



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

3 September 2020
EMA/476801/2020
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: amisulpride

Procedure no.: PSUSA/00000167/202001

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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 |
|--|-------------------------------------|--------------------------------------|---|---|
| Aktiprol 100 mg tabletes | DK/H/2386/002 | 15-0121 | MEDOCHEMIE LTD. | LV |
| AKTIPROL 400 mg tablete | DK/H/2386/003 | HR-H-558657784-01 | MEDOCHEMIE LTD. | HR |
| AKTIPROL 400 mg tablete | DK/H/2386/003 | HR-H-558657784-02 | MEDOCHEMIE LTD. | HR |
| AKTIPROL 400 mg tablete | DK/H/2386/003 | HR-H-558657784-03 | MEDOCHEMIE LTD. | HR |
| AKTIPROL 50 mg tablete | DK/H/2386/001 | HR-H-540991237-01 | MEDOCHEMIE LTD. | HR |
| AKTIPROL 50 mg tablete | DK/H/2386/001 | HR-H-540991237-02 | MEDOCHEMIE LTD. | HR |
| AKTIPROL 50 mg tablete | DK/H/2386/001 | HR-H-540991237-03 | MEDOCHEMIE LTD. | HR |
| Aktiprol 50 mg tabletes | DK/H/2386/001 | 15-0120 | MEDOCHEMIE LTD. | LV |
| Aktiprol 50mg δισκία | DK/H/2386/001 | 022276 | MEDOCHEMIE LTD. | CY |

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|---|-------------------------------------|--------------------------------------|---|---|
| Aktiprol, tableter | DK/H/2386/004 | 53966 | MEDOCHEMIE LTD. | DK |
| Amisulprid HEXAL 50 mg Tabletten | not available | 37872.00.00 | HEXAL AG | DE |
| Amisulprid PUREN 50 mg Tabletten | PT/H/1511/001 | 95879.00.00 | PUREN PHARMA GMBH & CO. KG | DE |
| Amisulprida Zentiva 100 mg comprimidos EFG | not available | 63.997 | ZENTIVA, K.S. | ES |
| Amisulprida Zentiva 200 mg comprimidos EFG | not available | 63.998 | ZENTIVA, K.S. | ES |
| Amisulprida Zentiva 400 mg comprimidos recubiertos con película EFG | not available | 63.999 | ZENTIVA, K.S. | ES |
| Amisulpride 100 mg Tablets | not available | PL 17780/0013 | ZENTIVA PHARMA UK LIMITED | UK |
| Amisulpride 200 mg Tablets | not available | PL 17780/0014 | ZENTIVA PHARMA UK LIMITED | UK |
| Amisulpride 400 mg Tablets | not available | PL 17780/0015 | ZENTIVA PHARMA UK LIMITED | UK |

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|---|-------------------------------------|--------------------------------------|---|---|
| Amisulpride 50 mg Tablets | not available | PL 17780/0012 | ZENTIVA PHARMA UK LIMITED | UK |
| Amisulpride 50 mg Tablets | not available | PL 17780/0012 | ZENTIVA PHARMA UK LIMITED | UK |
| AMISULPRIDE ARROW 100 mg, comprimé sécable | not available | NL29364 | ARROW GENERIQUES | FR |
| AMISULPRIDE ARROW 400 mg, comprimé pelliculé sécable | not available | NL30482 | ARROW GENERIQUES | FR |
| AMISULPRIDE EG 100 mg, comprimé sécable | FR/H/0271/002 | NL29224 | EG LABO LABORATOIRES EUROGENERICS | FR |
| AMISULPRIDE EG 200 mg, comprimé sécable | FR/H/0271/003 | NL28776 | EG LABO LABORATOIRES EUROGENERICS | FR |
| AMISULPRIDE EG 400 mg, comprimé pelliculé sécable | FR/H/0271/004 | NL29225 | EG LABO LABORATOIRES EUROGENERICS | FR |
| AMISULPRIDE EG 50 mg, comprimé sécable | FR/H/0271/001 | NL28401 | EG LABO LABORATOIRES EUROGENERICS | FR |
| AMISULPRIDE MYLAN 100 mg, comprimé sécable | not available | NL 29221 | MYLAN S.A.S | FR |

