



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 November 2015
EMA/16413/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: Spironolactone

Procedure no.: PSUSA-00002780-201503



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
Aldactone		019822028	Sanofi Spa	Italy
Aldactone		019822030	Sanofi Spa	Italy
Aldactone		2009010113 \$ 2009010114 \$ 2009010115	Continental Pharma, Inc.	Luxembourg
Aldactone		39.059 \$ 54.900	Pfizer, S.L.	Spain
Aldactone		4550 \$ 6191 \$ 6533	Pfizer As	Norway
Aldactone		5363-I-1175/10 5363-I-129/14	Riemser Pharma Gmbh	Slovenia
Aldactone		640211 (IS) \$ 792398 (IS)	Pfizer Aps	Iceland
Aldactone		6618622.00.01	Riemser Pharma Gmbh	Germany
Aldactone		7223 \$ 9357	Pfizer Ab	Sweden
Aldactone		9519	Pfizer Ab	Sweden
Aldactone		BE033476 \$ BE109024 \$ BE177484	Continental Pharma, Inc.	Belgium
Aldactone		MA505/00701	Pfizer Hellas, A.E.	Malta
Aldactone		PA 822/110/1 \$ PA 822/110/2 \$ PA 822/110/3	Pfizer Healthcare Ireland	Ireland
Aldactone		PL 00057/0927 \$ PL 00057/0928	Pfizer Limited	United Kingdom

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
Aldactone		PL 00057/0929	Pfizer Limited	United Kingdom
Aldactone 100 Mg		5363-I-1177/10 5363-I-131/14	Riemser Pharma Gmbh	Slovenia
Aldactone 25		6618622.00.00	Riemser Pharma Gmbh	Germany
Aldactone 50		5363-I-1176/10 5363-I-130/14	Riemser Pharma Gmbh	Slovenia
Aldactone 50		6618622.01.00	Riemser Pharma Gmbh	Germany
Spiro-Ct		6520573.00.00	Abz-Pharma Gmbh, Graf-Arco-Str. 3	Germany
Spirohexal	922.970	1-19819	Hexal Pharma Gmbh	Austria
Spirolang		019913019 \$ 019913021 \$ 019913033	Laboratorio Farmaceutico S.I.T. S.R.L.	Italy
Spironolactone Actavis	PL 0142/0370	0142/0370	Actavis Uk Ltd.	United Kingdom
Spironolactone Actavis Uk Ltd.	PL 0142/0368 \$ PL 0142/0369	0142/0368 \$ 0142/0369	Actavis Uk Ltd.	United Kingdom
Spironolactone Ratiopharm		NL13070	Ratiopharm Gmbh	France
Spironolactone Teva		NL23358 \$ NL23360	Teva Santé	France
Spironolakton Pfizer		9766	Pfizer Ab	Sweden
Spironolakton Pfizer		9899 \$ 9900	Pfizer Ab	Sweden

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Uractone		019408018	Spa – Società Prodotti Antibiotici S.P.A.	Italy
Verospiron		50/0026/02-S	Gedeon Richter Plc.	Slovakia
Verospiron		50/0027/02-S	Gedeon Richter Plc.	Slovakia
Verospiron		50/028/00-C \$ 50/029/00-C	Gedeon Richter Plc.	Czech Republic
Verospiron		50/0512/92-S	Gedeon Richter Plc.	Slovakia
Verospiron		50/512/92-S/C	Gedeon Richter Plc.	Czech Republic
Verospiron		LT/1/94/01032/001	Gedeon Richter Plc.	Lithuania
Verospiron		LT/1/94/1032/003	Gedeon Richter Plc.	Lithuania
Verospiron		OGYI-T-3381/01	Gedeon Richter Plc.	Hungary
Verospiron		OGYI-T-3381/02 \$ OGYI-T-3381/03	Gedeon Richter Plc.	Hungary
Verospiron	NULL	LT/1/94/1032/002	Gedeon Richter Plc.	Lithuania
SPIRONOLACTONE ZENTIVA 50 MG, COMPRIME SECABLE		NL21160	Sanofi -Aventis France	France
SPIRONOLACTONE ZENTIVA 75 MG, COMPRIME SECABLE		NL21161	Sanofi -Aventis France	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
25 mg Scored Tablet Spironolactone Pfizer 25mg		NL 23638	Pfizer Holding France	France
50 mg Scored Tablet Spironolactone Pfizer 50mg		NL 233357	Pfizer Holding France	France
75 mg Scored Tablet Spironolactone Pfizer 75mg		NL 21073	Pfizer Holding France	France
25 mg Scored Tablet Aldactone		NL 22667	Pfizer Holding France	France
50 mg Scored Tablet Aldactone		V01265	Pfizer Holding France	France
75 mg Scored TabletAldactone		NL 12882	Pfizer Holding France	France
25 mg Tablet Spironolactone Pfizer 25 mg		NL 23638	Pfizer Holding France	France
50 mg Tablet Spironolactone Pfizer 50 mg		NL 23357	Pfizer Holding France	France
75 mg Tablet Spironolactone Pfizer 75 mg		NL 21073	Pfizer Holding France	France
25 Tablet Aldactone		NL 22667	Pfizer Holding France	France
75 Tablet Aldactone		NL 12882	Pfizer Holding France	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
25 mg Tablet, Film Coated Aldactone		41132/10/31-5-2011	Pfizer Hellas A.E	Greece
100 mg Tablet, Film Coated Aldactone		41134/10/31-5-2011	Pfizer Hellas A.E	Greece
25 mg Tablet Aldactone 25 mg comprimidos		6/33/62 (4657391 \$ 4657490 \$ 5726799 \$ 9046714 \$ 9046755)	Laboratorios Pfizer, Lda	Portugal
100 mg Tablet Aldactone 100 mg comprimidos		6/33/75 (4657599)	Laboratorios Pfizer, Lda	Portugal
100mg Tablet, Film Coated Aldactone 100 mg comprimidos recubiertos con pelicula		54900	Pfizer S.L., Spain	Spain
Aldactone		HR-H-977451139 \$ HR-H-496664168 \$ HR-H-516520022	Phoenix Farmacija d.d.	Croatia
Verospiron		183797	Gedeon Richter Plc.	Estonia