



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 September 2016
EMA/660623/2016
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: acetylsalicylic acid

Procedure no.: PSUSA/00000039/201602



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
AAS		42956	Sanofi-Aventis, S.A.	Spain
AAS		42991	Sanofi-Aventis, S.A.	Spain
Acetylsalicylsyra Ellem		5284	Meda Ab	Sweden
Acetylsalicylzuur Apotex Cardio 80mg		RVG 26865	Apotex Europe Bv	Netherlands
Acetylsalicylzuur Apotex Neuro 30mg		RVG 28359	Apotex Europe Bv	Netherlands
Acetylsalicylzuur Cardio Aurobindo		RVG 102607	Aurobindo Pharma B.V.	Netherlands
Acetylsalicylzuur Cardio Teva		RVG 16466	Teva Nederland B.V.	Netherlands
Acetylsalicylzuur Cardio Pharmachemie		RVG 102648	Pharmachemie B.V	Netherlands
Acetylsalicylzuur Cardio Pharmachemie		RVG 102649	Pharmachemie B.V	Netherlands
Acetylsalicylzuur Cardio Pharmachemie		RVG 102650	Pharmachemie B.V	Netherlands
Acetylsalicylzuur Cardio Pharmachemie		RVG 102651	Pharmachemie B.V	Netherlands
Acetylsalicylzuur Neuro Aurobindo		RVG 102604	Aurobindo Pharma B.V.	Netherlands

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Acetylsalicylzuur Neuro Pch		RVG 18116	Pharmachemie B.V	Netherlands
Acetylsalicylzuur Neuro Pharmachemie		RVG 102652	Pharmachemie B.V	Netherlands
Acetylsalicylzuur Neuro Pharmachemie		RVG 102653 \$ RVG 102654 \$ RVG 102655	Pharmachemie B.V	Netherlands
Acetylsalicylzuur Sandoz		RVG 102615	Sandoz B.V.	Netherlands
Albyl Minor		4892	Meda Ab	Sweden
Asaflow		BE152695	Takeda Belgium Sca/Cva	Belgium
Asaflow		BE152695	Takeda Belgium Sca/Cva	Belgium
Alka Seltzer		8.050	Bayer Austria Gmbh	Austria
Aspiricor		1-20088	Bayer Austria Gmbh	Austria
ASA		1-20680	Bayer Austria Gmbh	Austria
ASA		3155	Bayer Austria Gmbh	Austria
ASA Akut	DE/H/0249/001	1-24114	Bayer Austria Gmbh	Austria
ASA Direk		1-31667	Bayer Austria Gmbh	Austria
ASA Express	FR/H/0482/001	135296	Bayer Austria Gmbh	Austria
ASA Protect		1-25792	Bayer Austria Gmbh	Austria
Alka-Seltzer		BE068792	Bayer Sa Nv	Belgium

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AS Ae		BE041307	Bayer Sa Nv	Belgium
AS Ae		BE163581	Bayer Sa Nv	Belgium
ASA Actavis		OGYI-T-22767/01-07 \$ OGYI-T-22767/08-14 \$ OGYI-T-22767/15-21	Actavis Group Ptc Ehf.	Hungary
Asacard	UK/H/0283/001	30512	New Haven Pharma (Uk) Limited	Denmark
Asacard	UK/H/0283/001	PA 1966-1-1	New Haven Pharma (Uk) Limited	Ireland
Asacard	UK/H/0283/001	RVG 23862	New Haven Pharma (Uk) Limited	Netherlands
Asaflow		BE152695	Takeda Belgium Sca/Cva	Belgium
Asaflow		BE187512	Takeda Belgium Sca/Cva	Belgium
Asaflow		BE187512	Takeda Belgium Sca/Cva	Belgium
Asaflow		BE187512	Takeda Belgium Sca/Cva	Belgium
Asaflow		BE429457	Takeda Belgium Sca/Cva	Belgium
Asaflow		BE429457	Takeda Belgium Sca/Cva	Belgium
Asaflow		BE429457	Takeda Belgium Sca/Cva	Belgium
Cardioflow		BE 321946	Takeda Belgium Sca/Cva	Belgium
Cardioflow		BE321946	Takeda Belgium Sca/Cva	Belgium

