Nasenspray, Lösung Für Kinder zwischen 2 und 6 Jahren	not available	57723.00.00	CASELLA-MED GMBH & CO. KG	DE
nasic® O.K. Xylometazolinhydrochlorid 0,1 % + Dexpanthenol 5 %, Nasenspray, Lösung Für Erwachsene und	not available	56969.00.00	CASELLA-MED GMBH & CO. KG	DE

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Kinder ab 6 Jahren				
nasic Xylometazolinhydrochlorid 1 mg/ml + Dexpanthenol 50 mg/ml, Nasenspray, Lösung Für Erwachsene und Schulkinder	not available	88126.00.00	CASELLA-MED GMBH & CO. KG	DE
Septanasal® für Kinder 0,5 mg/ml + 50 mg/ml Nasenspray, Lösung	CZ/H/0643/001	94778.00.00	TAD PHARMA GMBH	DE
Septanasal® 1 mg/ml + 50 mg/ml Nasenspray, Lösung	CZ/H/0643/002	94779.00.00	TAD PHARMA GMBH	DE
Otriven Protect 1 mg/ml + 50 mg/ml Nasenspray, Lösung	PT/H/1800/001	98934.00.00	GLAXOSMITHKLINE CONSUMER HEALTHCARE GMBH & CO. KG	DE
Olynth Plus 0,05 % / 5 % Nasenspray, Lösung	LV/H/0148/001/DC	99109.00.00	JOHNSON & JOHNSON GMBH	DE
NasenDuo Nasenspray Kinder 0,5 mg/ml + 50 mg/ml Nasenspray, Lösung	DE/H/3870/001	90012.00.00	RATIOPHARM GMBH	DE

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XyloDuo-ratiopharm Nasenspray 1 mg/ml + 50 mg/ml Nasenspray, Lösung	DE/H/3870/002	90013.00.00	RATIOPHARM GMBH	DE
nasic neo für Kinder Xylometazolinhydrochlorid 0,5 mg/ml + Dexpanthenol 50 mg/ml, Nasenspray, Lösung Für Kinder zwischen 2 und 6 Jahren	not available	95193.00.00	CASELLA-MED GMBH & CO. KG	DE
nasic® für Kinder O.K. Xylometazolinhydrochlorid 0,05 % + Dexpanthenol 5 %, Nasenspray, Lösung Für Kinder zwischen 2 und 6 Jahren	not available	57724.00.00	CASELLA-MED GMBH & CO. KG	DE
Klaridex, næsespray, opløsning	NO/H/0275/001	60062	ORIFARM GENERICS A/S	DK
Klaridex, næsespray, opløsning	NO/H/0275/002	60063	ORIFARM GENERICS A/S	DK
Sudafed Xylospray DEX 1 mg/50 mg/ml ninasprei, lahus	LV/H/0148/002	961918	MCNEIL HEALTHCARE (IRELAND) LIMITED	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
Otrinazil, 1 mg/50 mg/ml ninasprei, lahus	PT/H/1800/001	967618	GLAXOSMITHKLINE DUNGARVAN LIMITED	EE
Sudafed Xylospray DEX 0,5 mg/50 mg/ml ninasprei, lahus	LV/H/0148/001	961818	MCNEIL HEALTHCARE (IRELAND) LIMITED	EE
Septanazal, 0,5 mg/50 mg/ml ninasprei, lahus	CZ/H/0170/001	822313	KRKA, D.D., NOVO MESTO	EE
Septanazal, 1 mg/50 mg/ml ninasprei, lahus	CZ/H/0170/002	822413	KRKA, D.D., NOVO MESTO	EE
Sinomist, 1 mg/50 mg/ml ninasprei, lahus	DE/H/3870/002	856614	WICK PHARMA ZWEIGNIEDERLASSUNG DER PROCTER & GAMBLE GMBH	EE
Frenasal Plus 1 mg/ml + 50 mg/ml solución para pulverización nasal	not available	83634	JOHNSON & JOHNSON S.A.	ES
Xylometazoline/Dexpanth enol Billev 1 mg/ml + 50 mg/ml nenäsumute, liuos	not available	36108	BILLEV FARMACIJA VZHOD D.O.O.	FI
XYLOMETAZOLINE+DEXPANTHENOL/GSK 1,0 mg/ml + 50,0 mg/ml, ρινικό εκνέφωμα, διάλυμα	PT/H/1800/001	3161301	GLAXOSMITHKLINE CONSUMER HEALTHCARE HELLAS SA	GR

