



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 February 2024
EMA/145166/2024
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): paracetamol / pseudoephedrine

Procedure No. PSUSA/00002307/202306



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
Therafixx-CapitaNasal 500 mg/60 mg poeder voor drank.	not available	BE172751	HALEON BELGIUM	BE
THERAFIXX-CAPITANASAL 500 mg/60 mg poudre pour solution buvable.	not available	BE172751	HALEON BELGIUM	BE
THERAFIXX-CAPITANASAL, 500 mg/60 mg Pulver zur Herstellung einer Lösung zum Einnehmen	not available	BE172751	HALEON BELGIUM	BE
Panadol Cold & Flu 500 mg / 30 mg Επικαλυμμένα με λεπτό υμένιο δισκία	IE/H/0835/001	22174	GLAXOSMITHKLINE CONSUMER HEALTHCARE HELLAS SINGLE MEMBER SOCIETE ANONYME	CY
Theraflu Erkältung Heißgetränk 500 mg / 30 mg Pulver zur Herstellung einer Lösung zum Einnehmen	DE/H/3727/001	88876.00.00	GLAXOSMITHKLINE CONSUMER HEALTHCARE GMBH & CO. KG	DE
Theraflu SN, 500 mg/30 mg, suukaudse lahuse pulber	DE/H/3727/001	842414	GLAXOSMITHKLINE DUNGARVAN LIMITED	EE
Termalgin Resfriado 500 mg / 30 mg polvo para solución oral	DE/H/3727/001	78433	HALEON SPAIN, S.A.	ES
DOLIRHUME PARACETAMOL ET PSEUDOEPHEDRINE 500 mg/30 mg, comprimé	not available	34009 341 255 9 1	OPELLA HEALTHCARE FRANCE SAS	FR
RHUMAGRIP, comprimé	not available	34009 344 379 0 8	COOPERATION PHARMACEUTIQUE FRANCAISE	FR
COMTrex COLD DAY POWDER	DE/H/3727/001 /DC	303700102	GLAXOSMITHKLINE CONSUMER HEALTHCARE HELLAS SINGLE MEMBER SOCIETE ANONYME	GR
COMTrex COLD DAY POWDER	DE/H/3727/001 /DC	303700103	GLAXOSMITHKLINE CONSUMER HEALTHCARE HELLAS SINGLE MEMBER SOCIETE ANONYME	GR
Comtrex Cold Day Powder	DE/H/3727/001	303700105	GLAXOSMITHKLINE CONSUMER HEALTHCARE HELLAS SINGLE MEMBER SOCIETE ANONYME	GR

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Comtrex Cold Day Powder	DE/H/3727/001	303700101	GLAXOSMITHKLINE CONSUMER HEALTHCARE HELLAS SINGLE MEMBER SOCIETE ANONYME	GR
Comtrex Cold Day Powder	DE/H/3727/001	303700104	GLAXOSMITHKLINE CONSUMER HEALTHCARE HELLAS SINGLE MEMBER SOCIETE ANONYME	GR
Panadol Cold& Flu 500 mg / 30 mg Επικαλυμμένα με λεπτό υμένιο δισκία	IE/H/0835/001/MR	2596701	GLAXOSMITHKLINE CONSUMER HEALTHCARE HELLAS SINGLE MEMBER SOCIETE ANONYME	GR
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
Non-drowsy Sinutab Tablets Paracetamol 500mg Pseudoephedrine hydrochloride 30mg	not available	PA 330/38/1	JOHNSON & JOHNSON (IRELAND) LTD.	IE
Non-drowsy Sinutab Tablets Paracetamol 500mg Pseudoephedrine hydrochloride 30mg	not available	PA 330/38/1	JOHNSON & JOHNSON (IRELAND) LTD.	IE
Non-drowsy Sinutab Tablets Paracetamol 500mg Pseudoephedrine hydrochloride 30mg	not available	PA 330/38/1	JOHNSON & JOHNSON (IRELAND) LTD.	IE
Non-drowsy Sinutab Tablets Paracetamol 500mg Pseudoephedrine hydrochloride 30mg	not available	PA 330/38/1	JOHNSON & JOHNSON (IRELAND) LTD.	IE

