



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 February 2016
EMA/147027/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: ibuprofen / pseudoephedrine

Procedure no.: PSUSA/00001711/201507



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
Acatar Zatoki		11339	Us Pharmacia Sp. Z O.O.	Poland
Advil Cold	IE/H/0420/001	OGYI-T-22705/01 \$ OGYI-T-22705/02	Pfizer Corporation Austria Gesellschaft M.B.H.	Hungary
Advil Cold & Flu	IE/H/0420/001	PA 0822/164/001	Pfizer Healthcare Ireland	Ireland
Advil Cold & Flu		MA 111/00101	Pfizer Consumer Healthcare Ltd.	Malta
Advil Zatoki	IE/H/0420/001	22369	Pfizer Corporation Austria Gesellschaft M.B.H.	Poland
Algoflex Cold		OGYI-T-22831/01 \$ OGYI-T-22831/02 \$ OGYI-T-22831/03	Sanofi-Aventis Zrt	Hungary
Bisolfren	UK/H/4352/001	76389	Boehringer Ingelheim International Gmbh	Spain
Boxagrippal	UK/H/4352/001	1-31668	Boehringer Ingelheim International Gmbh	Austria
Boxagrippal	UK/H/4352/001	85528.00.00	Boehringer Ingelheim International Gmbh	Germany
Boxagrippal Erkältungssaft	UK/H/5545/001	90668.00.00	Boehringer Ingelheim International Gmbh	Germany
Cold & Flu Relief		00014/0600	The Boots Company Plc	United Kingdom
Extralgin Cold		20100639	Zentiva, K.S.	Bulgaria
Fidiprofen Flu		UP/I-530-09/11-01/363	Fidifarm D.O.O.	Croatia
Ibum Grip		10924	Hasco-Lek	Poland
Ibum Zatoki		21376	Hasco-Lek	Poland
Ibuprofen + Pseudoephedrine Procter & Gamble	IT/H/0331/001	70849/29-7-2014	Procter & Gamble Hellas Epe	Greece
Ibuprofen/Pseudoephedrine Hcl Pfizer	IE/H/0420/001	BE463680	Pfizer B.V.	Belgium
Ibuprofen/Pseudoephedrine Hcl Pfizer	IE/H/0420/001	2015040073	Pfizer B.V.	Luxembourg
Ibuprofen/Pseudoephedrine	UK/H/4352/001	BE445164	Boehringer Ingelheim	Belgium

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Hydrochloride Boehringer Ingelheim			International Gmbh	
Ibuprofen/Pseudoephedrine Hydrochloride Boehringer Ingelheim	UK/H/4352/001	2014040030	Boehringer Ingelheim International Gmbh	Luxembourg
Ibuprofen/Pseudoephedrine Hydrochloride Boehringer Ingelheim International Gmbh	UK/H/5545/001	PL14598/0103	Boehringer Ingelheim International Gmbh	United Kingdom
Ibuprofen/Pseudoefedrin	IT/H0331/001/DC	OGYI-T-22836/01 \$ OGYI-T-22836/02 \$ OGYI-T-22836/03	Wick Pharma Zweigniederlassung Der Procter & Gamble Gmbh	Hungary
Ibuprofene E Pseudoefedrina Boehringer Ingelheim	UK/H/4352/001	041218013 \$ 041218025	Boehringer Ingelheim International Gmbh	Italy
Ibuprofene E Pseudoefedrina Wick Pharma	IT/H/0331/001	042499018 \$ 042499020	Wick Pharma Zweigniederlassung Der Procter & Gamble Gmbh	Italy
Ibuprom Sinus		2330/2010/01-02-03	Us Pharmacia Sp. Z O.O.	Romania
Ibuprom Zatoki		9650	Us Pharmacia Sp. Z O.O.	Poland
Infex Zatoki	IT/H/0331/001	22111	Teva Pharmaceuticals Polska SP. Z.o.o.	Poland
Larofen Plus		119/2007/01	Laropharm	Romania
Lasynac	UK/H/4352/001	PL 14598/0091	Boehringer Ingelheim International Gmbh	United Kingdom
Medivicks	IT-H-0331-001-DC	78831	Laboratorios Vicks, S.L.	Spain
Metafen Zatoki		11005	Zakłady Farmaceutyczne "polpharma" Spolka Akcyjna	Poland
Modafen		07/136/98-C	Zentiva, K.S.	Czech Republic