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Cardioflow		BE321946	Takeda Belgium Sca/Cva	Belgium
Cardioflow		BE321955	Takeda Belgium Sca/Cva	Belgium
ASAc Bruis		BE108866	Bayer Sa Nv	Belgium
ASAc Fasttabs	FR/H/0482/001	BE445112	Bayer Sa Nv	Belgium
CardioASAc		BE186891	Bayer Sa Nv	Belgium
алка зелцер		20010171	Bayer Bulgaria Eood	Bulgaria
аспирин		20030406	Bayer Bulgaria Eood	Bulgaria
аспирин протект		20010168	Bayer Bulgaria Eood	Bulgaria
аспирин ултра		20160090	Bayer Bulgaria Eood	Bulgaria
ASA Zipp		UP/I-530-09/12-01/242	Bayer Doo	Croatia
ASA		19677	Bayer Hellas Sa	Cyprus
ASA	FR/H/0482/001	07/480/13-C	Bayer Sro	Czech Republic
ASA		00762	Bayer Ab	Denmark
ASA Cardio		17594	Bayer Ab	Denmark
Alka-Seltzer		065194	Bayer Uab	Estonia
ASA		019193	Bayer Uab	Estonia
ASA Cardio		680710	Bayer Uab	Estonia
ASA		138	Bayer Oy	Finland

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ASA Cardio		12236	Bayer Oy	Finland
ASA Zipp		16587	Bayer Oy	Finland
Alka Seltzer		34009 300 266 6 3 \$ 34009 300 267 2 4 \$ 34009 320 120 7 7 \$ 34009 329 110 4 2 \$ 34009 329 267 0 1 \$ 34009 329 268 7 9 \$ 34009 340 648 7 6	Bayer Healthcare	France
ASAE Bayer	FR/H/0483/001	34009 279 073 3 3 \$ 34009 279 075 6 2 \$ 34009 279 076 2 3 \$ 34009 279 077 9 1	Bayer Healthcare	France
ASA		0126/246/001	Clonmel Healthcare Ltd.	Ireland
ASAE Du Rhone		34009 334 247 4 9 \$ 34009 334 248 0 0 \$ 34009 363 984 3 6 \$ 34009 363 986 6 5	Bayer Healthcare	France
ASAE Du Rhône		34009 341 561 2 0 \$ 34009 351 467 9 3 \$ 34009 351 468 5 4 \$ 34009 351 469 1 5 \$ 34009 559 144 8 8	Bayer Healthcare	France
ASAE Protect		34009 269 399 3 9 \$ 34009 269 400 1 0 \$ 34009 269 401 8 8	Bayer Healthcare	France
ASAE Protect		343 000-8 \$ 343 001-4 \$ 343 002-0	Bayer Healthcare	France

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
Aspro		34009 300 781 8 1 \$ 34009 324 528 0 4 \$ 34009 326 893 8 5 \$ 34009 337 325 6 1 \$ 34009 337 326 2 2 \$ 34009 337 327 9 0 \$ 34009 337 328 5 1 \$ 34009 337 329 1 2 \$ 34009 351 252 2 4 \$ 34009 554 663 7 6 \$ 34009 560 926 6 6	Bayer Healthcare	France
Aspro		34009 320 623 9 3 \$ 34009 320 624 5 4 \$ 34009 320 625 1 5 \$ 34009 323 955 2 1	Bayer Healthcare	France
Asproflash	FR/H/0482/001	34009 279 069 6 1 \$ 34009 279 070 4 3 \$ 34009 279 071 0 4 \$ 34009 279 072 7 2	Bayer Healthcare	France
ASA BP		0142/0377	Actavis Uk Ltd.	United Kingdom
ASA Bp		PL 17907/0152 \$ PL 17907/0153	Bristol Laboratories Ltd	United Kingdom
ASA Bp		PL 17907/0155	Bristol Laboratories Ltd	United Kingdom
ASA Bp		PL 17907/0156	Bristol Laboratories Ltd	United Kingdom
ASA		PL 20416/0227	Crescent Pharma Limited	United Kingdom
ASA		PL 20395/0100	Relon Chem Limited	United Kingdom
Alka Seltzer Classic		37533.00.00	Bayer Vital Gmbh	Germany
Alka-Seltzer Classic		6621707.00.00	Bayer Vital Gmbh	Germany