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
MaxiRino Plus 0,5 mg/ml + 50 mg/ml sprej za nos, otopina	DE/H/3871/001	HR-H-205273753	PLIVA HRVATSKA D.O.O.	HR
MaxiRino Plus 1,0 mg/ml + 50 mg/ml sprej za nos, otopina	DE/H/3871/002	HR-H-013240400	PLIVA HRVATSKA D.O.O.	HR
nasic za djecu sprej za nos, otopina	not available	HR-H-772009823	CASELLA-MED GMBH & CO. KG	HR
nasic, sprej za nos, otopina	not available	HR-H-131882246	CASELLA-MED GMBH & CO. KG	HR
nasic 1 mg/ml + 50 mg/ml oldatos orrspray felnőtteknek és gyermekeknek	not available	OGYI-T-20508/02	CASELLA-MED GMBH & CO. KG	HU
nasic 1 mg/ml + 50 mg/ml oldatos orrspray felnőtteknek és gyermekeknek	not available	OGYI-T-20508/04	CASELLA-MED GMBH & CO. KG	HU
Otrivin Extra 1 mg/ml + 50 mg/ml adagoló oldatos orrspray	PT/H/1800/001	OGYI-T-23505/01	GLAXOSMITHKLINE-CONSUMER KFT.	HU
Septanazal 0,5 mg/ml + 50 mg/ml oldatos orrspray gyermekeknek	CZ/H/0170/001	OGYI-T-22535/01	KRKA, D.D., NOVO MESTO	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
Septanazal 1 mg/ml + 50 mg/ml oldatos orrspray felnőtteknek	CZ/H/0170/002	OGYI-T-22535/02	KRKA, D.D., NOVO MESTO	HU
Teva-Nazal 1 mg/ml + 50 mg/ml oldatos orrspray	DE/H/3870/002	OGYI-T-22725/02	TEVA GYÓGYSZERGYÁR ZRT	HU
Teva-Nazal 0,5 mg/ml + 50 mg/ml oldatos orrspray	DE/H/3870/001	OGYI-T-22725/01	TEVA GYÓGYSZERGYÁR ZRT	HU
Teva-Nazal 1 mg/ml + 50 mg/ml oldatos orrspray	DE/H/3870/002	OGYI-T-22725/04	TEVA GYÓGYSZERGYÁR ZRT	HU
nasic 0,5 mg/ml + 50 mg/ml oldatos orrspray kisgyermekeknek	not available	OGYI-T-20508/01	CASELLA-MED GMBH & CO. KG	HU
nasic 0,5 mg/ml + 50 mg/ml oldatos orrspray kisgyermekeknek	not available	OGYI-T-20508/03	CASELLA-MED GMBH & CO. KG	HU
Septanazal for children 0.5 mg/50 mg in 1 ml nasal spray, solution	CZ/H/0643/001	PA1347/058/001	KRKA, D.D., NOVO MESTO	IE
Septanazal 1 mg/50 mg in 1 ml nasal spray, solution	CZ/H/0643/002	PA1347/058/002	KRKA, D.D., NOVO MESTO	IE

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
Xilometazolina/Dexpanthenolo GSK CH 1,0 mg/ml + 50,0 mg/ml, spray nasale, soluzione	PT/H/1800/001	046643019	GLAXOSMITHKLINE CONSUMER HEALTHCARE S.P.A.	IT
Olydex 1 mg/50 mg/ml nosies purškals (tirpalas)	LV/H/0148/002/DC	LT/1/19/4377/001	MCNEIL HEALTHCARE (IRELAND) LIMITED	LT
Otrinazil 1 mg/50 mg/ml nosies purškals (tirpalas)	PT/H/1800/001	LT/1/18/4233/001	GLAXOSMITHKLINE DUNGARVAN LIMITED	LT
Olydex 0,5 mg/50 mg/ml nosies purškals (tirpalas)	LV/H/0148/001/DC	LT/1/19/4376/001	MCNEIL HEALTHCARE (IRELAND) LIMITED	LT
Septanazal 1 mg/50 mg/ml nosies purškals (tirpalas), suaugusiesiems	CZ/H/0170/002	LT/1/13/3376/001	KRKA, D.D., NOVO MESTO	LT
Septanazal 0,5 mg/50 mg/ml nosies purškals (tirpalas), vaikams	CZ/H/0170/001	LT/1/13/3376/002	KRKA, D.D., NOVO MESTO	LT
Sinomist 1 mg/50 mg/ml nosies purškals (tirpalas)	DE/H/3870/002	LT/1/14/3634/002	WICK PHARMA ZWEIGNIEDERLASSUNG DER PROCTER & GAMBLE GMBH	LT
NasenDuo Nasenspray Kinder 0,5 mg/ml + 50 mg/ml Nasenspray, Lösung	DE/H/3870/001	2014120445	RATIOPHARM GMBH	LU

