



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 May 2019
EMA/296287/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: mirtazapine

Procedure no.: PSUSA/00002068/201808

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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 |
|--|------------------------------|-------------------------------|------------------------------------|--|
| Mirtazapin Sandoz 15 mg szájban diszpergálódó tabletta | NL/H/0711/001 | OGYI-T-20584/01 | SANDOZ HUNGÁRIA KFT | HU |
| Mirtazapin Sandoz 15 mg szájban diszpergálódó tabletta | NL/H/0711/001 | OGYI-T-20584/02 | SANDOZ HUNGÁRIA KFT | HU |
| Mirtazapine 15 mg orodispersible tablets | not available | PL 36687/0319 | TORRENT PHARMA (UK) LTD. | UK |
| Mirtazapine 30 mg orodispersible tablets | not available | PL 36687/0320 | TORRENT PHARMA (UK) LTD. | UK |
| Mirtazapine 45 mg orodispersible tablets | not available | PL 36687/0321 | TORRENT PHARMA (UK) LTD. | UK |
| Mirtazapine 30 mg orodispersible tablets | not available | PL 21880/0108 | MEDREICH PLC | UK |
| Mirtazapine 15 mg orodispersible tablets | not available | PL 21880/0107 | MEDREICH PLC | UK |
| Mirtazapine 15 mg film-coated tablets | not available | PL 21880/0053 | MEDREICH PLC | UK |
| Mirtazapine 45 mg orodispersible tablets | not available | PL 21880/0109 | MEDREICH PLC | UK |
| Mirtazapine 45 mg film-coated tablets | not available | PL 21880/0055 | MEDREICH PLC | UK |
| MIRTAZAPINE EG 15 mg, comprimé pelliculé | not available | NL30913 | EG LABO LABORATOIRES EUROGENERICS | FR |
| Mirtazapine 15 PCH, filmomhulde tabletten 15 mg | not available | RVG 31844 | PHARMACHEMIE B.V | NL |
| MIRTAZAPINE/MYLAN 45 mg Επικαλυμμένα με λεπτό υμένιο δισκία | DE/H/4373/003 | 18662/ 15 / 02-06-2016 | MYLAN S.A.S | GR |
| Mirtazapin dura 15 mg | DE/H/4373/001 | 59878.00.00 | MYLAN DURA GMBH | DE |

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| Filmtabletten | | | | |
| Mirtazapine Mylan 15 mg, filmomhulde tabletten | DE/H/4373/001 | RVG 30732 | MYLAN B.V. | NL |
| Mirtazapine Mylan 15 mg filmomhulde tabletten | DE/H/4373/001 | BE266147 | MYLAN BVBA/SPRL | BE |
| Mirtazapine Mylan 15 mg filmomhulde tabletten | DE/H/4373/001 | BE266165 | MYLAN BVBA/SPRL | BE |
| Mirtazapina Mylan Generics 45 mg compresse rivestite con film | DE/H/4373/003 | 036621290 | MYLAN S.P.A. | IT |
| Mirtazapina Mylan Generics 45 mg compresse rivestite con film | DE/H/4373/003 | 036621302 | MYLAN S.P.A. | IT |
| Mirtazapina Mylan Generics 45 mg compresse rivestite con film | DE/H/4373/003 | 036621314 | MYLAN S.P.A. | IT |
| Mirtazapina Mylan Generics 45 mg compresse rivestite con film | DE/H/4373/003 | 036621326 | MYLAN S.P.A. | IT |
| Mirtazapina Mylan Generics 45 mg compresse rivestite con film | DE/H/4373/003 | 036621338 | MYLAN S.P.A. | IT |
| Mirtazapina Mylan Generics 45 mg compresse rivestite con film | DE/H/4373/003 | 036621340 | MYLAN S.P.A. | IT |
| Mirtazapina Mylan Generics 45 mg compresse rivestite con film | DE/H/4373/003 | 036621353 | MYLAN S.P.A. | IT |
| Mirtazapina Mylan Generics 45 mg compresse rivestite con film | DE/H/4373/003 | 036621365 | MYLAN S.P.A. | IT |
| Mirtazapin dura 45 mg Filmtabletten | DE/H/4373/003 | 59878.02.00 | MYLAN DURA GMBH | DE |
| Mirtazapine Mylan 45 mg, filmomhulde tabletten | DE/H/4373/003 | RVG 30734 | MYLAN B.V. | NL |