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ASA		25144.00.00 \$ 6092686.00.00 \$ 6245718.00.00 \$ 6245747.00.00	Bayer Vital Gmbh	Germany
ASA Cardio		30.00.00	Bayer Vital Gmbh	Germany
ASA	FR/H/0482/001	86750.00.00	Bayer Vital Gmbh	Germany
ASA Direkt		38117.00.00 \$ 51094.00.00	Bayer Vital Gmbh	Germany
ASA Effect		38118.00.00 \$ 52012.00.00	Bayer Vital Gmbh	Germany
ASA Migräne		50352.00.00	Bayer Vital Gmbh	Germany
Bayer-ASA Migräne	DE/H/0249/001	6245612.00.00	Bayer Vital Gmbh	Germany
ASA N		16854.00.00 \$ 16854.01.00 \$ 30828.00.00	Bayer Vital Gmbh	Germany
ASA Protect		16854.00.01 \$ 30828.00.01 \$ 33171.01.00	Bayer Vital Gmbh	Germany
ASA		PL 20416/0230	Crescent Pharma Limited	United Kingdom
ASA Protect		16854.01.01 \$ 30828.01.01 \$ 33171.00.00	Bayer Vital Gmbh	Germany
ASA		20713/1-4-2008 \$ 20714/1-4-2008	Bayer Hellas Sa	Greece
ASA Direct		20715/1-4-2008	Bayer Hellas Sa	Greece
ASA		20718/1-4-2008	Bayer Hellas Sa	Greece
ASA		20720/1-4-2008	Bayer Hellas Sa	Greece

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
ASA Ec		20716/1-4-2008	Bayer Hellas Sa	Greece
ASA Ec		20717/1-4-2008	Bayer Hellas Sa	Greece
Alka-Seltzer		OGYI-T-8081/01	Bayer Hungaria Kft	Hungary
ASA		OGYI-T-1505/02 \$ OGYI-T-1505/03 \$ OGYI-T-1505/07	Bayer Hungaria Kft	Hungary
ASA		PL 16028/0026	Galpharm Healthcare Limited	United Kingdom
ASA Effect		OGYI-T-1505/08 \$ OGYI-T-1505/09	Bayer Hungaria Kft	Hungary
ASA Protect		OGYI-T-5950/01 \$ OGYI-T-5950/02 \$ OGYI-T-5950/03 \$ OGYI-T-5950/04 \$ OGYI-T-5950/05 \$ OGYI-T-5950/06 \$ OGYI-T-5950/07 \$ OGYI-T-5950/08	Bayer Pharma Ag	Hungary
ASA Protect		OGYI-T-5950/09	Bayer Pharma Ag	Hungary
ASA Ultra	FR/H/0482/001	OGYI-T-01505/10 \$ OGYI-T-01505/11 \$ OGYI-T-01505/12 \$ OGYI-T-01505/13	Bayer Hungaria Kft	Hungary
ASA		PA 1410/37/1	Bayer Ltd	Ireland
ASAA		004763025 \$ 004763266	Bayer Spa	Italy

