



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Amsterdam, 11 November 2021
EMA/784388/2021
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: spironolactone

Procedure no.: PSUSA/00002780/202103

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



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	not available	41132/10/31-05-2011	PFIZER HELLAS, A.E.	GR
ALDACTONE	not available	41134/10/31-05-2011	PFIZER HELLAS, A.E.	GR
Aldactone 100 mg comprimés pelliculés	not available	BE109024	PFIZER S.A. (BELGIUM)	BE
Aldactone 100 mg comprimidos	not available	4657599	LABORATÓRIOS PFIZER, LDA.	PT
Aldactone 100 mg comprimidos	not available	9046714	LABORATÓRIOS PFIZER, LDA.	PT
Aldactone 100 mg comprimidos recubiertos con película.	not available	54.900	PFIZER, S.L.	ES
Aldactone 100 mg film-coated tablets	not available	PA 822/110/3	PFIZER HEALTHCARE IRELAND	IE
Aldactone 100 mg Filmtabletten	not available	2009010115	PFIZER S.A. (BELGIUM)	LU
Aldactone 100 mg tvrde kapsule	not available	HR-H-516520022	RIEMSER PHARMA GMBH	HR
Aldactone 100 mg, filmdragerade tabletter	not available	9357	PFIZER AB	SE
Aldactone 25 mg comprimidos	not available	9046755	LABORATÓRIOS PFIZER, LDA.	PT
Aldactone 25 mg comprimidos	not available	4657490	LABORATÓRIOS PFIZER, LDA.	PT
Aldactone 25 mg comprimidos	not available	4657391	LABORATÓRIOS PFIZER, LDA.	PT
Aldactone 25 mg comprimidos	not available	5726799	LABORATÓRIOS PFIZER, LDA.	PT
Aldactone 25 mg comprimidos recubiertos con película.	not available	39.059	PFIZER, S.L.	ES
Aldactone 25 mg film-coated tablets	not available	PA 822/110/1	PFIZER HEALTHCARE IRELAND	IE
Aldactone 25 mg film-coated tablets	not available	MA505/00701	PFIZER HELLAS, A.E.	MT
Aldactone 25 mg Filmtabletten	not available	BE033476	PFIZER S.A. (BELGIUM)	BE
Aldactone 25 mg Filmtabletten	not available	2009010113	PFIZER S.A. (BELGIUM)	LU

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 25 mg obložene tablete	not available	HR-H-977451139	RIEMSER PHARMA GMBH	HR
ALDACTONE 25 mg, comprimé sécable	not available	34009 560 976 3 0	PFIZER HOLDING FRANCE	FR
ALDACTONE 25 mg, comprimé sécable	not available	34009 344 663 0 4	PFIZER HOLDING FRANCE	FR
ALDACTONE 25 mg, comprimé sécable	not available	34009 372 959 8 7	PFIZER HOLDING FRANCE	FR
ALDACTONE 25 mg, comprimé sécable	not available	34009 344 662 4 3	PFIZER HOLDING FRANCE	FR
Aldactone 25 mg, filmdragerade tabletter	not available	7223	PFIZER AB	SE
Aldactone 50 mg comprimés pelliculés	not available	2009010114	PFIZER S.A. (BELGIUM)	LU
Aldactone 50 mg Film-coated tablets	not available	PA 822/110/2	PFIZER HEALTHCARE IRELAND	IE
Aldactone 50 mg Filmtabletten	not available	BE177484	PFIZER S.A. (BELGIUM)	BE
Aldactone 50 mg obložene tablete	not available	HR-H-496664168	RIEMSER PHARMA GMBH	HR
ALDACTONE 50 mg, comprimé sécable	not available	34009 552 457 0 4	PFIZER HOLDING FRANCE	FR
ALDACTONE 50 mg, comprimé sécable	not available	34009 351 253 9 2	PFIZER HOLDING FRANCE	FR
ALDACTONE 50 mg, comprimé sécable	not available	34009 327 250 3 8	PFIZER HOLDING FRANCE	FR
ALDACTONE 50 mg, comprimé sécable	not available	34009 372 335 4 5	PFIZER HOLDING FRANCE	FR
Aldactone 50 mg, filmdragerade tabletter	not available	9519	PFIZER AB	SE
ALDACTONE 75 mg, comprimé sécable	not available	34009 326 080 7 2	PFIZER HOLDING FRANCE	FR
ALDACTONE 75 mg, comprimé sécable	not available	34009 326 079 9 0	PFIZER HOLDING FRANCE	FR
ALDACTONE 75 mg, comprimé sécable	not available	34009 554 778 9 1	PFIZER HOLDING FRANCE	FR