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| Mirtazapine Mylan 45 mg filmomhulde tabletten | DE/H/4373/003 | BE266192 | MYLAN BVBA/SPRL | BE |
| Mirtazapine Mylan 45 mg filmomhulde tabletten | DE/H/4373/003 | BE266201 | MYLAN BVBA/SPRL | BE |
| Mirtazapina Mylan Generics 45 mg compresse rivestite con film | DE/H/4373/003 | 036621199 | MYLAN S.P.A. | IT |
| Mirtazapina Mylan Generics 45 mg compresse rivestite con film | DE/H/4373/003 | 036621201 | MYLAN S.P.A. | IT |
| Mirtazapina Mylan Generics 45 mg compresse rivestite con film | DE/H/4373/003 | 036621213 | MYLAN S.P.A. | IT |
| Mirtazapina Mylan Generics 45 mg compresse rivestite con film | DE/H/4373/003 | 036621225 | MYLAN S.P.A. | IT |
| Mirtazapina Mylan Generics 45 mg compresse rivestite con film | DE/H/4373/003 | 036621237 | MYLAN S.P.A. | IT |
| Mirtazapina Mylan Generics 45 mg compresse rivestite con film | DE/H/4373/003 | 036621249 | MYLAN S.P.A. | IT |
| Mirtazapina Mylan Generics 45 mg compresse rivestite con film | DE/H/4373/003 | 036621252 | MYLAN S.P.A. | IT |
| Mirtazapina Mylan Generics 45 mg compresse rivestite con film | DE/H/4373/003 | 036621264 | MYLAN S.P.A. | IT |
| Mirtazapina Mylan Generics 45 mg compresse rivestite con film | DE/H/4373/003 | 036621276 | MYLAN S.P.A. | IT |
| Mirtazapina Mylan Generics 45 mg compresse rivestite con film | DE/H/4373/003 | 036621288 | MYLAN S.P.A. | IT |
| Mirtazapine 15 mg film-coated tablets | not available | PL 44041/0023 | NOUMED LIFE SCIENCES | UK |
| Mirtazapine 30 mg film-coated tablets | not available | PL 44041/0024 | NOUMED LIFE SCIENCES | UK |

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| Mirtazapine 45 mg film-coated tablets | not available | PL 44041/0025 | NOUMED LIFE SCIENCES | UK |
| Yarocen 15 mg szájban diszpergálódó tableta | EE/H/0143/001/MR | OGYI-T-20595/01-02 | EGIS PHARMACEUTICALS PLC | HU |
| Mirtazapine 30mg Film-coated Tablets | not available | PL 20075/0616 | ACCORD HEALTHCARE LIMITED | UK |
| Mirtazapine 45mg Film-coated Tablets | not available | PL 20075/0618 | ACCORD HEALTHCARE LIMITED | UK |
| Mirtazapine 15mg Film-coated Tablets | not available | PL 20075/0614 | ACCORD HEALTHCARE LIMITED | UK |
| Mirtazapine 30 mg film-coated tablets | not available | PL 21880/0054 | MEDREICH PLC | UK |
| Remeron 30 mg szájban diszpergálódó tableta | NL/H/0132/004 | OGYI-T-6022/04 | MSD PHARMA HUNGARY KFT. | HU |
| NORSET 15 mg, comprimé pelliculé | NL/H/0132/006 | 34009 344 542 9 5 | MSD FRANCE | FR |
| NORSET 15 mg, comprimé pelliculé | NL/H/0132/006 | 34009 344 543 5 6 | MSD FRANCE | FR |
| REMERGIL SolTab® 15 mg Schmelztabletten | NL/H/0132/003 | 52428.00.00 | MSD SHARP & DOHME GMBH | DE |
| Remeron Smelt, smeltetabletter | NL/H/0132/005 | 32872 | MERCK SHARP & DOHME BV | DK |
| REMERGIL SolTab® 30 mg Schmelztabletten | NL/H/0132/004 | 52428.01.00 | MSD SHARP & DOHME GMBH | DE |
| Remeron Smelt, smeltetabletter | NL/H/0132/003 | 32870 | MERCK SHARP & DOHME BV | DK |
| Zispin SolTab® 45 mg orodispersible tablets | NL/H/0132/005 | PL 00025/0548 | MERCK SHARP & DOHME LTD. | UK |
| Remeron 15 mg/ml drank | NL/H/0132/002 | RVG 24466 | NV ORGANON | NL |