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|--|-------------------------------------|--------------------------------------|---|---|
| Amisulpride Mylan 400 mg, comprimé pelliculé sécable | not available | NL 28 096 | MYLAN S.A.S | FR |
| AMISULPRIDE TEVA 100 mg, comprimé sécable | not available | NL30425 | TEVA SANTÉ | FR |
| AMISULPRIDE TEVA 400 mg, comprimé pelliculé sécable | not available | NL30702 | TEVA SANTÉ | FR |
| AMISULPRIDE ZENTIVA 100 mg, comprimé sécable | not available | 34009 367 424 2 0 | ZENTIVA FRANCE | FR |
| AMISULPRIDE ZENTIVA 100 mg, comprimé sécable | not available | 34009 565 440 4 2 | ZENTIVA FRANCE | FR |
| AMISULPRIDE ZENTIVA 200 mg, comprimé sécable | not available | 34009 367 425 9 8 | ZENTIVA FRANCE | FR |
| AMISULPRIDE ZENTIVA 200 mg, comprimé sécable | not available | 34009 565 441 0 3 | ZENTIVA FRANCE | FR |
| AMISULPRIDE ZENTIVA 400 mg, comprimé pelliculé sécable | not available | 34009 365 581 3 7 | ZENTIVA FRANCE | FR |
| AMISULPRIDE ZENTIVA 400 mg, comprimé pelliculé sécable | not available | 34009 535 980 9 0 | ZENTIVA FRANCE | FR |

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|--|-------------------------------------|--------------------------------------|---|---|
| AMISULPRIDE ZENTIVA 400 mg, comprimé pelliculé sécable | not available | 34009 365 580 7 6 | ZENTIVA FRANCE | FR |
| AmisulpridLich 100 mg Tabletten | not available | 37875.02.00 | WINTHROP ARZNEIMITTEL GMBH | DE |
| AmisulpridLich 200 mg Tabletten | not available | 37875.01.00 | WINTHROP ARZNEIMITTEL GMBH | DE |
| AmisulpridLich 400 mg Filmtabletten | not available | 37875.00.01 | WINTHROP ARZNEIMITTEL GMBH | DE |
| AmisulpridLich 50 mg Tabletten | not available | 37875.00.00 | WINTHROP ARZNEIMITTEL GMBH | DE |
| AMITREX 100 mg tabletta | not available | OGYI-T-8231/01 | SANOFI-AVENTIS ZRT | HU |
| AMITREX 100 mg tabletta | not available | OGYI-T-8231/03 | SANOFI-AVENTIS ZRT | HU |
| AMITREX 100 mg tabletta | not available | OGYI-T-8231/02 | SANOFI-AVENTIS ZRT | HU |
| AMITREX 200 MG TABLETTA | not available | OGYI-T-8231/05 | SANOFI-AVENTIS ZRT | HU |

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|--|-------------------------------------|--------------------------------------|---|---|
| AMITREX 200 MG TABLETTA | not available | OGYI-T-8231/04 | SANOFI-AVENTIS ZRT | HU |
| AMITREX 200 MG TABLETTA | not available | OGYI-T-8231/06 | SANOFI-AVENTIS ZRT | HU |
| Amitrex 400 mg filmtabletta | not available | OGYI-T-8231/09 | SANOFI-AVENTIS ZRT | HU |
| Amitrex 400 mg filmtabletta | not available | OGYI-T-8231/07 | SANOFI-AVENTIS ZRT | HU |
| Amitrex 400 mg filmtabletta | not available | OGYI-T-8231/08 | SANOFI-AVENTIS ZRT | HU |
| DENIBAN | not available | 30/013/01-C | SANOFI-AVENTIS SRO | CZ |
| DENIBAN | not available | 30/013/01-C | SANOFI-AVENTIS SRO | CZ |
| DENIBAN 50 mg compresse | not available | 027491012 | SANOFI S.P.A | IT |
| Socian 50 mg comprimidos | not available | 9613422 | SANOFI - PRODUTOS FARMACEUTICOS LDA | PT |

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|--|-------------------------------------|--------------------------------------|---|---|
| Socian 50 mg comprimidos | not available | 9613406 | SANOFI - PRODUTOS FARMACEUTICOS LDA | PT |
| Socian 50 mg/10 ml solução oral | not available | 9672808 | SANOFI - PRODUTOS FARMACEUTICOS LDA | PT |
| SOLIAN | not available | 20095 | SANOFI-AVENTIS CYPRUS LTD | CY |
| SOLIAN | not available | 18669 | SANOFI A/S | DK |
| SOLIAN | not available | 18669 | SANOFI A/S | DK |
| SOLIAN | not available | 18670 | SANOFI A/S | DK |
| SOLIAN | not available | 18670 | SANOFI A/S | DK |
| SOLIAN | not available | 2958/24-01-02 | SANOFI-AVENTIS AEBE | GR |
| SOLIAN | not available | 63423/01-12-03 | SANOFI-AVENTIS AEBE | GR |

