



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

13 May 2016  
EMA/344225/2016  
Procedure Management and Committees Support

## List of nationally authorised medicinal products

Active substance: acetylcysteine

Procedure no.: PSUSA/00000034/201509

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30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom

**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5525

**Send a question via our website** [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact)

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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
Acc		368101	Sandoz Pharmaceuticals D.D.	Estonia
Acc	DE/H/3624	87763.00.00	Hexal Ag	Germany
Acetylcysteine Alpex	NL/2843/001	34009 278 260 4 7 \$ 34009 278 261 0 8 \$ 34009 278 262 7 6 \$ 34009 586 442 6 9 \$ 34009 586 443 2 0 \$ 34009 586 444 9 8 \$ 34009 586 445 5 9 \$ 586 439-5 \$ 586 440-3	Alpex Pharma (UK) Limited	France
Acetylcysteine Alpex	NL/H/2843/001	278 260-4 \$ 278 261-0 \$ 278 262-7 \$ 278 263-3 \$ 34009 278 263 3 7 \$ 34009 586 439 5 8 \$ 34009 586 440 3 0 \$ 586 442-6 \$ 586 443-2 \$ 586 444-9 \$ 586 445-5	Alpex Pharma (UK) Limited	France
Acetylcysteine Mylan		BE216352	Mylan Bvba/Sprl	Belgium
Bronchocil		BE179627 \$ BE208512	S.A. Menarini Benelux N.V.	Belgium
Bronchocil		BE179636	S.A. Menarini Benelux N.V.	Belgium
Brunac		024593016	Bruschettini S.R.L	Italy
Brunac		3437/2003/01	Bruschettini S.R.L	Romania
Euronac		34009 336 477 7 3	NICOX (ex-Doliage Laboratoires)	France
Fluimucil		020582019	Zambon Italia S.R.L.	Italy

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Fluimucil		020582021 \$ 020582235	Zambon Italia S.R.L.	Italy
Fluimucil		020582033	Zambon Italia S.R.L.	Italy
Fluimucil		020582173 \$ 020582211 \$ 020582223	Zambon Italia S.R.L.	Italy
Fluimucil		020582185	Zambon Italia S.R.L.	Italy
Fluimucil		020582209	Zambon Italia S.R.L.	Italy
Fluimucil		020582262	Zambon Italia S.R.L.	Italy
Fluimucil		020582274	Zambon Italia S.R.L.	Italy
Fluimucil		11577.00.00	Zambon Gmbh	Germany
Fluimucil		2195782	Zambon - Produtos Farmacêuticos, Lda.	Portugal
Fluimucil		2195881 \$ 2195980	Zambon - Produtos Farmacêuticos, Lda.	Portugal
Fluimucil		2196087	Zambon - Produtos Farmacêuticos, Lda.	Portugal
Fluimucil		2274/2009/01 \$ 2275/2009/01	Zambon S.P.A.	Romania

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Fluimucil		2276/2009/01	Zambon S.P.A.	Romania
Fluimucil		3400934385995	Zambon France S.A.	France
Fluimucil		3400934386077 \$ 3400934386138 \$ 3400934386367 \$ 3400934386428	Zambon France S.A.	France
Fluimucil		5269188 \$ 5269287	Zambon - Produtos Farmacêuticos, Lda.	Portugal
Fluimucil		5427216	Zambon - Produtos Farmacêuticos, Lda.	Portugal
Fluimucil		62665	Zambon, S.A.U.	Spain
Fluimucil		63532	Zambon, S.A.U.	Spain
Fluimucil		64924	Zambon, S.A.U.	Spain
Fluimucil		7716/2015/01	Zambon S.P.A.	Romania
Fluimucil		8595.00.01 \$ 8595.01.01	Zambon Gmbh	Germany
Fluimucil		OGYI-T-5351/01 \$ OGYI-T-5351/02 \$ OGYI-T-5351/03 \$ OGYI-T-5351/04 \$ OGYI-T-5351/05 \$ OGYI-T-5351/06	Zambon S.P.A.	Hungary

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Fluimucil		OGYI-T-5351/07 \$ OGYI-T-5351/08	Zambon S.P.A.	Hungary
Fluimucil		OGYI-T-5351/09	Zambon S.P.A.	Hungary
Fluimucil		OGYI-T-5351/10	Zambon S.P.A.	Hungary
Fluimucil		PA 1441/1/1	Zambon S.P.A.	Ireland
Fluimucil		RVG 06742	Zambon Nederland B.V.	Netherlands
Fluimucil		RVG 07289	Zambon Nederland B.V.	Netherlands
Fluimucil		RVG 09988	Zambon Nederland B.V.	Netherlands
Fluimucil		RVG 10701	Zambon Nederland B.V.	Netherlands
Fluimucil		RVG 10903	Zambon Nederland B.V.	Netherlands
Fluimucil		RVG 109369	Zambon Nederland B.V.	Netherlands
Fluimucil		RVG 12151	Zambon Nederland B.V.	Netherlands
Fluimucil		RVG 17273	Zambon Nederland B.V.	Netherlands