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Modafen		9603	Zentiva, K.S.	Poland
Modafen		480/2007/01 \$ 480/2007/02 \$ 480/2007/03 \$ 480/2007/04	Zentiva, K.S.	Romania
Modafen		07/0263/01-S	Zentiva, K.S.	Slovakia
Mucocold	UK/H/4352/001	21691	Boehringer Ingelheim International Gmbh	Cyprus
Mucocold	UK/H/4352/001	91698	Boehringer Ingelheim International Gmbh	Greece
Mucogrip	UK/H/4352/001	OGYI-T-22371/01 \$ OGYI-T-22371/02	Boehringer Ingelheim International Gmbh	Hungary
Mucogrip	UK/H/4352/001	5566/2013/01 \$ 5566/2013/02	Boehringer Ingelheim International Gmbh	Romania
Mucogrip	UK/H/4352/001	07/0346/12-S	Boehringer Ingelheim International Gmbh	Slovakia
Nurofen		9800356	Reckitt Benckiser Healthcare International Limited	Bulgaria
Nurofen		2305501	Reckitt Benckiser Hellas Chemicals Abee	Greece
Nurofen		034246013 \$ 034246025	Reckitt Benckiser Healthcare International Limited	Italy
Nurofen Antigrip		04 - 0197	Reckitt Benckiser (Poland) S.A.	Latvia
Nurofen Cold & Flu		19671	Reckitt Benckiser Hellas Chemicals Abee	Cyprus
Nurofen Cold & Flu		MA190/00404	Crookes Healthcare Limited	Malta
Nurofen Cold & Flu		PL 00063/0375	Reckitt Benckiser Healthcare (Uk) Limited	United Kingdom
Nurofen Cold And Flu		UP/I-530-09/11-02/20	Reckitt Benckiser (Croatia) D.O.O.	Croatia

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Nurofen Cold And Flu		OGYI-T-6797/01	Reckitt Benckiser Healthcare International Limited	Hungary
Nurofen Cold And Flu		OGYI-T-6797/02	Reckitt Benckiser Healthcare International Limited	Hungary
Nurofen Cold And Flu		PA 979/33/1	Reckitt Benckiser Ireland Ltd.	Ireland
Nurofen Raceala Si Gripa		68 IP/2012/01	Sc Mara Med Srl	Romania
Nurofen Răceală și Gripă		4144/2011/01-02	Reckitt Benckiser Healthcare International Limited	Romania
Nurofen Rhume		343 625-8	Reckitt Benckiser Healthcare France	France
Nurofen Sinus And Pain		PA 979/65/1	Reckitt Benckiser Ireland Ltd.	Ireland
Nurofen Stopgrip		07/612/96-C	Reckitt Benckiser Healthcare International Limited	Czech Republic
Nurofen Stopgrip		07/0662/96-S	Reckitt Benckiser Healthcare International Limited	Slovakia
Nurofen Zatoki		7787	Reckitt Benckiser (Poland) S.A.	Poland
Rhinadvil Rhume	FR/H/0238/001	334 084-8	Pfizer Sante Familiale Sas	France
Rhinathiol Cold		OGYI-T-9161/01 \$ OGYI-T-9161/02 \$ OGYI-T-9161/03	Sanofi-Aventis Private Co Ltd	Hungary
Rhinureflex		338 856-5	Reckitt Benckiser Healthcare France	France
Rinafen Zatoki		21816	Bio Profil Polska Sp Z Oo	Poland
Robicold	IE/H/0420/001	07/040/15-C	Pfizer Corporation Austria Gesellschaft M.B.H.	Czech Republic

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Robicold	IE/H/0420/001	07/0264/14-S	Pfizer Corporation Austria Gesellschaft M.B.H.	Slovakia
RobiCold Sinus Relief	IE/H/0420/001	PL 00165/0391	Pfizer Consumer Healthcare Ltd.	United Kingdom
Spalt Effekt	FR/H/0238/001	62958.00.00	Pfizer Consumer Healthcare GmbH	Germany
Tedolfen	IT/H/0331/001	6744/2014/01-04	Teva Pharmaceuticals S.R.L.	Romania
Wick DayMed Duo	IT/H/0331/001	135488	ratiopharm Arzneimittel Vertriebs-GmbH Austria	Austria
Wick Duogrippal	IT/H/0331/001	88707.00.00	Wick Pharma Zweigniederlassung Der Procter & Gamble GmbH	Germany
ибупром синус		20080222	Us Pharmacia Sp. Z O.O.	Bulgaria
мукогrip	UK/H/4352/001	20120408	Boehringer Ingelheim International GmbH	Bulgaria