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| SOLIAN | not available | 2959/24-01-02 | SANOFI-AVENTIS AEBE | GR |
| SOLIAN | not available | 2959/24-01-02 | SANOFI-AVENTIS AEBE | GR |
| SOLIAN | not available | 2958/24-01-02 | SANOFI-AVENTIS AEBE | GR |
| SOLIAN | not available | 2959/24-01-02 | SANOFI-AVENTIS AEBE | GR |
| SOLIAN | not available | 2958/24-01-02 | SANOFI-AVENTIS AEBE | GR |
| SOLIAN 100 | not available | PL 04425/0651 | AVENTIS PHARMA LTD | UK |
| SOLIAN 100 | not available | PL 04425/0651 | AVENTIS PHARMA LTD | UK |
| SOLIAN 100 | not available | PL 04425/0651 | AVENTIS PHARMA LTD | UK |
| SOLIAN 100 COMPRIME | not available | 0335985 | SANOFI BELGIUM | LU |

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|--|-------------------------------------|--------------------------------------|---|---|
| SOLIAN 100 COMPRIME | not available | 0335971 | SANOFI BELGIUM | LU |
| SOLIAN 100 COMPRIME | not available | 0336013 | SANOFI BELGIUM | LU |
| SOLIAN 100 COMPRIME | not available | 0335999 | SANOFI BELGIUM | LU |
| SOLIAN 100 COMPRIME | not available | 0335968 | SANOFI BELGIUM | LU |
| SOLIAN 100 mg COMPRESSE | not available | 033462019 | SANOFI S.P.A | IT |
| SOLIAN 100 MG COMPRIMIDOS | not available | 63.994 | SANOFI-AVENTIS, S.A. | ES |
| Solian 100 mg tablete | not available | H/03/01437/001 | SANOFI-AVENTIS D.O.O. | SI |
| Solian 100 mg Tabletten | not available | BE230106 | SANOFI BELGIUM | BE |
| Solian 100 mg Tabletten | not available | BE230106 | SANOFI BELGIUM | BE |

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|--|-------------------------------------|--------------------------------------|---|---|
| Solian 100 mg Tabletten | not available | BE230106 | SANOFI BELGIUM | BE |
| Solian 100 mg Tabletten | not available | BE230106 | SANOFI BELGIUM | BE |
| Solian 100 mg Tabletten | not available | BE230106 | SANOFI BELGIUM | BE |
| SOLIAN 100 MG TABLETTE | not available | 37869.02.00 | SANOFI-AVENTIS DEUTSCHLAND GMBH | DE |
| SOLIAN 100 MG TABLETTE | not available | 37869.02.00 | SANOFI-AVENTIS DEUTSCHLAND GMBH | DE |
| SOLIAN 100 MG TABLETTE | not available | 37869.02.00 | SANOFI-AVENTIS DEUTSCHLAND GMBH | DE |
| SOLIAN 100 MG TABLETTE | not available | 37869.02.00 | SANOFI-AVENTIS DEUTSCHLAND GMBH | DE |
| SOLIAN 100 MG TABLETTE | not available | 37869.02.00 | SANOFI-AVENTIS DEUTSCHLAND GMBH | DE |
| Solian 100 mg tablety | not available | 68/0200/00-S | SANOFI-AVENTIS SLOVAKIA SRO | SK |

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|--|-------------------------------------|--------------------------------------|---|---|
| Solian 100 mg tablety | not available | 68/0200/00-S | SANOFI-AVENTIS SLOVAKIA SRO | SK |
| Solian 100 mg tablety | not available | 68/0200/00-S | SANOFI-AVENTIS SLOVAKIA SRO | SK |
| Solian 100 mg tablety | not available | 68/0200/00-S | SANOFI-AVENTIS SLOVAKIA SRO | SK |
| SOLIAN 100 MG, COMPRIME SECABLE | not available | 34009 351 477 4 5 | SANOFI-AVENTIS FRANCE | FR |
| SOLIAN 100 MG, COMPRIME SECABLE | not available | 34009 561 312 1 1 | SANOFI-AVENTIS FRANCE | FR |
| SOLIAN 100 MG, COMPRIME SECABLE | not available | 34009 576 662 3 1 | SANOFI-AVENTIS FRANCE | FR |
| SOLIAN 100 MG, COMPRIME SECABLE | not available | 34009 348 747 4 1 | SANOFI-AVENTIS FRANCE | FR |
| SOLIAN 100 mg, comprimés | not available | BE230106 | SANOFI BELGIUM | BE |
| SOLIAN 100 mg, comprimés | not available | BE230106 | SANOFI BELGIUM | BE |