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Fluimucil		RVG 25408	Zambon Nederland B.V.	Netherlands
Fluimucil		3486487 \$ 3486586	Zambon - Produtos Farmacêuticos, Lda.	Portugal
Fluimucil		5626072	Zambon - Produtos Farmacêuticos, Lda.	Portugal
Fluimucil		3311180	Zambon - Produtos Farmacêuticos, Lda.	Portugal
Fluimucil Antidot Injektionslösung		8709.00.00	Zambon Gmbh	Germany
Fluimucil Antidote		OGYI-T- 5351/11	Zambon S.P.A.	Hungary
Fluimucil Expectorant Acetylcysteine		3400932373697 \$ 3400933182113 \$ 3400934318122	Zambon France S.A.	France
Fluimucil Expectorant Adultes Sans Sucre, édulcorée à La Saccharine Sodique, Au Cyclamate De Sodium Et Au Sucralose		34009 353 926 0 2 \$ 34009 353 927 7 0 \$ 34009 353 928 3 1	Zambon France S.A.	France
Fluimucil Expectorant Acetylcysteine		3400935068521 \$ 3400935068699 \$ 3400935068750	Zambon France S.A.	France
Fluimucil Expectorant Adultes Sans Sucre édulcorée à La		3400935392541	Zambon France S.A.	France

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Fluimucil Expectorant Enfants Sans Sucre édulcorée à La		3400935319333	Zambon France S.A.	France
Fluimucil Expectorant Enfants Sans Sucre, édulcorée à La Saccharine Sodique, Au Cyclamate De Sodium Et Au Sucralose		34009 353 195 6 2 \$ 34009 353 196 2 3	Zambon France S.A.	France
Fluimucil Forte		62663	Zambon, S.A.U.	Spain
Fluimucil Forte		78984	Zambon, S.A.U.	Spain
Fluimucil		RVG 29360	Zambon Nederland B.V.	Netherlands
Fluimucil Hustenlöser Akut		32364.02.00	Zambon Gmbh	Germany
Fluimucil Junior		32360.00.00	Zambon Gmbh	Germany
Fluimucil Kindersaft		29683.00.00	Zambon Gmbh	Germany
Fluimucil Long		8753.00.00	Zambon Gmbh	Germany
Fluimucil Mucolitico		034936017	Zambon Italia S.R.L.	Italy

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Fluimucil Mucolitico		034936031 \$ 034936106	Zambon Italia S.R.L.	Italy
Fluimucil Mucolitico		034936082 \$ 034936118	Zambon Italia S.R.L.	Italy
Fluimucil Mucolitico		034936094 \$ 034936120	Zambon Italia S.R.L.	Italy
Fluimucil Mucolitico		034936043	Zambon Italia S.R.L.	Italy
Fluimucil N		8595.01.00	Zambon Gmbh	Germany
Fluimucil Pediatric		7715/2015/01	Zambon S.P.A.	Romania
Fluimucil		17263.00.00	Zambon Gmbh	Germany
Flumil		41 474	Zambon, S.A.U.	Spain
Flumil		63 512	Zambon, S.A.U.	Spain
Flumil Infantil		62664	Zambon, S.A.U.	Spain
Hidonac		032268017	Zambon Italia S.R.L.	Italy
Hidonac		34009 560 355 95	Zambon France S.A.	France



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Hidonac		3400955583912	Zambon France S.A.	France
Hidonac		7728/2015/01	Zambon S.P.A.	Romania
Hidonac Antídoto		58931	Zambon, S.A.U.	Spain
Husten Acc	DE/H/3624	135466	Hexal Pharma Gmbh	Austria
Ilube		PL 11412/0003	Moorfields Pharmaceuticals	United Kingdom
Lysomucil		0411/03/04/7227	Zambon Nv	Luxembourg
Lysomucil		0411/04090036 \$ 0411/06018340	Zambon Nv	Luxembourg
Lysomucil		0411/04098407 \$ 0411/04098408	Zambon Nv	Luxembourg
Lysomucil		0411/06018341	Zambon Nv	Luxembourg
Lysomucil		0411/06058568	Zambon Nv	Luxembourg
Lysomucil		0411/06058569	Zambon Nv	Luxembourg
Lysomucil		2013060188	Zambon Nv	Luxembourg

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Lysomucil		411/03/04/7226	Zambon Nv	Luxembourg
Lysomucil		BE 196262	Zambon Nv	Belgium
Lysomucil		BE027885 \$ BE027894	Zambon Nv	Belgium
Lysomucil		BE125081	Zambon Nv	Belgium
Lysomucil		BE128387	Zambon Nv	Belgium
Lysomucil		BE150202	Zambon Nv	Belgium
Lysomucil		BE161384	Zambon Nv	Belgium
Lysomucil		BE220525 \$ BE260933	Zambon Nv	Belgium
Lysomucil		BE279422	Zambon Nv	Belgium
Lysomucil Pastille		0411/06018342	Zambon Nv	Luxembourg
Lysomucil Pastille		BE225251	Zambon Nv	Belgium
Lysox		0115/03057253 \$ 0115/06018336 \$ 0115/06018337	S.A. Menarini Benelux N.V.	Luxembourg