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ASAA		004763037 \$ 004763049 \$ 004763241 \$ 004763254 \$ 004763367 \$ 004763557	Bayer Spa	Italy
ASAA		004763393 \$ 004763405 \$ 004763544 \$ 004763595	Bayer Spa	Italy
ASAA Rapida		004763379	Bayer Spa	Italy
ASAA Dolore E Infiammazione	FR/H/0483/001	041962010 \$ 041962022 \$ 041962034 \$ 041962046	Bayer Spa	Italy
ASAA Rapida		004763417	Bayer Spa	Italy
ASAetta		026721035 \$ 026721100	Bayer Spa	Italy
Aspro		001363062 \$ 001363086	Bayer Spa	Italy
Aspro		001363074	Bayer Spa	Italy
Aspro		001363112 \$ 001363124	Bayer Spa	Italy
CardioASA		024840074	Bayer Spa	Italy
CardioASA		024840086 \$ 024840098	Bayer Spa	Italy
Alka-Seltzer		LT/1/94/0845/001	Bayer Uab	Lithuania
ASA		LT/1/94/0846/001 \$ LT/1/94/0846/002	Bayer Uab	Lithuania
ASA Cardio		LT/1/10/2038/001 \$ LT/1/10/2038/003	Bayer Uab	Lithuania

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Alka-Seltzer		2011081252	Bayer Sa Nv	Luxembourg
ASAc		1996045237	Bayer Sa Nv	Luxembourg
ASAc		1999065236	Bayer Sa Nv	Luxembourg
ASAc Bruis		1970120093	Bayer Sa Nv	Luxembourg
ASAc Fasttabs	FR/H/0482/001	2014040012	Bayer Sa Nv	Luxembourg
CardioASAc		1998020010	Bayer Sa Nv	Luxembourg
ASA Protect		MA002/00402	Bayer Healthcare Ag	Malta
Alka-Seltzer N		RVG 01147	Bayer Bv	Netherlands
ASAc		RVG 00613	Bayer Bv	Netherlands
ASAc		RVG 01414	Bayer Bv	Netherlands
ASAc		RVG 16362	Bayer Bv	Netherlands
ASAc		RVG 28834	Bayer Bv	Netherlands
ASAc Ec Protect		RVG 20952	Bayer Bv	Netherlands
Aspro		RVG 03049	Bayer Bv	Netherlands
Aspro Bruis		RVG 08186	Bayer Bv	Netherlands
ASA		95-1663	Bayer Ab	Norway
ASA Cardio		95/01662	Bayer Ab	Norway
Alka-Seltzer		R/1927	Bayer Sp.Z.O.O	Poland

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ASA		R/1926	Bayer Sp.Z.O.O	Poland
ASA		R/6840	Bayer Sp.Z.O.O	Poland
ASA Cardio		R/6841	Bayer Sp.Z.O.O	Poland
ASA Effect		17668	Bayer Sp.Z.O.O	Poland
ASA Pro	FR/H/0482/001	21625	Bayer Sp.Z.O.O	Poland
ASA Ultra Fast		R/7312	Bayer Sp.Z.O.O	Poland
ASAA		2002194	Bayer Portugal Sa	Portugal
ASAA		3209384	Bayer Portugal Sa	Portugal
ASAA		5273289	Bayer Portugal Sa	Portugal
ASAA GR		3045580	Bayer Portugal Sa	Portugal
ASAA GR		5481379	Bayer Portugal Sa	Portugal
ASAA Microactive	FR/H/0482/001	5588165 \$ 5588173 \$ 5588207 \$ 5588215	Bayer Portugal Sa	Portugal
MigrASAA	DE/H/0249/001	3638681 \$ 3638780	Bayer Portugal Sa	Portugal
Alka-Seltzer		7880/2015/01	Bayer Srl	Romania
ASAE Ph8		300 746-8 \$ 300 747-4 \$ 550 075-3	Meda Pharma Sas	France
ASA		7157/2006/01	Bayer Srl	Romania
ASA		7157/2006/02	Bayer Srl	Romania