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| SOLIAN 100 mg, comprimés | not available | BE230106 | SANOFI BELGIUM | BE |
| SOLIAN 100 mg, comprimés | not available | BE230106 | SANOFI BELGIUM | BE |
| SOLIAN 100 mg, comprimés | not available | BE230106 | SANOFI BELGIUM | BE |
| SOLIAN 100 mg, tabletten | not available | BE230106 | SANOFI BELGIUM | BE |
| SOLIAN 100 mg, tabletten | not available | BE230106 | SANOFI BELGIUM | BE |
| SOLIAN 100 mg, tabletten | not available | BE230106 | SANOFI BELGIUM | BE |
| SOLIAN 100 mg, tabletten | not available | BE230106 | SANOFI BELGIUM | BE |
| SOLIAN 100 mg, tabletten | not available | BE230106 | SANOFI BELGIUM | BE |
| Solian 100 mg/ml Lösung zum Einnehmen | not available | BE263767 | SANOFI BELGIUM | BE |

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| Solian 100 mg/ml šķīdums iekšķīgai lietošanai | not available | 09-0346 | SANOFI-AVENTIS LATVIA SIA | LV |
| SOLIAN 100 MG/ML SOLUCION ORAL | not available | 65.991 | SANOFI-AVENTIS, S.A. | ES |
| SOLIAN 100 MG/ML TROPFEN | not available | 1-24891 | SANOFI-AVENTIS GMBH OSTERREICH | AT |
| SOLIAN 100 MG/ML TROPFEN | not available | 1-24891 | SANOFI-AVENTIS GMBH OSTERREICH | AT |
| SOLIAN 100 MG/ML TROPFEN | not available | 1-24891 | SANOFI-AVENTIS GMBH OSTERREICH | AT |
| Solian 100 mg/ml, drank | not available | BE263767 | SANOFI BELGIUM | BE |
| Solian 100 mg/ml, solution buvable | not available | BE263767 | SANOFI BELGIUM | BE |
| SOLIAN 100 MG/ML, SOLUTION BUVABLE | not available | 34009 352 870 1 4 | SANOFI-AVENTIS FRANCE | FR |
| SOLIAN 100 MG/ML, SOLUTION BUVABLE | not available | 0446291 | SANOFI BELGIUM | LU |

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|--|-------------------------------------|--------------------------------------|---|---|
| SOLIAN 100MG TABLETS | not available | PA 540/158/2 | SANOFI-AVENTIS IRELAND LTD. T/A SANOFI | IE |
| SOLIAN 100MG TABLETS | not available | PA 540/158/2 | SANOFI-AVENTIS IRELAND LTD. T/A SANOFI | IE |
| SOLIAN 100MG TABLETS | not available | PA 540/158/2 | SANOFI-AVENTIS IRELAND LTD. T/A SANOFI | IE |
| SOLIAN 200 | not available | PL 04425/0652 | AVENTIS PHARMA LTD | UK |
| SOLIAN 200 | not available | PL 04425/0652 | AVENTIS PHARMA LTD | UK |
| SOLIAN 200 | not available | PL 04425/0652 | AVENTIS PHARMA LTD | UK |
| SOLIAN 200 | not available | PL 04425/0652 | AVENTIS PHARMA LTD | UK |
| SOLIAN 200 | not available | PL 04425/0652 | AVENTIS PHARMA LTD | UK |
| SOLIAN 200 mg COMPRESSE | not available | 033462021 | SANOFI S.P.A | IT |

