



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 October 2018
EMA/775536/2018
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: spironolactone

Procedure no.: PSUSA/00002780/201803

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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 |
|---|-------------------------------------|--------------------------------------|---|---|
| SPIRONOLACTONE ZENTIVA 75 mg, comprimé sécable | not available | 34009 367 382 8 7 | SANOFI-AVENTIS FRANCE | FR |
| SPIRONOLACTONE ZENTIVA 75 mg, comprimé sécable | not available | 367 381-1 | SANOFI-AVENTIS FRANCE | FR |
| SPIRONOLACTONE ZENTIVA 50 mg, comprimé sécable | not available | 367 379-7 | SANOFI-AVENTIS FRANCE | FR |
| SPIRONOLACTONE ZENTIVA 75 mg, comprimé sécable | not available | 378 750-3 | SANOFI-AVENTIS FRANCE | FR |
| SPIRONOLACTONE ZENTIVA 50 mg, comprimé sécable | not available | 34009 367 380 5 8 | SANOFI-AVENTIS FRANCE | FR |
| SPIRONOLACTONE ZENTIVA 50 mg, comprimé sécable | not available | 378 749-5 | SANOFI-AVENTIS FRANCE | FR |
| Aldactone 100 mg compresse rivestite | not available | 019822030 | CHEPLAPHARM ARZNEIMITTEL GMBH | IT |
| Aldactone 25 mg capsule rigide | not available | 019822028 | CHEPLAPHARM ARZNEIMITTEL GMBH | IT |
| 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 |
| Aldactone® 100 100 mg Hartkapseln | not available | 6618622.00.01 | RIEMSER PHARMA GMBH | DE |
| Aldactone® 25 25 mg überzogene Tabletten | not available | 6618622.00.00 | RIEMSER PHARMA GMBH | DE |
| Aldactone® 50 50 mg | not available | 6618622.01.00 | RIEMSER PHARMA GMBH | DE |

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| überzogene Tabletten | | | | |
| Aldactone oblozene tablete 25 mg | not available | H/98/00135/001 | RIEMSER PHARMA GMBH | SI |
| SPIRONOLACTONE RPG 50 mg, comprimé | not available | NL 21 085 | RANBAXY PHARMACIE GENERIQUES | FR |
| SPIRONOLACTONE RPG 75 mg, comprimé | not available | NL 21086 | RANBAXY PHARMACIE GENERIQUES | FR |
| 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 |
| Aldactone oblozene tablete 50 mg | not available | H/98/00135/002 | RIEMSER PHARMA GMBH | SI |
| Aldactone 100 mg film-coated tablets | not available | PA 822/110/3 | PFIZER HEALTHCARE IRELAND | IE |
| Aldactone 50 mg Film-coated tablets | not available | PA 822/110/2 | PFIZER HEALTHCARE IRELAND | IE |
| Aldactone 25 mg film-coated tablets | not available | PA 822/110/1 | PFIZER HEALTHCARE IRELAND | IE |
| 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 |

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| mg, comprimé sécable | | | | |
| SPIRONOLACTONE BIOGARAN 75 mg, comprimé sécable | not available | 3400934792625 | BIOGARAN | FR |
| SPIRONOLACTONE TEVA 75 mg, comprimé pelliculé sécable | not available | NL23360 | TEVA SANTÉ | FR |
| SPIRONOLACTONE TEVA 50 mg, comprimé pelliculé sécable | not available | NL23358 | TEVA SANTÉ | FR |
| 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 |
| Spirolang 100 mg capsule rigide | not available | 019913033 | LABORATORIO FARMACEUTICO S.I.T. S.R.L. | IT |
| URACTONE 100 mg compresse | not available | 019408018 | SPA – SOCIETÀ PRODOTTI ANTIBIOTICI S.P.A. | IT |
| Spironolactone 25mg Tablets | not available | PL 20395/0125 | RELON CHEM LIMITED | UK |
| Aldactone 50 mg Filmtabletten | not available | 2009010114 | CONTINENTAL PHARMA, INC. | LU |
| Aldactone 25 mg filmomhulde tabletten | not available | BE033476 | CONTINENTAL PHARMA, INC. | BE |
| Aldactone 50 mg comprimés pelliculés | not available | BE177484 | CONTINENTAL PHARMA, INC. | BE |
| Aldactone 100 mg filmomhulde tabletten | not available | BE109024 | CONTINENTAL PHARMA, INC. | BE |
| Aldactone 25 mg comprimés | not available | BE033476 | CONTINENTAL PHARMA, | BE |

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| pelliculés | | | INC. | |
| Aldactone 25 mg Filmtabletten Spironolacton | not available | 2009010113 | CONTINENTAL PHARMA, INC. | LU |
| Aldactone 25 mg comprimés pelliculés | not available | 2009010113 | CONTINENTAL PHARMA, INC. | LU |
| Aldactone 100 mg Filmtabletten | not available | 2009010115 | CONTINENTAL PHARMA, INC. | LU |
| Aldactone 100 mg comprimés pelliculés | not available | 2009010115 | CONTINENTAL PHARMA, INC. | LU |
| Aldactone 50 mg comprimés pelliculés | not available | 2009010114 | CONTINENTAL PHARMA, INC. | LU |
| Aldactone 100 mg comprimés pelliculés | not available | BE109024 | CONTINENTAL PHARMA, INC. | BE |
| Aldactone 100 mg Filmtabletten | not available | BE109024 | CONTINENTAL PHARMA, INC. | BE |
| Aldactone 50 mg filmomhulde tabletten | not available | BE177484 | CONTINENTAL PHARMA, INC. | BE |
| Aldactone 50 mg Filmtabletten | not available | BE177484 | CONTINENTAL PHARMA, INC. | BE |
| Aldactone 25 mg Filmtabletten | not available | BE033476 | CONTINENTAL PHARMA, INC. | BE |
| 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 25 mg Film-coated Tablets | not available | MA505/00701 | PFIZER HELLAS, A.E. | MT |
| Aldactone 100 mg filmdrasjerte tabletter | not available | 6191 | PFIZER AS | NO |
| Aldactone 25 mg filmdrasjerte | not available | 4550 | PFIZER AS | NO |