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| Remeron SolTab 45 mg orodispergeerbare tabletten | NL/H/0132/005 | RVG 25782 | NV ORGANON | NL |
| Remeron 30 mg szájban diszpergálódó tableta | NL/H/0132/004 | OGYI-T-6022/03 | MSD PHARMA HUNGARY KFT. | HU |
| Remeron 45 mg szájban diszpergálódó tableta | NL/H/0132/005 | OGYI-T-6022/05 | MSD PHARMA HUNGARY KFT. | HU |
| Remeron Smelt, smeltetabletter | NL/H/0132/004 | 32871 | MERCK SHARP & DOHME BV | DK |
| Remeron SolTab 30 mg orodispergeerbare tabletten | NL/H/0132/004 | RVG 25781 | NV ORGANON | NL |
| Remeron SolTab 15 mg orodispergeerbare tabletten | NL/H/0132/003 | RVG 25780 | NV ORGANON | NL |
| Remeron 15 mg filmomhulde tabletten | NL/H/0132/006 | RVG 16685 | NV ORGANON | NL |
| REMERGIL SolTab® 45 mg Schmelztabletten | NL/H/0132/005 | 52428.02.00 | MSD SHARP & DOHME GMBH | DE |
| Zispin SolTab® 15 mg orodispersible tablets | NL/H/0132/003 | PL 00025/0546 | MERCK SHARP & DOHME LTD. | UK |
| Remeron 30 mg filmomhulde tabletten | NL/H/0132/007 | RVG 16686 | NV ORGANON | NL |
| Remeron 45 mg filmomhulde tabletten | NL/H/0132/001 | RVG 18217 | NV ORGANON | NL |
| Zispin 30 mg orodispersible tablets | NL/H/0132/004 | PA 1286/47/2 | MERCK SHARP & DOHME IRELAND (HUMAN HEALTH) LTD | IE |
| Zispin 30 mg film-coated tablets | NL/H/0132/007 | PA 0964/007/002 | NV ORGANON | IE |
| Rexer Flas 15 mg comprimidos bucodispersables | NL/H/0132/003 | 64.819 | MERCK SHARP & DOHME DE ESPAÑA, S.A | ES |
| Zispin 15 mg orodispersible | NL/H/0132/003 | PA 1286/47/1 | MERCK SHARP & DOHME | IE |

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| tablets | | | IRELAND (HUMAN HEALTH) LTD | |
| Zispin SolTab® 30 mg orodispersible tablets | NL/H/0132/004 | PL 00025/0547 | MERCK SHARP & DOHME LTD. | UK |
| Zispin 45 mg orodispersible tablets | NL/H/0132/005 | PA 1286/47/3 | MERCK SHARP & DOHME IRELAND (HUMAN HEALTH) LTD | IE |
| Zispin 15 mg film-coated tablets | NL/H/0132/006 | PA 0964/007/001 | NV ORGANON | IE |
| Rexer Flas 30 mg comprimidos bucodispersables | NL/H/0132/004 | 64.817 | MERCK SHARP & DOHME DE ESPAÑA, S.A | ES |
| Remeron® SolTab 15 mg tablety dispergovatelne v ústech | NL/H/0132/003 | 30/245/03-C | NV ORGANON | CZ |
| Remeron® SolTab 45 mg tablety dispergovatelne v ústech | NL/H/0132/005 | 30/247/03-C | NV ORGANON | CZ |
| Remeron® SolTab 30 mg tablety dispergovatelne v ústech | NL/H/0132/004 | 30/246/03-C | NV ORGANON | CZ |
| Remeron SolTab 15 mg comprimidos orodispersíveis | NL/H/0132/003 | 4060281 | MERCK SHARP & DOHME, LDA. | PT |
| Remeron SolTab 15 mg comprimidos orodispersíveis | NL/H/0132/003 | 3862380 | MERCK SHARP & DOHME, LDA. | PT |
| Remeron SolTab 15 mg comprimidos orodispersíveis | NL/H/0132/003 | 4060588 | MERCK SHARP & DOHME, LDA. | PT |
| Remeron SolTab 15 mg comprimidos orodispersíveis | NL/H/0132/003 | 4060885 | MERCK SHARP & DOHME, LDA. | PT |
| REMERGON SolTab® 15 mg comprimés orodispersibles | NL/H/0132/003 | 2002090040 | MSD BELGIUM BVBA/SPRL | LU |
| Remeron SolTab 15 mg comprimidos orodispersíveis | NL/H/0132/003 | 3862489 | MERCK SHARP & DOHME, LDA. | PT |
| Remeron SolTab 30 mg | NL/H/0132/004 | 3862885 | MERCK SHARP & DOHME, LDA. | PT |