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|--|-------------------------------------|--------------------------------------|---|---|
| Solian 200 mg comprimate | not available | 9817/2017/01 | SANOFI ROMANIA SRL | RO |
| SOLIAN 200 MG COMPRIMIDOS | not available | 63995 | SANOFI-AVENTIS, S.A. | ES |
| SOLIAN 200 MG TABLETE | not available | HR-H-345193647-01 | SANOFI-AVENTIS CROATIA D.O.O. | HR |
| SOLIAN 200 MG TABLETE | not available | H/03/01437/002 | SANOFI-AVENTIS D.O.O. | SI |
| SOLIAN 200 mg tabletes | not available | 99-0625 | SANOFI-AVENTIS LATVIA SIA | LV |
| SOLIAN 200 MG TABLETS | not available | 99-0625 | SANOFI-AVENTIS LATVIA SIA | LV |
| SOLIAN 200 MG TABLETS | not available | 99-0625 | SANOFI-AVENTIS LATVIA SIA | LV |
| SOLIAN 200 MG TABLETS | not available | 99-0625 | SANOFI-AVENTIS LATVIA SIA | LV |
| SOLIAN 200 MG TABLETS | not available | 99-0625 | SANOFI-AVENTIS LATVIA SIA | LV |

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| SOLIAN 200 MG TABLETTEN | not available | 1-20500 | SANOFI-AVENTIS GMBH OSTERREICH | AT |
| SOLIAN 200 MG TABLETTEN | not available | 1-20500 | SANOFI-AVENTIS GMBH OSTERREICH | AT |
| SOLIAN 200 MG TABLETTEN | not available | 1-20500 | SANOFI-AVENTIS GMBH OSTERREICH | AT |
| Solian 200 mg Tabletten | not available | BE 201494 | SANOFI BELGIUM | BE |
| Solian 200 mg Tabletten | not available | BE 201494 | SANOFI BELGIUM | BE |
| SOLIAN 200 MG TABLETTEN | not available | 37869.01.00 | SANOFI-AVENTIS DEUTSCHLAND GMBH | DE |
| SOLIAN 200 MG TABLETTEN | not available | 37869.01.00 | SANOFI-AVENTIS DEUTSCHLAND GMBH | DE |
| SOLIAN 200 MG TABLETTEN | not available | 37869.01.00 | SANOFI-AVENTIS DEUTSCHLAND GMBH | DE |
| SOLIAN 200 MG TABLETTEN | not available | 37869.01.00 | SANOFI-AVENTIS DEUTSCHLAND GMBH | DE |

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| SOLIAN 200 MG TABLETTEN | not available | 37869.01.00 | SANOFI-AVENTIS DEUTSCHLAND GMBH | DE |
| Solian 200 mg tableter | not available | 97-3715 | SANOFI-AVENTIS NORGE AS | NO |
| Solian 200 mg tableter | not available | 97-3715 | SANOFI-AVENTIS NORGE AS | NO |
| Solian 200 mg tablety | not available | 68/459/99-C | SANOFI-AVENTIS SRO | CZ |
| Solian 200 mg tablety | not available | 68/459/99-C | SANOFI-AVENTIS SRO | CZ |
| Solian 200 mg tablety | not available | 68/459/99-C | SANOFI-AVENTIS SRO | CZ |
| Solian 200 mg tablety | not available | 68/0201/00-S | SANOFI-AVENTIS SLOVAKIA SRO | SK |
| Solian 200 mg tablety | not available | 68/0201/00-S | SANOFI-AVENTIS SLOVAKIA SRO | SK |
| Solian 200 mg tablety | not available | 68/0201/00-S | SANOFI-AVENTIS SLOVAKIA SRO | SK |

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| Solian 200 mg tablety | not available | 68/0201/00-S | SANOFI-AVENTIS SLOVAKIA SRO | SK |
| Solian 200 mg töflur | not available | 990153 | SANOFI-AVENTIS NORGE AS | IS |
| Solian 200 mg töflur | not available | 990153 | SANOFI-AVENTIS NORGE AS | IS |
| SOLIAN 200 MG, COMPRIME SECABLE | not available | 34009 556 654 5 8 | SANOFI-AVENTIS FRANCE | FR |
| SOLIAN 200 MG, COMPRIME SECABLE | not available | 34009 576 789 3 7 | SANOFI-AVENTIS FRANCE | FR |
| SOLIAN 200 MG, COMPRIME SECABLE | not available | 34009 347 362 1 6 | SANOFI-AVENTIS FRANCE | FR |
| SOLIAN 200 MG, COMPRIME SECABLE | not available | 34009 328 444 6 3 | SANOFI-AVENTIS FRANCE | FR |
| SOLIAN 200 MG, COMPRIME SECABLE | not available | 34009 334 385 8 6 | SANOFI-AVENTIS FRANCE | FR |
| SOLIAN 200 mg, comprimés | not available | BE201494 | SANOFI BELGIUM | BE |