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ASAE Upsa		34009 335 151 0 2 \$ 34009 335 152 7 0	Upsa Sas	France
ASA	FR/H/0482/001	6006/2013/01 \$ 6006/2013/02 \$ 6006/2013/03 \$ 6006/2013/04 \$ 6006/2013/05	Bayer Srl	Romania
ASA Cardio		6754/2014/01	Bayer Srl	Romania
ASA Cardio		6754/2014/02	Bayer Srl	Romania
ASA Cardio		6755/2014/01	Bayer Srl	Romania
ASA		07/0136/91-C/S \$ 07/0190/15-S	Bayer Spol Sro	Slovakia
ASA Migren		07/0124/04-S	Bayer Spol Sro	Slovakia
ASA		H/92/00220/001 \$ H/92/00220/002	Bayer D.O.O	Slovenia
ASA	FR/H/0482/001	H/14/1909/001	Bayer D.O.O	Slovenia
ASA Direkt		H/92/00220/003	Bayer D.O.O	Slovenia
ASS-ratiopharm		6367456.01.00	Ratiopharm Gmbh	Germany
Bamyl		14792	Meda Ab	Sweden
Bamyl		8845	Meda Ab	Sweden
ASA Protect		H/92/00220/005 \$ H/92/00220/006	Bayer D.O.O	Slovenia
ASA Zipp		H/92/00220/008	Bayer D.O.O	Slovenia
ASAA		2.011	Bayer Hispania Sl	Spain

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ASAA		57.838	Bayer Hispania SI	Spain
Cardioflow		BE321955	Takeda Belgium Sca/Cva	Belgium
Cardioflow		BE321955	Takeda Belgium Sca/Cva	Belgium
Hjertemagnyl		34891	Takeda Pharma A/S	Denmark
Hjertemagnyl		34892	Takeda Pharma A/S	Denmark
Asaflow		2000075786	Takeda Belgium Sca/Cva	Luxembourg
Asaflow		2001116613	Takeda Belgium Sca/Cva	Luxembourg
Cartia		9729509	Instituto Luso-Fármaco, Lda	Portugal
Dispersible ASA		PL 04077/0182	M&A Pharmachem Ltd	United Kingdom
Dispersible ASA		PL 16028/0019	Galpharm Healthcare Limited	United Kingdom
Disprin		PL 00063/0017	Reckitt Benckiser Healthcare (Uk) Limited	United Kingdom
Disprin Direct		PL 00063/0018	Reckitt Benckiser Healthcare (Uk) Limited	United Kingdom
Flamasacard	UK/H/0283/001	PL 43011/0001	New Haven Pharma (Uk) Limited	United Kingdom
HerzASS-ratiopharm		0687/07/11/9545	Ratiopharm Gmbh	Luxembourg
HerzASS-ratiopharm		6043848.00.00	Ratiopharm Gmbh	Germany

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Albyl-E		7616	Takeda As	Norway
Albyl-E		7905	Takeda As	Norway
Magnecyl Brus		9333	Meda Ab	Sweden
ASAA		67.875	Bayer Hispania SI	Spain
ácido Acetilsalicílico Bayfarma		62.826 \$ 62.828	Bayer Hispania SI	Spain
Nu-Seals		PA 943/6/1	Alliance Pharmaceuticals Ltd	Ireland
Nu-Seals		PA 943/6/2	Alliance Pharmaceuticals Ltd	Ireland
Nu-Seals		PL 16853/0062	Alliance Pharmaceuticals Ltd	United Kingdom
Nu-Seals		PL 16853/0063	Alliance Pharmaceuticals Ltd	United Kingdom
Nu-Seals ASA		16122	Phadisco Ltd	Cyprus
Nu-Seals ASA		MA056/00501	Phadisco Ltd	Malta
Salospir		17903 \$ S00041	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Cyprus
Salospir		22011/26.03.2012 \$ 22014/26.03.2012 \$ 22018/26.03.2012 \$ 69249/26.03.2012	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Greece