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XyloDuo-ratiopharm Nasenspray 1 mg/ml + 50 mg/ml Nasenspray, Lösung	DE/H/3870/002	2014120446	RATIOPHARM GMBH	LU
Olydex 1 mg/50 mg/ml deguna aerosols, šķīdums	LV/H/0148/002	18-0051	MCNEIL HEALTHCARE (IRELAND) LIMITED	LV
Otrinazil 1 mg/50 mg/ml deguna aerosols, šķīdums	PT/H/1800/001	18-0101	GLAXOSMITHKLINE DUNGARVAN LIMITED	LV
Olydex 0,5 mg/50 mg/ml deguna aerosols, šķīdums	LV/H/0148/001	18-0050	MCNEIL HEALTHCARE (IRELAND) LIMITED	LV
Septanazal 0,5 mg/50 mg/ml deguna aerosols, šķīdums bērniem	CZ/H/0170/001	13-0207	KRKA, D.D., NOVO MESTO	LV
Septanazal 1 mg/50 mg/ml deguna aerosols, šķīdums pieaugušajiem	CZ/H/0170/002	13-0208	KRKA, D.D., NOVO MESTO	LV
Sinomist 1 mg/50 mg/ml deguna aerosols, šķīdums	DE/H/3870/002	14-0223	WICK PHARMA ZWEIGNIEDERLASSUNG DER PROCTER & GAMBLE GMBH	LV
Xylodex 1 mg/ml / 50 mg/ml nesenspray, oppløsning	NO/H/0275/001	17-11866	ORIFARM GENERICS A/S	NO

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
Xylodex 0,5 mg/ml / 50 mg/ml nesespray, oppløsning	NO/H/0275/002	17-11867	ORIFARM GENERICS A/S	NO
Otrivin Regeneracja, (1 mg + 50 mg)/ml, aerozol do nosa, roztwór	PT/H/1800/001	25017	GLAXOSMITHKLINE CONSUMER HEALTHCARE SP. Z O.O.	PL
Sudafed Xylospray DEX, (1 mg + 50 mg)/ml, aerozol do nosa, roztwór	LV/H/0148/002	24739	MCNEIL HEALTHCARE (IRELAND) LIMITED	PL
Xylodex 0,05% regeneracja, (0,05 mg + 5,0 mg)/dawkę, aerozol do nosa, roztwór	not available	21115	WARSZAWSKIE ZAKLADY FARMACEUTYCZNE POLFA S.A.	PL
Xylodex 0,1% regeneracja, (0,1 mg + 5,0 mg)/dawkę, aerozol do nosa, roztwór	not available	21116	WARSZAWSKIE ZAKLADY FARMACEUTYCZNE POLFA S.A.	PL
Sudafed Xylospray DEX dla dzieci, (0,5 mg + 50 mg)/ml, aerozol do nosa, roztwór	LV/H/0148/001	24754	MCNEIL HEALTHCARE (IRELAND) LIMITED	PL
Septanazal dla dzieci, 0,5 mg+50 mg w 1 ml, aerozol do nosa, roztwór	CZ/H/0170/001	21545	KRKA, D.D., NOVO MESTO	PL
Septanazal dla dorosłych, 1 mg+50 mg w 1 ml, aerozol do nosa, roztwór	CZ/H/0170/002	21546	KRKA, D.D., NOVO MESTO	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
Vibrocil ActilongProtect 1,0 mg/ml + 50,0 mg/ml, solução para pulverização nasal	PT/H/1800/001	5752811	GLAXOSMITHKLINE CONSUMER HEALTHCARE, PRODUTOS PARA A SAÚDE E HIGIENE, LDA	PT
Nasex Duo 1 mg/ml + 50 mg/ml solução para pulverização nasal	LV/H/0148/002/DC	5738406	JOHNSON & JOHNSON LDA	PT
Septanazal para adultos 1 mg/ml + 50 mg/ml solução para pulverização nasal	CZ/H/0643/002	5689674	KRKA, D.D., NOVO MESTO	PT
Septanazal para crianças 0,5 mg/ml + 50 mg/ml solução para pulverização nasal	CZ/H/0643/001	5689708	KRKA, D.D., NOVO MESTO	PT
Vibrocil Actilong Plus 1,0 mg/ml + 50,0 mg/ml spray nazal, soluție	PT/H/1800/001	11039/2018/01	GLAXOSMITHKLINE CONSUMER HEALTHCARE S.R.L.	RO
NASIC 1 mg/ml + 50 mg/ml spray nazal, soluție	not available	9132/2016/01	CASELLA-MED GMBH & CO. KG	RO
Nasic 1 mg/ml + 50 mg/ml spray nazal, solutie	not available	9132/2016/02	CASELLA-MED GMBH & CO. KG	RO
Nasic pentru copii 0,5 mg/ml + 50 mg/ml spray nazal, solutie	not available	9133/2016/01	CASELLA-MED GMBH & CO. KG	RO

