27 February 2019
EMA/214710/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: paracetamol / pseudoephedrine

Procedure no.: PSUSA/00002307/201806

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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
Saniduo febbre e naso chiuso 500 mg + 60 mg compresse effervescenti	not available	036517011	BAYER SPA	IT
Theraflu Erkältungsgetränk 500 mg/30 mg Pulver zur Herstellung einer Lösung zum Einnehmen	DE/H/3727/001	135650	GSK-GEBRO CONSUMER HEALTHCARE GMBH	AT
Comtrex Cold Day Powder, κόνις για πόσιμο διάλυμα. Παρακεταμόλη 500 mg, υδροχλωρική ψευδοεφεδρίνη 30 mg	DE/H/3727/001	303700102	GLAXOSMITHKLINE CONSUMER HEALTHCARE HELLAS SA	GR
Comtrex Cold Day Powder, κόνις για πόσιμο διάλυμα. Παρακεταμόλη 500 mg, υδροχλωρική ψευδοεφεδρίνη 30 mg	DE/H/3727/001	303700103	GLAXOSMITHKLINE CONSUMER HEALTHCARE HELLAS SA	GR
Comtrex Cold Day Powder, κόνις για πόσιμο διάλυμα. Παρακεταμόλη 500 mg, υδροχλωρική ψευδοεφεδρίνη 30 mg	DE/H/3727/001	303700105	GLAXOSMITHKLINE CONSUMER HEALTHCARE HELLAS SA	GR
Comtrex Cold Day Powder, κόνις για πόσιμο διάλυμα. Παρακεταμόλη 500 mg, υδροχλωρική ψευδοεφεδρίνη 30 mg	DE/H/3727/001	303700101	GLAXOSMITHKLINE CONSUMER HEALTHCARE HELLAS SA	GR
Comtrex Cold Day Powder, κόνις για πόσιμο διάλυμα. Παρακεταμόλη 500 mg, υδροχλωρική ψευδοεφεδρίνη 30 mg	DE/H/3727/001	303700104	GLAXOSMITHKLINE CONSUMER HEALTHCARE HELLAS SA	GR
Theraflu Erkältung	DE/H/3727/001/DC	88876.00.00	GLAXOSMITHKLINE	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
Heißgetränk 500 mg / 30 mg Pulver zur Herstellung einer Lösung zum Einnehmen Paracetamol 500 mg, Pseudoephedrinhydrochlorid 30 mg			CONSUMER HEALTHCARE GMBH & CO. KG	
Theraflu Przeziębienie, proszek do sporządzania roztworu doustnego Paracetamol 500 mg, chlorowodorek pseudoefedryny 30 mg	DE/H/3727/001/DC	21776	GLAXOSMITHKLINE CONSUMER HEALTHCARE SP. Z O.O.	PL
Neo Citran Cold and Sinus por belsőleges oldathoz	DE/H/3727/001	OGYI-T-22589/01	GLAXOSMITHKLINE-CONSUMER KFT.	HU
Neo Citran Cold and Sinus por belsőleges oldathoz	DE/H/3727/001	OGYI-T-22589/04	GLAXOSMITHKLINE-CONSUMER KFT.	HU
Neo Citran Cold and Sinus por belsőleges oldathoz	DE/H/3727/001	OGYI-T-22589/03	GLAXOSMITHKLINE-CONSUMER KFT.	HU
Neo Citran Cold and Sinus por belsőleges oldathoz	DE/H/3727/001	OGYI-T-22589/05	GLAXOSMITHKLINE-CONSUMER KFT.	HU
Neo Citran Cold and Sinus por belsőleges oldathoz	DE/H/3727/001	OGYI-T-22589/02	GLAXOSMITHKLINE-CONSUMER KFT.	HU
Termadec polvere per soluzione orale Paracetamolo 500 mg, pseudoefedrina cloridrato 30 mg	DE/H/3727/001/DC	042344022	IODOSAN S.P.A.	IT
Termadec polvere per	DE/H/3727/001/DC	042344010	IODOSAN 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
soluzione orale Paracetamolo 500 mg, pseudoefedrina cloridrato 30 mg				
Termadec polvere per soluzione orale Paracetamolo 500 mg, pseudoefedrina cloridrato 30 mg	DE/H/3727/001/DC	042344059	IODOSAN S.P.A.	IT