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|--|-------------------------------------|--------------------------------------|---|---|
| SOLIAN 200 mg, comprimés | not available | BE201494 | SANOFI BELGIUM | BE |
| SOLIAN 200 mg, tabletten | not available | BE201494 | SANOFI BELGIUM | BE |
| SOLIAN 200 mg, tabletten | not available | BE201494 | SANOFI BELGIUM | BE |
| SOLIAN 200 MG/4 ML, SOLUTION INJECTABLE | not available | 34009 332 208 1 5 | SANOFI-AVENTIS FRANCE | FR |
| Solian 200 mg tabletės | not available | LT/1/98/0282/002 | UAB SANOFI-AVENTIS LIETUVA | LT |
| SOLIAN 200MG COMPRIMES | not available | 0265846 | SANOFI BELGIUM | LU |
| SOLIAN 200MG COMPRIMES | not available | 0265832 | SANOFI BELGIUM | LU |
| SOLIAN 200MG TABLETS | not available | PA 540/158/3 | SANOFI-AVENTIS IRELAND LTD. T/A SANOFI | IE |
| Solian 200mg Tablets | not available | PA 540/158/3 | SANOFI-AVENTIS IRELAND LTD. T/A SANOFI | IE |

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| SOLIAN 200MG TABLETS | not available | PA 540/158/3 | SANOFI-AVENTIS IRELAND LTD. T/A SANOFI | IE |
| SOLIAN 200MG TABLETS | not available | PA 540/158/3 | SANOFI-AVENTIS IRELAND LTD. T/A SANOFI | IE |
| SOLIAN 200MG TABLETS | not available | PA 540/158/3 | SANOFI-AVENTIS IRELAND LTD. T/A SANOFI | IE |
| SOLIAN 400 | not available | PL 04425/0653 | AVENTIS PHARMA LTD | UK |
| SOLIAN 400 | not available | PL 04425/0653 | AVENTIS PHARMA LTD | UK |
| SOLIAN 400 | not available | PL 04425/0653 | AVENTIS PHARMA LTD | UK |
| Solian 400 mg apvalkotās tabletes | not available | 02-0276 | SANOFI-AVENTIS LATVIA SIA | LV |
| Solian 400 mg apvalkotās tabletes | not available | 02-0276 | SANOFI-AVENTIS LATVIA SIA | LV |
| Solian 400 mg apvalkotās tabletes | not available | 02-0276 | SANOFI-AVENTIS LATVIA SIA | LV |

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| SOLIAN 400 mg COMPRESSE RIVESTITE | not available | 033462045 | SANOFI S.P.A | IT |
| Solian 400 mg comprimato filmate | not available | 722/2008/01 | SANOFI ROMANIA SRL | RO |
| Solian 400 mg comprimidos recubiertos con película | not available | 63.996 | SANOFI-AVENTIS, S.A. | ES |
| Solian 400 mg filmom obalené tablety | not available | 68/0202/00-S | SANOFI-AVENTIS SLOVAKIA SRO | SK |
| Solian 400 mg filmom obalené tablety | not available | 68/0202/00-S | SANOFI-AVENTIS SLOVAKIA SRO | SK |
| Solian 400 mg filmom obalené tablety | not available | 68/0202/00-S | SANOFI-AVENTIS SLOVAKIA SRO | SK |
| Solian 400 mg filmom obalené tablety | not available | 68/0202/00-S | SANOFI-AVENTIS SLOVAKIA SRO | SK |
| SOLIAN 400 MG FILMSKO OBLOZENE TABLETE | not available | H/03/01437/003 | SANOFI-AVENTIS D.O.O. | SI |
| SOLIAN 400 MG FILMTABLETTEN | not available | 1-24890 | SANOFI-AVENTIS GMBH OSTERREICH | AT |

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|--|-------------------------------------|--------------------------------------|---|---|
| Solian 400 mg Filmtabletten | not available | 1-24890 | SANOFI-AVENTIS GMBH OSTERREICH | AT |
| Solian 400 mg Filmtabletten | not available | BE 230115 | SANOFI BELGIUM | BE |
| Solian 400 mg Filmtabletten | not available | BE 230115 | SANOFI BELGIUM | BE |
| Solian 400 mg Filmtabletten | not available | BE 230115 | SANOFI BELGIUM | BE |
| SOLIAN 400 MG FILMTABLETTEN | not available | 37869.00.01 | SANOFI-AVENTIS DEUTSCHLAND GMBH | DE |
| SOLIAN 400 MG FILMTABLETTEN | not available | 37869.00.01 | SANOFI-AVENTIS DEUTSCHLAND GMBH | DE |
| SOLIAN 400 MG FILMTABLETTEN | not available | 37869.00.01 | SANOFI-AVENTIS DEUTSCHLAND GMBH | DE |
| SOLIAN 400 MG FILMTABLETTEN | not available | 37869.00.01 | SANOFI-AVENTIS DEUTSCHLAND GMBH | DE |
| SOLIAN 400 MG FILMTABLETTEN | not available | 37869.00.01 | SANOFI-AVENTIS DEUTSCHLAND GMBH | DE |