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Non-Drowsy Sudaplus Tablets Paracetamol 500mg Pseudoephedrine hydrochloride 30mg	not available	PA 330/39/1	JOHNSON & JOHNSON (IRELAND) LTD.	IE
Non-Drowsy Sudaplus Tablets Paracetamol 500mg Pseudoephedrine hydrochloride 30mg	not available	PA 330/39/1	JOHNSON & JOHNSON (IRELAND) LTD.	IE
Non-Drowsy Sudaplus Tablets Paracetamol 500mg Pseudoephedrine hydrochloride 30mg	not available	PA 330/39/1	JOHNSON & JOHNSON (IRELAND) LTD.	IE
Non-Drowsy Sudaplus Tablets Paracetamol 500mg Pseudoephedrine hydrochloride 30mg	not available	PA 330/39/1	JOHNSON & JOHNSON (IRELAND) LTD.	IE
Panadol Fever and Congestion 500mg/30mg Film-coated Tablets	IE/H/0835/001	PA 0678/094/001	HALEON IRELAND LIMITED	IE
Solpa-Sinus Film-coated Tablets Paracetamol 500mg Pseudoephedrine Hydrochloride 30mg	IE/H/900/001	PA 1186/012/001	CHEFARO IRELAND DAC	IE
Ilmodec febbre e naso chiuso 500 mg + 60 mg compresse effervescenti	not available	036517011	FARMITALIA S.R.L.	IT
Theraflu SN 500 mg/30 mg milteliai geriamajam tirpalui	DE/H/3727/001	LT/1/14/3541/001	GLAXOSMITHKLINE DUNGARVAN LIMITED	LT
Theraflu SN 500 mg/30 mg milteliai geriamajam tirpalui	DE/H/3727/001	LT/1/14/3541/006	GLAXOSMITHKLINE DUNGARVAN LIMITED	LT
Theraflu SN 500 mg/30 mg milteliai geriamajam tirpalui	DE/H/3727/001	LT/1/14/3541/004	GLAXOSMITHKLINE DUNGARVAN LIMITED	LT
Theraflu SN 500 mg/30 mg milteliai geriamajam tirpalui	DE/H/3727/001	LT/1/14/3541/002	GLAXOSMITHKLINE DUNGARVAN LIMITED	LT
Theraflu SN 500 mg/30 mg milteliai geriamajam tirpalui	DE/H/3727/001	LT/1/14/3541/003	GLAXOSMITHKLINE DUNGARVAN LIMITED	LT

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Theraflu SN 500 mg/30 mg pulveris iekšķīgi lietojama šķīduma pagatavošanai	DE/H/3727/001	14-0136	GLAXOSMITHKLINE DUNGARVAN LIMITED	LV
Panadol Cold and Flu 500mg / 30mg Film Coated Tablets	IE/H/0835/001	MA1177/00701	GLAXOSMITHKLINE CONSUMER HEALTHCARE HELLAS SINGLE MEMBER SOCIETE ANONYME	MT
SINUTAB II 500 mg + 30 mg comprimidos	not available	9754119	JOHNSON & JOHNSON, LDA.	PT
Coldact Sinus 500 mg/30 mg comprimate filmate	not available	12888/2019/01	TERAPIA S.A.	RO
Coldact Sinus 500 mg/30 mg comprimate filmate	not available	12888/2019/02	TERAPIA S.A.	RO
Prosinus 500 mg/30 mg comprimate filmate	not available	11792/2019/01	FITERMAN PHARMA S.R.L.	RO
Prosinus 500 mg/30 mg comprimate filmate	not available	11792/2019/02	FITERMAN PHARMA S.R.L.	RO
Sinufen 500 mg/30 mg comprimate filmate	not available	13425/2020/01	LAROPHARM SRL	RO
Sinufen 500 mg/30 mg comprimate filmate	not available	13425/2020/02	LAROPHARM SRL	RO
Boots Decongestant with Pain Relief Tablets	not available	PL 00014/0594	THE BOOTS COMPANY PLC	XI
Day Nurse Sinus and Pain Relief, 500 mg/30 mg film-coated tablet (tablet)	not available	PL 44673/0073	HALEON UK TRADING LIMITED	XI
NON-DROWSY SINUTAB	not available	PL 15513/0027	MCNEIL PRODUCTS LIMITED (HIGH WYCOMBE)	XI
NON-DROWSY SINUTAB	not available	PL 15513/0027	MCNEIL PRODUCTS LIMITED (HIGH WYCOMBE)	XI
NON-DROWSY SINUTAB	not available	PL 15513/0027	MCNEIL PRODUCTS LIMITED (HIGH WYCOMBE)	XI
NON-DROWSY SINUTAB	not available	PL 15513/0027	MCNEIL PRODUCTS LIMITED (HIGH WYCOMBE)	XI
Panadol Cold & Sinus 500mg / 30mg Film-Coated Tablets	IE/H/900/001	PL 02855/0076	OMEGA PHARMA LTD	XI

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Panadol Cold and Flu 500mg / 30mg Film Coated Tablets	IE/H/0835/001	PL 15545/0011	GLAXOSMITHKLINE DUNGARVAN LIMITED	XI