Termadec polvere per soluzione orale Paracetamolo 500 mg, pseudoefedrina cloridrato 30 mg	DE/H/3727/001/DC	042344046	IODOSAN S.P.A.	IT
Termadec polvere per soluzione orale Paracetamolo 500 mg, pseudoefedrina cloridrato 30 mg	DE/H/3727/001/DC	042344034	IODOSAN S.P.A.	IT
Theraflu SN, suukaudse lahuse pulber Paratsetamool 500 mg, pseudoefedriinvesinikkloriid 30 mg	DE/H/3727/001	842414	GLAXOSMITHKLINE CONSUMER HEALTHCARE (UK) TRADING LIMITED	EE
Theraflu SN pulveris iekšķīgi lietojama šķīduma pagatavošanai	DE/H/3727/001	14-0136	GLAXOSMITHKLINE CONSUMER HEALTHCARE (UK) TRADING LIMITED	LV
Theraflu SN 500 mg/30 mg milteliai geriamajam tirpalui	DE/H/3727/001/DC	LT/1/14/3541/001	GLAXOSMITHKLINE CONSUMER HEALTHCARE (UK) TRADING LIMITED	LT
Theraflu SN 500 mg/30 mg milteliai geriamajam tirpalui	DE/H/3727/001/DC	LT/1/14/3541/006	GLAXOSMITHKLINE CONSUMER HEALTHCARE (UK) TRADING LIMITED	LT
Theraflu SN 500 mg/30	DE/H/3727/001/DC	LT/1/14/3541/004	GLAXOSMITHKLINE	LT

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
mg milteliai geriamajam tirpalui			CONSUMER HEALTHCARE (UK) TRADING LIMITED	
Theraflu SN 500 mg/30 mg milteliai geriamajam tirpalui	DE/H/3727/001/DC	LT/1/14/3541/002	GLAXOSMITHKLINE CONSUMER HEALTHCARE (UK) TRADING LIMITED	LT
Theraflu SN 500 mg/30 mg milteliai geriamajam tirpalui	DE/H/3727/001/DC	LT/1/14/3541/003	GLAXOSMITHKLINE CONSUMER HEALTHCARE (UK) TRADING LIMITED	LT
LISOFLU	not available	036307027	SANOFI SPA	IT
LISOFLU	not available	036307015	SANOFI SPA	IT
Boots Decongestant with Pain Relief Tablets	not available	PL 00014/0594	THE BOOTS COMPANY PLC	UK
NIOCITRAN, 500mg/60mg Pulver zur Herstellung einer Lösung zum Einnehmen	not available	BE172751	GLAXOSMITHKLINE CONSUMER HEALTHCARE S.A/N.V.	BE
NIOCITRAN 500mg/60mg poeder voor drank.	not available	BE172751	GLAXOSMITHKLINE CONSUMER HEALTHCARE S.A/N.V.	BE
NIOCITRAN 500mg/60mg poudre pour solution buvable	not available	BE172751	GLAXOSMITHKLINE CONSUMER HEALTHCARE S.A/N.V.	BE
RHUMAGRIP, comprimé	not available	NL 22530-3400934437908	COOPERATION PHARMACEUTIQUE FRANCAISE	FR
Theraflu Erkältungsgetränk 500 mg/30 mg Pulver zur Herstellung einer Lösung zum Einnehmen	DE/H/3727/001	135650	GSK-GEBRO CONSUMER HEALTHCARE GMBH	AT
Comtrex Cold Day Powder, κόνις για πόσιμο διάλυμα. Παρακεταμόλη 500 mg, υδροχλωρική	DE/H/3727/001	303700102	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
ψευδοεφεδρίνη 30 mg				
Comtrex Cold Day Powder, κόνις για πόσιμο διάλυμα. Παρακεταμόλη 500 mg, υδροχλωρική ψευδοεφεδρίνη 30 mg	DE/H/3727/001	303700103	GLAXOSMITHKLINE CONSUMER HEALTHCARE HELLAS SA	GR
Comtrex Cold Day Powder, κόνις για πόσιμο διάλυμα. Παρακεταμόλη 500 mg, υδροχλωρική ψευδοεφεδρίνη 30 mg	DE/H/3727/001	303700105	GLAXOSMITHKLINE CONSUMER HEALTHCARE HELLAS SA	GR
Comtrex Cold Day Powder, κόνις για πόσιμο διάλυμα. Παρακεταμόλη 500 mg, υδροχλωρική ψευδοεφεδρίνη 30 mg	DE/H/3727/001	303700101	GLAXOSMITHKLINE CONSUMER HEALTHCARE HELLAS SA	GR
Comtrex Cold Day Powder, κόνις για πόσιμο διάλυμα. Παρακεταμόλη 500 mg, υδροχλωρική ψευδοεφεδρίνη 30 mg	DE/H/3727/001	303700104	GLAXOSMITHKLINE CONSUMER HEALTHCARE HELLAS SA	GR