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 75 mg, comprimé sécable	not available	34009 351 254 5 3	PFIZER HOLDING FRANCE	FR
ALDACTONE 75 mg, comprimé sécable	not available	34009 372 960 6 9	PFIZER HOLDING FRANCE	FR
ALDACTONE® 100 mg trde kapsule	not available	H/98/00135/003	RIEMSER PHARMA GMBH	SI
Aldactone® 100, 100 mg Hartkapseln	not available	6618622.00.01	RIEMSER PHARMA GMBH	DE
ALDACTONE® 25 mg obložene tablete	not available	H/98/00135/001	RIEMSER PHARMA GMBH	SI
Aldactone® 25, 25 mg überzogene Tabletten	not available	6618622.00.00	RIEMSER PHARMA GMBH	DE
ALDACTONE® 50 mg obložene tablete	not available	H/98/00135/002	RIEMSER PHARMA GMBH	SI
Aldactone® 50, 50 mg überzogene Tabletten	not available	6618622.01.00	RIEMSER PHARMA GMBH	DE
Spirohexasal 100 mg - Tabletten	not available	1-19819	HEXAL PHARMA GMBH	AT
Spirolang 100 mg capsule rigide	not available	019913033	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IT
Spirolang 25 mg capsule rigide	not available	019913019	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IT
Spirolang 50 mg capsule rigide	not available	019913021	LABORATORIO FARMACEUTICO S.I.T. S.R.L.	IT
Spironol, 50 mg, tabletki powlekane	not available	22755	GEDEON RICHTER POLSKA SP. Z. O.O.	PL
Spirolactone 12.5 mg Film-coated Tablets	not available	PL 12762/0544	MERCURY PHARMACEUTICALS LTD.	XI
SPIRONOLACTONE BIOGARAN 25 mg, comprimé sécable	not available	3400939627748	BIOGARAN	FR
SPIRONOLACTONE BIOGARAN 25 mg, comprimé sécable	not available	3400934850738	BIOGARAN	FR
SPIRONOLACTONE BIOGARAN 25 mg, comprimé sécable	not available	3400934850677	BIOGARAN	FR
SPIRONOLACTONE BIOGARAN 25 mg, comprimé sécable	not available	3400956118205	BIOGARAN	FR

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
SPIRONOLACTONE BIOGARAN 25 mg, comprimé sécable	not available	3400955050919	BIOGARAN	FR
SPIRONOLACTONE BIOGARAN 25 mg, comprimé sécable	not available	3400930136492	BIOGARAN	FR
SPIRONOLACTONE BIOGARAN 50 mg, comprimé sécable	not available	3400937847469	BIOGARAN	FR
SPIRONOLACTONE BIOGARAN 50 mg, comprimé sécable	not available	3400934965913	BIOGARAN	FR
SPIRONOLACTONE BIOGARAN 50 mg, comprimé sécable	not available	3400934792564	BIOGARAN	FR
SPIRONOLACTONE BIOGARAN 50 mg, comprimé sécable	not available	3400956145867	BIOGARAN	FR
SPIRONOLACTONE BIOGARAN 50 mg, comprimé sécable	not available	3400930136508	BIOGARAN	FR
SPIRONOLACTONE BIOGARAN 50 mg, comprimé sécable	not available	340095050926	BIOGARAN	FR
SPIRONOLACTONE BIOGARAN 75 mg, comprimé sécable	not available	3400937847230	BIOGARAN	FR
SPIRONOLACTONE BIOGARAN 75 mg, comprimé sécable	not available	3400934847486	BIOGARAN	FR
SPIRONOLACTONE BIOGARAN 75 mg, comprimé sécable	not available	3400956145928	BIOGARAN	FR
SPIRONOLACTONE BIOGARAN 75 mg, comprimé sécable	not available	3400934792625	BIOGARAN	FR
Spironolactone Mylan 75mg, comprimé pelliculé	not available	NL 21265	MYLAN S.A.S	FR
SPIRONOLACTONE TABLETS BP 100mg	not available	PL 0142/0370	ACCORD-UK LIMITED	XI
SPIRONOLACTONE TABLETS BP 25mg	not available	PL 0142/0368	ACCORD-UK LIMITED	XI
SPIRONOLACTONE TABLETS BP 50mg	not available	PL 0142/0369	ACCORD-UK LIMITED	XI
SPIRONOLACTONE TEVA 50 mg, comprimé pelliculé sécable	not available	NL23358	TEVA SANTÉ	FR
SPIRONOLACTONE TEVA 75 mg, comprimé pelliculé sécable	not available	NL23360	TEVA SANTÉ	FR

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
SPIRONOLACTONE ZENTIVA 50 mg, comprimé sécable	not available	34009 367 380 5 8	ZENTIVA FRANCE	FR
SPIRONOLACTONE ZENTIVA 50 mg, comprimé sécable	not available	34009 378 749 5 3	ZENTIVA FRANCE	FR
SPIRONOLACTONE ZENTIVA 50 mg, comprimé sécable	not available	34009 367 379 7 6	ZENTIVA FRANCE	FR
SPIRONOLACTONE ZENTIVA 75 mg, comprimé sécable	not available	34009 367 382 8 7	ZENTIVA FRANCE	FR
SPIRONOLACTONE ZENTIVA 75 mg, comprimé sécable	not available	34009 367 381 1 9	ZENTIVA FRANCE	FR
SPIRONOLACTONE ZENTIVA 75 mg, comprimé sécable	not available	34009 378 750 3 5	ZENTIVA FRANCE	FR
Spironolakton Pfizer 100 mg tabletter	not available	9900	PFIZER AB	SE
Spironolakton Pfizer 25 mg tabletter	not available	9766	PFIZER AB	SE
Spironolakton Pfizer 50 mg tabletter	not available	9899	PFIZER AB	SE
URACTONE 100 mg compresse	not available	019408018	SPA – SOCIETÀ PRODOTTI ANTIBIOTICI S.P.A.	IT
Verospiron 100 mg kemény kapszula	not available	OGYI-T-3381/03	GEDEON RICHTER PLC.	HU
Verospiron 25 mg tablettá	not available	OGYI-T-3381/01	GEDEON RICHTER PLC.	HU
Verospiron 50 mg kemény kapszula	not available	OGYI-T-3381/04	GEDEON RICHTER PLC.	HU