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Nasic pentru copii 0,5 mg/ml + 50 mg/ml spray nazal, solutie	not available	9133/2016/02	CASELLA-MED GMBH & CO. KG	RO
Septanazal 1 mg/50 mg/ml spray nazal, soluție	CZ/H/0170/001	10977/2018/01	KRKA, D.D., NOVO MESTO	RO
Septanazal pentru copii 0,5 mg/50 mg/ml spray nazal, soluție	CZ/H/0170/002	10978/2018/01	KRKA, D.D., NOVO MESTO	RO
Septanazal za odrasle 1 mg/50 mg v 1 ml pršilo za nos, raztopina	CZ/H/0170/002	H/13/01403/001	KRKA, D.D., NOVO MESTO	SI
Septanazal za otroke 0,5 mg/50 mg v 1 ml pršilo za nos, raztopina	CZ/H/0170/001	H/13/01403/002	KRKA, D.D., NOVO MESTO	SI
OLYNTH PLUS 1 mg/50 mg/ml nosová roztoková aerodisperzia	LV/H/0148/002/DC	69/0018/18-S	MCNEIL HEALTHCARE (IRELAND) LIMITED	SK
nasic pre deti nosová roztoková aerodisperzia xylometazolíniumchlorid 0,05 %, dexpanthenol 5 %	not available	69/0130/13-S	CASELLA-MED GMBH & CO. KG	SK
Otrivin Plus 1 mg/ml + 50 mg/ml	PT/H/1800/001	69/0266/18-S	GLAXOSMITHKLINE CONSUMER HEALTHCARE CZECH REPUBLIC S.R.O.	SK

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OLYNTH PLUS 0,5 mg/50 mg/ml nosová roztoková aerodisperzia	LV/H/0148/001/DC	69/0017/18-S	MCNEIL HEALTHCARE (IRELAND) LIMITED	SK
Septanazal sprej pre dospelých 1 mg/ml + 50 mg/ml nosovej roztokovej aerodisperzie	CZ/H/0170/001	69/0369/13-S	KRKA, D.D., NOVO MESTO	SK
Septanazal sprej pre deti 0,5 mg/ml + 50 mg/ml nosovej roztokovej aerodisperzie	CZ/H/0170/002	69/0370/13-S	KRKA, D.D., NOVO MESTO	SK
nasic nosová roztoková aerodisperzia xylometazolíniumchlorid 0,1 %, dexpanthenol 5 %	not available	69/0129/13-S	CASELLA-MED GMBH & CO. KG	SK
NASAL DUO ACTIVE 0,5/50 mg/ml nosová roztoková aerodisperzia	DE/H/3870/001	69/0300/14-S	TEVA PHARMACEUTICALS SLOVAKIA S.R.O	SK
NASAL DUO ACTIVE 1,0/50 mg/ml nosová roztoková aerodisperzia	DE/H/3870/002	69/0301/14-S	TEVA PHARMACEUTICALS SLOVAKIA S.R.O	SK