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Lysox		0115/06018338	S.A. Menarini Benelux N.V.	Luxembourg
Lysox		0115/06018339	S.A. Menarini Benelux N.V.	Luxembourg
Lysox		0115/03087252	S.A. Menarini Benelux N.V.	Luxembourg
Lysox		BE159214	S.A. Menarini Benelux N.V.	Belgium
Lysox		BE166634	S.A. Menarini Benelux N.V.	Belgium
Lysox		BE166652	S.A. Menarini Benelux N.V.	Belgium
Lysox		BE166661 \$ BE191265	S.A. Menarini Benelux N.V.	Belgium
Lysox		BE214751 \$ BE214767	S.A. Menarini Benelux N.V.	Belgium
Lysox Junior		0115/06018335	S.A. Menarini Benelux N.V.	Luxembourg
Lysox Junior		BE166643	S.A. Menarini Benelux N.V.	Belgium
Mucolysin		51688	Sandoz A/S	Denmark
Mucolysin		51689	Sandoz A/S	Denmark

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Mucomyst		10154	Meda Oy	Finland
Mucomyst		10802	Meda As	Denmark
Mucomyst		34009 326 883 2 6 \$ 34009 340 651 8 7 \$ 34009 343 346 1 0	Upsa Sas	France
Mucomyst		34009 326 885 5 5	Upsa Sas	France
Mucomyst		34009 329 165 3 5	Upsa Sas	France
Mucomyst		4896	Meda As	Denmark
Mucomyst		5107	Meda As	Norway
Mucomyst		7141	Meda As	Norway
Mucomyst		9918	Meda Ab	Sweden
Pulmosal		5519285	Laboratórios Azevedos - Indústria Farmacêutica, S.A.	Portugal
Rinofluimucil	2/80/89	2196285	Zambon - Produtos Farmacêuticos, Lda.	Portugal
Solmucol		019527	Andreas Constantinides	Cyprus

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Solmucol		34009 331 566 1 9 \$ 34009 331 568 4 8 \$ 34009 332 196 3 5 \$ 34009 377 164 3 7	Laboratoires Genevrier	France
Solmucol		52/0055/92-S	Ibsa Slovakia S.R.O.	Slovakia
Solmucol		52/0533/92-S	Ibsa Slovakia S.R.O.	Slovakia
Solmucol		52/055/92-S/C	Ibsa Slovakia S.R.O.	Czech Republic
Solmucol		52/0615/94-S	Ibsa Slovakia S.R.O.	Slovakia
Solmucol		52/278/96-C	Ibsa Slovakia S.R.O.	Czech Republic
Solmucol 100 \$ Solmucol 200		52/533/92-A/C \$ 52/533/92-B/C	Ibsa Slovakia S.R.O.	Czech Republic
Tirocular		028165025	Aziende Chimiche Riunite Angelini Francesco - A.C.R.A.F. S.P.A.	Italy
Trebon-N		13418	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Greece
Trebon-N		13420	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Greece
Trebon-N		022102	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Cyprus

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Trebon-N		35997	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Greece
Trebon-N		66200	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Greece
Trebon-N		89132	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Greece
флуимуцил		20060667	Angelini Pharma Bulgaria Eood	Bulgaria
флуимуцил		20060668 \$ 20060669	Angelini Pharma Bulgaria Eood	Bulgaria
Trebon-N		66199	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Greece
Trebon-N		31588, 35997	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Greece
Mucomyst Endo		380 263-9	Bristol-Myers Squibb	France
Mucomyst Endo		570 956-5	Bristol-Myers Squibb	France
Exomuc		NL13526	Bouchara Recordati	France
Solmucol		34009 336 478 3 4 \$ 34009 353 202 2 3	Laboratoires Genevrier	France

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Acetylcystein Meda		11502	Meda Ab	Sweden
Acetylcystein Meda		11537	Meda Ab	Sweden
Acetylsalicylzuur Sandoz		RVG 102615	Sandoz B.V.	Netherlands
Acetylcysteine Mylan		NL 23025	Mylan S.A.S.	France
Ilube		PA 1464/2/1	Moorfields Pharmaceuticals	Ireland
Granon	DK/H/2352/002/MR	50408	Takeda Pharma A/S	Denmark
Granon	DK/H/2352/002	15/10523	Takeda Nycomed AS	Norway
Acetylcysteine Imphos		RVG 20882	ZAMBON NEDERLAND B.V.	Netherlands
Fluimukan	DE/H/3623/003	H/14/02013/001 \$ H/14/02013/002	Lek d.d.	Slovenia