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| comprimidos orodispersíveis | | | | |
| REMERGON SolTab® 30 mg orodispergeerbare tabletten | NL/H/0132/004 | BE239355 | MSD BELGIUM BVBA/SPRL | BE |
| Remeron SolTab 45 mg comprimidos orodispersíveis | NL/H/0132/005 | 4060786 | MERCK SHARP & DOHME, LDA. | PT |
| REMERGON SolTab® 15 mg orodispergeerbare tabletten | NL/H/0132/003 | BE239346 | MSD BELGIUM BVBA/SPRL | BE |
| REMERGON SolTab® 45 mg comprimés orodispersibles | NL/H/0132/005 | 2002090042 | MSD BELGIUM BVBA/SPRL | LU |
| Remeron SolTab 45 mg comprimidos orodispersíveis | NL/H/0132/005 | 3863289 | MERCK SHARP & DOHME, LDA. | PT |
| Remeron SolTab 30 mg comprimidos orodispersíveis | NL/H/0132/004 | 4060687 | MERCK SHARP & DOHME, LDA. | PT |
| Remeron SolTab 45 mg comprimidos orodispersíveis | NL/H/0132/005 | 3863180 | MERCK SHARP & DOHME, LDA. | PT |
| REMERGON SolTab® 45 mg orodispergeerbare tabletten | NL/H/0132/005 | BE239364 | MSD BELGIUM BVBA/SPRL | BE |
| Remeron SolTab 30 mg comprimidos orodispersíveis | NL/H/0132/004 | 4060380 | MERCK SHARP & DOHME, LDA. | PT |
| Remeron SolTab 30 mg comprimidos orodispersíveis | NL/H/0132/004 | 4060984 | MERCK SHARP & DOHME, LDA. | PT |
| Remeron SolTab 45 mg comprimidos orodispersíveis | NL/H/0132/005 | 4060489 | MERCK SHARP & DOHME, LDA. | PT |
| Remeron SolTab 45 mg comprimidos orodispersíveis | NL/H/0132/005 | 4061081 | MERCK SHARP & DOHME, LDA. | PT |
| Remeron SolTab 30 mg comprimidos orodispersíveis | NL/H/0132/004 | 3862786 | MERCK SHARP & DOHME, LDA. | PT |

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| REMERGON SolTab® 30 mg comprimés orodispersibles | NL/H/0132/004 | 2002090041 | MSD BELGIUM BVBA/SPRL | LU |
| NORSET 15 mg, comprimé pelliculé | NL/H/0132/006 | 34009 344 541 2 7 | MSD FRANCE | FR |
| Rexer 30 mg comprimidos recubiertos con película | NL/H/0132/007 | 61.017 | MERCK SHARP & DOHME DE ESPAÑA, S.A | ES |
| Remeron 30 mg filmdrasjerte tabletter | NL/H/0132/007 | 97-3657 | MERCK SHARP & DOHME BV | NO |
| Remeron-S 15 mg smeltetabletter | NL/H/0132/003 | 01-815 | MERCK SHARP & DOHME BV | NO |
| Remeron-S 30 mg smeltetabletter | NL/H/0132/004 | 01-816 | MERCK SHARP & DOHME BV | NO |
| Remeron-S 45 mg smeltetabletter | NL/H/0132/005 | 01-817 | MERCK SHARP & DOHME BV | NO |
| Remeron 30 mg επικαλυμμένα με λεπτό υμένιο δισκία | NL/H/0132/007 | 30721/6-4-2016 | MSD GREECE | GR |
| Remeron SolTab 15 mg munsönderfallande tabletter | NL/H/0132/003 | 16137 | MERCK SHARP & DOHME BV | FI |
| Remeron SolTab 30 mg tabletti, suussa hajoava | NL/H/0132/004 | 16138 | MERCK SHARP & DOHME BV | FI |
| Remeron SolTab 45 mg tabletti, suussa hajoava | NL/H/0132/005 | 16139 | MERCK SHARP & DOHME BV | FI |
| Remeron-S 15 mg munsönderfallande tabletter | NL/H/0132/003 | 16657 | MERCK SHARP & DOHME BV | SE |
| Remeron-S 30 mg munsönderfallande tabletter | NL/H/0132/004 | 16658 | MERCK SHARP & DOHME BV | SE |
| Remeron-S 45 mg munsönderfallande tabletter | NL/H/0132/005 | 16659 | MERCK SHARP & DOHME BV | SE |