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Salospir		22015/26.03.2012 \$ 57968/26.08.2010 (product code 1925511)	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Greece
Salospir		22019/26.03.2012 \$ 8570/06.02.2007 (product code 1925503)	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Greece
Salospir		57967/26.08.2010 \$ 8570/06.02.2007 (EOF CODE 1925508)	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Greece
Salospir		57969/26.08.2010 \$ 57974/26.08.2010 \$ 57975/26.08.2010	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Greece
Salospir		57970/26.08.2010 \$ 8570/06.02.2007 (product code 1925509)	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Greece
Salospir		57971/26.08.2010 \$ 57973/26.08.2010	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Greece
Salospir		8570/06.02.2007 (product code 1925504)	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Greece

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Salospir		S00782	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Cyprus
Sedergine		BE184807 \$ BE213577	Bristol-Myers Squibb Belgium Nv	Belgium
Toldex Retard		9302919	Bial - Portela & C ^a , Sa	Portugal
Toldex Retard		9302935	Bial - Portela & C ^a , Sa	Portugal
Tromalyt		58.791 \$ 59.210	Rottapharm, S.L.	Spain
Tromalyt		3809787	Neo-Farmacêutica, S.A.	Portugal
ASA		00137	Bayer Ab	Sweden
ácido Acetilsalicílico Farmalider		78184	Farmalider, S.A.	Spain
ASA Cardio		13516	Bayer Ab	Sweden
ASA Migraine	DE/H/0249/001	18479	Bayer Ab	Sweden
Aspro Clear		PL 00010/0309	Bayer Plc	United Kingdom
Maximum Strength Aspro Clear		PL 00010/0332	Bayer Plc	United Kingdom
ASAe Upsa		335 885-4 \$ 557 941-8	Upsa Sas	France
ASAe Upsa Tamponnee Effervescente		34009 335 314-7 8 \$ 34009 335 315-3 9	Upsa Sas	France

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
Sedergine		184773	Bristol-Myers Squibb Belgium S.A. NV	Belgium
Sedergine Forte		225181	Bristol-Myers Squibb Belgium S.A. NV	Belgium
Sedergine		0457/11031022	Bristol-Myers Squibb Belgium S.A. NV	Luxembourg
Sedergine		0457/11031023	Bristol-Myers Squibb Belgium S.A. NV	Luxembourg
Sedergine Forte		0457/11031024	Bristol-Myers Squibb Belgium S.A. NV	Luxembourg
ASA		AA737/00201 & AA737/00202	Bristol Laboratories Ltd	Malta
Magnyl DAK		13760	Takeda Pharma A/S	Denmark
Magnyl DAK		13761	Takeda Pharma A/S	Denmark
Magnyl Svage DAK		34914	Takeda Pharma A/S	Denmark
Salospir		1787/13.01.2016	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Greece
Salospir		8570/06.02.2007 (product code 1925512)	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Greece
ASA		PL 04077/0025	M&A Pharmachem Ltd	United Kingdom

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Acetylsalicylzuur cardio		RVG 26194	Meda Pharma BV	Netherlands
Acetylsalicylzuur neuro		RVG 26195	Meda Pharma BV	Netherlands
ASA Mylan		BE240511	Mylan bvba sprl	Belgium
Dispersible ASA; Mandaprin Dispersible ASA		PL 04077/0175	M&A Pharmachem Ltd	United Kingdom
Disprin Original		PA979/6/1	Reckitt Benckiser Ireland Limited	Ireland
Disprin Direct		PA979/7/1	Reckitt Benckiser Ireland Limited	Ireland
Disprin Extra Strength		PA979/6/2	Reckitt Benckiser Ireland Limited	Ireland
ASA ULTRA FORTE 1000 mg bevont tabletta	PT/H/1384/001/DC	OGYI-T-01505/14-21	Bayer Hungaria Kft.	Hungary