| 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 |
|--|-------------------------------------|--------------------------------------|---|---|
| Solian 400 mg tableter, filmdrasjerte | not available | 98-5801 | SANOFI-AVENTIS NORGE AS | NO |
| Solian 400 mg tableter, filmdrasjerte | not available | 98-5801 | SANOFI-AVENTIS NORGE AS | NO |
| SOLIAN 400 MG, COMPRIME PELLICULE SECABLE | not available | 34009 351 207 7 9 | SANOFI-AVENTIS FRANCE | FR |
| SOLIAN 400 MG, COMPRIME PELLICULE SECABLE | not available | 34009 576 788 7 6 | SANOFI-AVENTIS FRANCE | FR |
| SOLIAN 400 MG, COMPRIME PELLICULE SECABLE | not available | 34009 561 313 8 9 | SANOFI-AVENTIS FRANCE | FR |
| SOLIAN 400 MG, COMPRIME PELLICULE SECABLE | not available | 34009 348 748 0 2 | SANOFI-AVENTIS FRANCE | FR |
| SOLIAN 400 MG, COMPRIME PELLICULE SECABLE | not available | 0336044 | SANOFI BELGIUM | LU |
| SOLIAN 400 MG, COMPRIME PELLICULE SECABLE | not available | 0336027 | SANOFI BELGIUM | LU |
| SOLIAN 400 MG, COMPRIME PELLICULE SECABLE | not available | 0336031 | SANOFI 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 |
|--|-------------------------------------|--------------------------------------|---|---|
| SOLIAN 400 mg, comprimés pelliculés | not available | BE230115 | SANOFI BELGIUM | BE |
| SOLIAN 400 mg, comprimés pelliculés | not available | BE230115 | SANOFI BELGIUM | BE |
| SOLIAN 400 mg, comprimés pelliculés | not available | BE230115 | SANOFI BELGIUM | BE |
| SOLIAN 400 mg, filmomhulde tabletten | not available | BE230115 | SANOFI BELGIUM | BE |
| SOLIAN 400 mg, filmomhulde tabletten | not available | BE230115 | SANOFI BELGIUM | BE |
| SOLIAN 400 mg, filmomhulde tabletten | not available | BE230115 | SANOFI BELGIUM | BE |
| Solian 400 mg plėvele dengtos tabletės | not available | LT/1/98/0282/004 | UAB SANOFI-AVENTIS LIETUVA | LT |
| SOLIAN 400MG FILM-COATED TABLETS | not available | PA 540/158/4 | SANOFI-AVENTIS IRELAND LTD. T/A SANOFI | IE |
| SOLIAN 400MG FILM-COATED TABLETS | not available | PA 540/158/4 | SANOFI-AVENTIS IRELAND LTD. T/A SANOFI | IE |

| 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 |
|--|-------------------------------------|--------------------------------------|---|---|
| SOLIAN 400MG FILM-COATED TABLETS | not available | PA 540/158/4 | SANOFI-AVENTIS IRELAND LTD. T/A SANOFI | IE |
| SOLIAN 50 MG TABLETTE | not available | 1-20499 | SANOFI-AVENTIS GMBH OSTERREICH | AT |
| SOLIAN 50 MG TABLETTE | not available | 1-20499 | SANOFI-AVENTIS GMBH OSTERREICH | AT |
| SOLIAN 50 MG TABLETTE | not available | 1-20499 | SANOFI-AVENTIS GMBH OSTERREICH | AT |
| Solian 50 mg Tabletten | not available | BE201485 | SANOFI BELGIUM | BE |
| Solian 50 mg Tabletten | not available | BE201485 | SANOFI BELGIUM | BE |
| Solian 50 mg tablett | not available | 97-3714 | SANOFI-AVENTIS NORGE AS | NO |
| Solian 50 mg tablett | not available | 97-3714 | SANOFI-AVENTIS NORGE AS | NO |
| Solian 50 mg töflur | not available | 990152 | SANOFI-AVENTIS NORGE AS | IS |