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| Remeron Smelt 45 mg munndreifitafla | NL/H/0132/005 | IS/1/02/124/03 | MERCK SHARP & DOHME BV | IS |
| Remeron Smelt 15 mg munndreifitafla | NL/H/0132/003 | IS/1/02/124/01 | MERCK SHARP & DOHME BV | IS |
| Remeron Smelt 30 mg munndreifitafla | NL/H/0132/004 | IS/1/02/124/02 | MERCK SHARP & DOHME BV | IS |
| Remeron SolTab 30 mg comprimato orodispersabile | NL/H/0132/004 | 5746/2013/04 | MERCK SHARP & DOHME ROMANIA SRL | RO |
| Remeron SolTab 30 mg comprimato orodispersabile | NL/H/0132/004 | 5746/2013/05 | MERCK SHARP & DOHME ROMANIA SRL | RO |
| Remeron SolTab 30 mg comprimato orodispersabile | NL/H/0132/004 | 5746/2013/01 | MERCK SHARP & DOHME ROMANIA SRL | RO |
| Remeron SolTab 30 mg comprimato orodispersabile | NL/H/0132/004 | 5746/2013/02 | MERCK SHARP & DOHME ROMANIA SRL | RO |
| Remeron SolTab 30 mg comprimato orodispersabile | NL/H/0132/004 | 5746/2013/03 | MERCK SHARP & DOHME ROMANIA SRL | RO |
| Remeron 30 mg επικαλυμμένα με λεπτό υμένιο δισκία | NL/H/0132/007 | 17755 | MSD GREECE | CY |
| Remeron 15 mg compresse orodispersibili | NL/H/0132/003 | 029444128 | MSD ITALIA S.R.L. | IT |
| Remeron 30 mg compresse orodispersibili | NL/H/0132/004 | 029444205 | MSD ITALIA S.R.L. | IT |
| Remeron 15 mg compresse orodispersibili | NL/H/0132/003 | 029444130 | MSD ITALIA S.R.L. | IT |
| Remeron 30 mg compresse orodispersibili | NL/H/0132/004 | 029444181 | MSD ITALIA S.R.L. | IT |
| Remeron 15 mg compresse orodispersibili | NL/H/0132/003 | 029444155 | MSD ITALIA S.R.L. | IT |

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| Remeron 30 mg compresse orodispersibili | NL/H/0132/004 | 029444179 | MSD ITALIA S.R.L. | IT |
| Remeron 15 mg compresse orodispersibili | NL/H/0132/003 | 029444142 | MSD ITALIA S.R.L. | IT |
| Remeron 15 mg compresse orodispersibili | NL/H/0132/003 | 029444116 | MSD ITALIA S.R.L. | IT |
| Remeron 30 mg compresse orodispersibili | NL/H/0132/004 | 029444193 | MSD ITALIA S.R.L. | IT |
| Remeron 30 mg compresse orodispersibili | NL/H/0132/004 | 029444167 | MSD ITALIA S.R.L. | IT |
| REMERON Soltab 45 mg orodispergovateľné tablety | NL/H/0132/005 | 30/0168/03-S | MERCK SHARP & DOHME BV | SK |
| REMERON Soltab 30 mg orodispergovateľné tablety | NL/H/0132/004 | 30/0167/03-S | MERCK SHARP & DOHME BV | SK |
| REMERON Soltab 15 mg orodispergovateľné tablety | NL/H/0132/003 | 30/0166/03-S | MERCK SHARP & DOHME BV | SK |