



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

27 February 2019  
EMA/223046/2019  
Human Medicines Evaluation Division

## List of nationally authorised medicinal products

Active substance: pseudoephedrine, acetylsalicylic acid / pseudoephedrine

Procedure no.: PSUSA/00010667/201806



<b>Product Name (in authorisation country)</b>	<b>MRP/DCP Authorisation number</b>	<b>National Authorisation Number</b>	<b>MAH of product in the member state</b>	<b>Member State where product is authorised</b>
Aspirin Complex	not available	78359.00.00	BAYER VITAL GMBH	DE
Aspirin Complex	not available	78358.00.00	BAYER VITAL GMBH	DE
Aspirin Complex 500 mg / 30 mg granulátum belsőleges szuszpenzióhoz	DE/H/2228/001	OGYI-T-20613/02	BAYER HUNGARIA KFT	HU
Aspirin Complex 500 mg / 30 mg granulátum belsőleges szuszpenzióhoz	DE/H/2228/001	OGYI-T-20613/01	BAYER HUNGARIA KFT	HU
ASPIRIN COMPLEX 500 mg + 30 mg granule za oralnu suspenziju	not available	UP/I-530-09/12-02/536	BAYER DOO	HR
Aspirin Complex 500 mg/30 mg - Granulat zur Herstellung einer Suspension zum Einnehmen	DE/H/2228/001	1-24837	BAYER AUSTRIA GMBH	AT
ASPIRIN COMPLEX 500 mg/30 mg granulát na perorálnu suspenziu	DE/H/2228/001	07/0249/08-S	BAYER SPOL SRO	SK
Aspirin Complex 500 mg/30 mg zrnca za peroralno suspenzijo	DE/H/2228/001	H/08/00221/002	BAYER D.O.O	SI
Aspirin Complex 500 mg/30 mg zrnca za peroralno suspenzijo	DE/H/2228/001	H/08/00221/001	BAYER D.O.O	SI
Aspirin Complex Forró Ital 500 mg/ 30 mg granulátum belsőleges szuszpenzióhoz	DE/H/3635/001	OGYI-T-20613/03	BAYER HUNGARIA KFT	HU
Aspirin Complex Forró Ital 500 mg/ 30 mg granulátum belsőleges szuszpenzióhoz	DE/H/3635/001	OGYI-T-20613/04	BAYER HUNGARIA KFT	HU

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ASPIRIN COMPLEX HEISSGETRÄNK 500 mg / 30 mg Granulat	not available	78357.00.00	BAYER VITAL GMBH	DE
ASPIRIN COMPLEX HEISSGETRÄNK 500 mg / 30 mg Granulat	DE/H/3635/001	87846.00.00	BAYER VITAL GMBH	DE
Aspirin Complex Heißgetränk 500 mg / 30 mg Granulat zur Herstellung einer Suspension zum Einnehmen	DE/H/3635/001	135243	BAYER AUSTRIA GMBH	AT
ASPIRIN COMPLEX Horúci nápoj 500 mg/30 mg granulát na perorálnu suspenziu	DE/H/3635/001	07/0444/13-S	BAYER SPOL SRO	SK
ASPIRIN COMPLEX HOT DRINK 500 mg/30 mg granule pentru suspensie orală	DE/H/3635/001	5914/2013/01	BAYER SRL	RO
ASPIRIN COMPLEX HOT DRINK 500 mg/30 mg granule pentru suspensie orală	DE/H/3635/001	5914/2013/02	BAYER SRL	RO
Aspirin Complex Hot, 500 mg + 30 mg, granulát do sporządzania zawiesiny doustnej	DE/H/3635/001	21635	BAYER SP.Z.O.O	PL
ASPIRIN COMPLEX ZATOKI, 500 mg + 30 mg, granulát do sporządzania zawiesiny doustnej	DE/H/2228/001	15078	BAYER SP.Z.O.O	PL

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ASPIRIN COMPLEX, granule pentru suspensie orală	not available	7848/2006/02	BAYER SRL	RO
ASPIRIN COMPLEX, granule pentru suspensie orală	not available	7848/2006/01	BAYER SRL	RO
Aspirin Sinucomplex 500 mg / 30 mg Granulat zur Herstellung einer Suspension zum Einnehmen	not available	78356.00.00	BAYER VITAL GMBH	DE
ASPIRIN® COMPLEX 500 mg / 30 mg Granulat zur Herstellung einer Suspension zum Einnehmen	DE/H/2228/001	54618.00.00	BAYER VITAL GMBH	DE
Boots Pharmaceuticals Decongestant 60mg Tablets	not available	PA 4/64/1	THE BOOTS COMPANY PLC	IE
Decongestant Tablets	not available	00014/0375	THE BOOTS COMPANY PLC	UK
NON-DROWSY SUDAFED CHILDREN'S SYRUP	not available	PL 15513/0023	MCNEIL PRODUCTS LIMITED	UK
Non-Drowsy SUDAFED Decongestant 30mg/5ml Syrup	not available	PA 823/9/1	MCNEIL HEALTHCARE (IRELAND) LIMITED	IE
Non-Drowsy Sudafed Decongestant 60 mg Film-Coated Tablets	not available	PA 330/57/2	JOHNSON & JOHNSON (IRELAND) LTD.	IE
Non-Drowsy Sudafed Decongestant 60 mg Film-Coated Tablets	not available	PA 330/57/2	JOHNSON & JOHNSON (IRELAND) LTD.	IE
Non-Drowsy Sudafed Decongestant 60 mg Film-Coated Tablets	not available	PA 330/57/2	JOHNSON & JOHNSON (IRELAND) LTD.	IE

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Sudafed Decongestant Liquid	not available	PL 15513/0023	MCNEIL PRODUCTS LIMITED	UK
Sudafed Decongestant Tablets	not available	PL 15513/0024	MCNEIL PRODUCTS LIMITED	UK
SUDAFED Syrup	not available	19791	GLAXO GROUP LIMITED	CY
SUDAFED Tablets	not available	19784	GLAXO GROUP LIMITED	CY
Sudafed, 60 mg, tabletki powlekane	not available	8438	MCNEIL HEALTHCARE (IRELAND) LIMITED	PL
АСПИРИН КОМПЛЕКС 500 mg / 30 mg гранули за перорална суспензия	DE/H/2228/001	20090034	BAYER BULGARIA EOOD	BG
Аспирин Комплекс Топла Напитка 500 mg / 30 mg гранули за перорална суспензия	DE/H/3635/001	20130361	BAYER BULGARIA EOOD	BG