Theraflu Erkältung Heißgetränk 500 mg / 30 mg Pulver zur Herstellung einer Lösung zum Einnehmen Paracetamol 500 mg, Pseudoephedrinhydrochlorid 30 mg	DE/H/3727/001/DC	88876.00.00	GLAXOSMITHKLINE CONSUMER HEALTHCARE GMBH & CO. KG	DE
Theraflu Przeziębienie, proszek do sporządzania roztworu doustnego Paracetamol 500 mg, chlorowodorek	DE/H/3727/001/DC	21776	GLAXOSMITHKLINE CONSUMER HEALTHCARE SP. Z O.O.	PL

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pseudoefedryny 30 mg				
Neo Citran Cold and Sinus por belsőleges oldathoz	DE/H/3727/001	OGYI-T-22589/01	GLAXOSMITHKLINE-CONSUMER KFT.	HU
Neo Citran Cold and Sinus por belsőleges oldathoz	DE/H/3727/001	OGYI-T-22589/04	GLAXOSMITHKLINE-CONSUMER KFT.	HU
Neo Citran Cold and Sinus por belsőleges oldathoz	DE/H/3727/001	OGYI-T-22589/03	GLAXOSMITHKLINE-CONSUMER KFT.	HU
Neo Citran Cold and Sinus por belsőleges oldathoz	DE/H/3727/001	OGYI-T-22589/05	GLAXOSMITHKLINE-CONSUMER KFT.	HU
Neo Citran Cold and Sinus por belsőleges oldathoz	DE/H/3727/001	OGYI-T-22589/02	GLAXOSMITHKLINE-CONSUMER KFT.	HU
Termadec polvere per soluzione orale Paracetamolo 500 mg, pseudoefedrina cloridrato 30 mg	DE/H/3727/001/DC	042344022	IODOSAN S.P.A.	IT
Termadec polvere per soluzione orale Paracetamolo 500 mg, pseudoefedrina cloridrato 30 mg	DE/H/3727/001/DC	042344010	IODOSAN S.P.A.	IT
Termadec polvere per soluzione orale Paracetamolo 500 mg, pseudoefedrina cloridrato 30 mg	DE/H/3727/001/DC	042344059	IODOSAN S.P.A.	IT
Termadec polvere per soluzione orale Paracetamolo 500 mg,	DE/H/3727/001/DC	042344046	IODOSAN 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
pseudoefedrina cloridrato 30 mg				
Termadec polvere per soluzione orale Paracetamolo 500 mg, pseudoefedrina cloridrato 30 mg	DE/H/3727/001/DC	042344034	IODOSAN S.P.A.	IT
Theraflu SN, suukaudse lahuse pulber Paratsetamool 500 mg, pseudoefedriinvesinikkloriid 30 mg	DE/H/3727/001	842414	GLAXOSMITHKLINE CONSUMER HEALTHCARE (UK) TRADING LIMITED	EE
Theraflu SN pulveris iekšķīgi lietojama šķīduma pagatavošanai	DE/H/3727/001	14-0136	GLAXOSMITHKLINE CONSUMER HEALTHCARE (UK) TRADING LIMITED	LV
Theraflu SN 500 mg/30 mg milteliai geriamajam tirpalui	DE/H/3727/001/DC	LT/1/14/3541/001	GLAXOSMITHKLINE CONSUMER HEALTHCARE (UK) TRADING LIMITED	LT
Theraflu SN 500 mg/30 mg milteliai geriamajam tirpalui	DE/H/3727/001/DC	LT/1/14/3541/006	GLAXOSMITHKLINE CONSUMER HEALTHCARE (UK) TRADING LIMITED	LT
Theraflu SN 500 mg/30 mg milteliai geriamajam tirpalui	DE/H/3727/001/DC	LT/1/14/3541/004	GLAXOSMITHKLINE CONSUMER HEALTHCARE (UK) TRADING LIMITED	LT
Theraflu SN 500 mg/30 mg milteliai geriamajam tirpalui	DE/H/3727/001/DC	LT/1/14/3541/002	GLAXOSMITHKLINE CONSUMER HEALTHCARE (UK) TRADING LIMITED	LT
Theraflu SN 500 mg/30 mg milteliai geriamajam tirpalui	DE/H/3727/001/DC	LT/1/14/3541/003	GLAXOSMITHKLINE CONSUMER HEALTHCARE (UK) TRADING LIMITED	LT