| 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 |
|--|-------------------------------------|--------------------------------------|---|---|
| Solian 50 mg töflur | not available | 990152 | SANOFI-AVENTIS NORGE AS | IS |
| SOLIAN 50 MG, COMPRIME | not available | 34009 328 445 2 4 | SANOFI-AVENTIS FRANCE | FR |
| SOLIAN 50 MG, COMPRIME | not available | 3400955665519 | SANOFI-AVENTIS FRANCE | FR |
| SOLIAN 50 MG, COMPRIME | not available | 34009 346 589 2 1 | SANOFI-AVENTIS FRANCE | FR |
| SOLIAN 50 mg, comprimés | not available | BE201485 | SANOFI BELGIUM | BE |
| SOLIAN 50 mg, comprimés | not available | BE201485 | SANOFI BELGIUM | BE |
| SOLIAN 50 mg, tabletten | not available | BE201485 | SANOFI BELGIUM | BE |
| SOLIAN 50 mg, tabletten | not available | BE201485 | SANOFI BELGIUM | BE |
| Solian 50 mg tabletės | not available | LT/1/98/0282/001 | UAB SANOFI-AVENTIS LIETUVA | LT |

| 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 |
|--|-------------------------------------|--------------------------------------|---|---|
| SOLIAN 50MG COMPRIMES | not available | 0265863 | SANOFI BELGIUM | LU |
| SOLIAN 50MG COMPRIMES | not available | 0265877 | SANOFI BELGIUM | LU |
| SOLIAN 50MG TABLETS | not available | PA 540/158/1 | SANOFI-AVENTIS IRELAND LTD. T/A SANOFI | IE |
| SOLIAN 50MG TABLETS | not available | PA 540/158/1 | SANOFI-AVENTIS IRELAND LTD. T/A SANOFI | IE |
| SOLIAN 50MG TABLETS | not available | PA 540/158/1 | SANOFI-AVENTIS IRELAND LTD. T/A SANOFI | IE |
| SOLIAN 50MG TABLETS | not available | PA 540/158/1 | SANOFI-AVENTIS IRELAND LTD. T/A SANOFI | IE |
| Solian Lösung, 100 mg/ml Lösung zum Einnehmen | not available | 48617.00.00 | SANOFI-AVENTIS DEUTSCHLAND GMBH | DE |
| Solian Lösung, 100 mg/ml Lösung zum Einnehmen | not available | 48617.00.00 | SANOFI-AVENTIS DEUTSCHLAND GMBH | DE |
| Solian Lösung, 100 mg/ml Lösung zum Einnehmen | not available | 48617.00.00 | SANOFI-AVENTIS DEUTSCHLAND GMBH | DE |

| 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 |
|--|-------------------------------------|--------------------------------------|---|---|
| Solian Lösung, 100 mg/ml Lösung zum Einnehmen | not available | 48617.00.00 | SANOFI-AVENTIS DEUTSCHLAND GMBH | DE |
| Solian Lösung, 100 mg/ml Lösung zum Einnehmen | not available | 48617.00.00 | SANOFI-AVENTIS DEUTSCHLAND GMBH | DE |
| SOLIAN, 100 mg, tabletki | not available | 8408 | SANOFI-AVENTIS FRANCE | PL |
| Solian, 200 mg tabletid | not available | 324400 | SANOFI-AVENTIS ESTONIA OÜ | EE |
| Solian, 200 mg tabletid | not available | 324400 | SANOFI-AVENTIS ESTONIA OÜ | EE |
| SOLIAN, 200 mg, tabletki | not available | 8409 | SANOFI-AVENTIS FRANCE | PL |
| SOLIAN, 200 mg, tabletki | not available | 8409 | SANOFI-AVENTIS FRANCE | PL |
| SOLIAN, 400 mg, tabletki powlekane | not available | 8410 | SANOFI-AVENTIS FRANCE | PL |
| SULAMID 50 mg compresse | not available | 027547013 | SANOFI S.P.A | IT |

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|--|-------------------------------------|--------------------------------------|---|---|
| Sulamid 50mg tablets | not available | 022361 | CODAL SYNTO LTD | CY |
| СОЛИАН 400 mg филмирани таблетки | not available | 20010129 | SANOFI BULGARIA EOOD | BG |