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| tableter | | | | |
| Aldactone 50 mg filmdrasjerte tableter | not available | 6533 | PFIZER AS | NO |
| Spironolakton Pfizer 25 mg tableter | not available | 9766 | 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 100 mg comprimidos | not available | 4657599 | LABORATÓRIOS PFIZER, LDA. | PT |
| Spironolakton Pfizer 50 mg tableter | not available | 9899 | PFIZER AB | SE |
| Spironolakton Pfizer 100 mg tableter | not available | 9900 | PFIZER AB | SE |
| Aldactone 25 mg comprimidos | not available | 5726799 | LABORATÓRIOS PFIZER, LDA. | PT |
| Aldactone 100 mg comprimidos | not available | 9046714 | LABORATÓRIOS PFIZER, LDA. | PT |
| Aldactone 25 mg comprimidos recubiertos con película | not available | 39.059 | PFIZER, S.L. | ES |
| ALDACTONE 25 mg, comprimé sécable | not available | 34009 560 976 3 0 | PFIZER HOLDING FRANCE (S.C.A.) | FR |
| Aldactone 100 mg comprimidos recubiertos con película | not available | 54.900 | PFIZER, S.L. | ES |
| ALDACTONE 50 mg, comprimé | not available | 34009 552 457 0 4 | PFIZER HOLDING FRANCE | FR |

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| sécable | | | | |
| ALDACTONE 75 mg, comprimé sécable | not available | 34009 326 080 7 2 | 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 25 mg, comprimé sécable | not available | 34009 344 663 0 4 | PFIZER HOLDING FRANCE (S.C.A.) | FR |
| Aldactone 100 mg, filmdragerade tablettor | not available | 9357 | PFIZER AB | SE |
| Aldactone 25 mg, filmdragerade tablettor | not available | 7223 | PFIZER AB | SE |
| 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 |
| ALDACTONE 75 mg, comprimé sécable | not available | 34009 351 254 5 3 | PFIZER HOLDING FRANCE | FR |
| ALDACTONE 25 mg, comprimé sécable | not available | 34009 372 959 8 7 | PFIZER HOLDING FRANCE (S.C.A.) | FR |
| ALDACTONE 25 mg, comprimé sécable | not available | 34009 344 662 4 3 | PFIZER HOLDING FRANCE (S.C.A.) | FR |
| ALDACTONE 50 mg, comprimé sécable | not available | 34009 372 335 4 5 | PFIZER HOLDING FRANCE | FR |
| ALDACTONE 75 mg, comprimé sécable | not available | 34009 372 960 6 9 | PFIZER HOLDING FRANCE | FR |
| Aldactone 50 mg, filmdragerade | not available | 9519 | PFIZER AB | SE |

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| tabletter | | | | |
| Aldactone 100 mg Film-coated Tablets | not available | PL 00057/0927 | PFIZER LIMITED | UK |
| Aldactone 50 mg Film-coated Tablets | not available | PL 00057/0929 | PFIZER LIMITED | UK |
| Aldactone 25 mg Film-coated Tablets | not available | PL 00057/0928 | PFIZER LIMITED | UK |
| Spirohexal 100 mg - Tabletten | not available | 1-19819 | HEXAL PHARMA GMBH | AT |
| Spironol, 50 mg, tabletki powlekane | not available | 22755 | GEDEON RICHTER POLSKA SP. Z. O.O. | PL |
| Verospiron 100 mg kemény kapszula | not available | OGYI-T-3381/03 | GEDEON RICHTER PLC. | HU |
| Verospiron 100 mg tvrdé tobolky | not available | 50/028/00-C | GEDEON RICHTER PLC. | CZ |
| Verospiron 25 mg tableta | not available | OGYI-T-3381/01 | GEDEON RICHTER PLC. | HU |
| VEROSPIRON 25 mg tablety | not available | 50/512/92-S/C | GEDEON RICHTER PLC. | CZ |
| Verospiron 50 mg tvrdé kapsuly | not available | 50/0026/02-S | GEDEON RICHTER PLC. | SK |
| Verospiron 50 mg, tvrdé tobolky | not available | 50/029/00-C | GEDEON RICHTER PLC. | CZ |
| Verospiron | not available | 50/0512/92-S | GEDEON RICHTER PLC. | SK |
| Verospiron 100 mg tvrdé kapsuly | not available | 50/0027/02-S | GEDEON RICHTER PLC. | SK |
| Verospiron 50 mg kemény kapszula | not available | OGYI-T-3381/04 | GEDEON RICHTER PLC. | HU |
| Aldactone 100 mg kapsules | not available | H/98/00135/003 | RIEMSER PHARMA GMBH | SI |