Termalgin Resfriado 500 mg/30 mg polvo para solución oral	DE/H/3727/001/DC	78433	GLAXOSMITHKLINE CONSUMER HEALTHCARE, S.A.	ES
Panadol Cold and Flu	UK/H/0587/001	MA932/00601	GLAXOSMITHKLINE	MT

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
500mg / 30mg Film Coated Tablets			CONSUMER HEALTHCARE (UK) TRADING LIMITED	
Panadol Cold & Flu 500 mg / 30 mg Επικαλυμμένα με λεπτό υμένιο δισκία	UK/H/0587/001	22174	GLAXOSMITHKLINE CONSUMER HEALTHCARE (UK) TRADING LIMITED	CY
Panadol Cold & Flu 500 mg / 30 mg Επικαλυμμένα με λεπτό υμένιο δισκία	UK/H/0587/001	2596701	GLAXOSMITHKLINE CONSUMER HEALTHCARE HELLAS SA	GR
Panadol Fever and Congestion Film-coated Tablets Paracetamol 500mg Pseudoephedrine Hydrochloride 30mg	UK/H/0587/001	PA 0678/094/001	GLAXOSMITHKLINE CONSUMER HEALTHCARE (IRELAND) LTD	IE
Panadol Cold and Flu 500mg / 30mg Film Coated Tablets	UK/H/0587/001	PL 44673/0091	GLAXOSMITHKLINE CONSUMER HEALTHCARE (UK) TRADING LIMITED	UK
Solpa-Sinus Film-coated Tablets Paracetamol 500mg Pseudoephedrine Hydrochloride 30mg	UK/H/0586/001	PA 1186/012/001	CHEFARO IRELAND LIMITED	IE
Panadol Cold & Sinus 500mg / 30mg Film-Coated Tablets	UK/H/0586/001	PL 02855/0076	OMEGA PHARMA LTD	UK
Theraflu Przeziębienie MAX, 500 mg + 30 mg, tabletki powlekane	not available	17306	GLAXOSMITHKLINE CONSUMER HEALTHCARE SP. Z O.O.	PL
Day Nurse Sinus and Pain Relief, 500 mg/30 mg film-coated tablet (tablet)	not available	PL 44673/0073	GLAXOSMITHKLINE CONSUMER HEALTHCARE (UK) TRADING LIMITED	UK
NIOCITRAN 500mg/60mg poudre	not available	2003057300	GLAXOSMITHKLINE CONSUMER HEALTHCARE	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
pour solution buvable			S.A/N.V.	
ACTIGRIP GIORNO & NOTTE compresse	not available	035400023	JOHNSON & JOHNSON S.P.A.	IT
Benylin Day and Night Tablets	not available	PL 15513/0108	MCNEIL PRODUCTS LIMITED	UK
Sudafed Decongestant & Pain Tablets	not available	PL 15513/0108	MCNEIL PRODUCTS LIMITED	UK
NON-DROWSY SINUTAB	not available	PL 15513/0027	MCNEIL PRODUCTS LIMITED	UK
SINUTAB II 500 mg + 30 mg comprimidos	not available	9754119	JOHNSON & JOHNSON LDA	PT
NON-DROWSY SINUTAB	not available	PL 15513/0027	MCNEIL PRODUCTS LIMITED	UK
NON-DROWSY SINUTAB	not available	PL 15513/0027	MCNEIL PRODUCTS LIMITED	UK
NON-DROWSY SINUTAB	not available	PL 15513/0027	MCNEIL PRODUCTS LIMITED	UK
Non-Drowsy Sudaplus Tablets	not available	PA 330/39/1	JOHNSON & JOHNSON (IRELAND) LTD.	IE
Non-Drowsy Sudaplus Tablets	not available	PA 330/39/1	JOHNSON & JOHNSON (IRELAND) LTD.	IE
Non-Drowsy Sudaplus Tablets	not available	PA 330/39/1	JOHNSON & JOHNSON (IRELAND) LTD.	IE
Non-Drowsy Sudaplus Tablets	not available	PA 330/39/1	JOHNSON & JOHNSON (IRELAND) LTD.	IE
Non-drowsy Sinutab Tablets	not available	PA 330/38/1	JOHNSON & JOHNSON (IRELAND) LTD.	IE
Non-drowsy Sinutab Tablets	not available	PA 330/38/1	JOHNSON & JOHNSON (IRELAND) LTD.	IE
Non-drowsy Sinutab Tablets	not available	PA 330/38/1	JOHNSON & JOHNSON (IRELAND) LTD.	IE
Non-drowsy Sinutab Tablets	not available	PA 330/38/1	JOHNSON & JOHNSON (IRELAND) LTD.	IE