



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 April 2024
EMA/177093/2024
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: Mirtazapine

Procedure no.: PSUSA/00002068/202308

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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 dura 15 mg Filmtabletten	DE/H/4373/001	59878.00.00	MYLAN GERMANY GMBH	DE
Mirtazapin dura 45 mg Filmtabletten	DE/H/4373/003	59878.02.00	MYLAN GERMANY GMBH	DE
Mirtazapina Mylan Generics 30 mg compresse rivestite con film	DE/H/4373/002	036621011	MYLAN S.P.A.	IT
Mirtazapina Mylan Generics 30 mg compresse rivestite con film	DE/H/4373/002	036621023	MYLAN S.P.A.	IT
Mirtazapina Mylan Generics 30 mg compresse rivestite con film	DE/H/4373/002	036621035	MYLAN S.P.A.	IT
Mirtazapina Mylan Generics 30 mg compresse rivestite con film	DE/H/4373/002	036621047	MYLAN S.P.A.	IT
Mirtazapina Mylan Generics 30 mg compresse rivestite con film	DE/H/4373/002	036621050	MYLAN S.P.A.	IT
Mirtazapina Mylan Generics 30 mg compresse rivestite con	DE/H/4373/002	036621062	MYLAN S.P.A.	IT

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
film				
Mirtazapina Mylan Generics 30 mg compresse rivestite con film	DE/H/4373/002	036621074	MYLAN S.P.A.	IT
Mirtazapina Mylan Generics 30 mg compresse rivestite con film	DE/H/4373/002	036621086	MYLAN S.P.A.	IT
Mirtazapina Mylan Generics 30 mg compresse rivestite con film	DE/H/4373/002	036621098	MYLAN S.P.A.	IT
Mirtazapina Mylan Generics 30 mg compresse rivestite con film	DE/H/4373/002	036621100	MYLAN S.P.A.	IT
Mirtazapina Mylan Generics 30 mg compresse rivestite con film	DE/H/4373/002	036621136	MYLAN S.P.A.	IT
Mirtazapina Mylan Generics 30 mg compresse rivestite con film	DE/H/4373/002	036621148	MYLAN S.P.A.	IT

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Mirtazapina Mylan Generics 30 mg compresse rivestite con film	DE/H/4373/002	036621151	MYLAN S.P.A.	IT
Mirtazapina Mylan Generics 30 mg compresse rivestite con film	DE/H/4373/002	036621163	MYLAN S.P.A.	IT
Mirtazapina Mylan Generics 30 mg compresse rivestite con film	DE/H/4373/002	036621175	MYLAN S.P.A.	IT
Mirtazapina Mylan Generics 30 mg compresse rivestite con film	DE/H/4373/002	036621187	MYLAN S.P.A.	IT
Mirtazapina Mylan Generics 30 mg compresse rivestite con film.	DE/H/4373/002	036621112	MYLAN S.P.A.	IT
Mirtazapina Mylan Generics 30 mg compresse rivestite con film.	DE/H/4373/002	036621124	MYLAN S.P.A.	IT
Mirtazapina Mylan Generics 45 mg compresse rivestite con film	DE/H/4373/003	036621290	MYLAN S.P.A.	IT

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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

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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

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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	XI
Mirtazapine 15 mg orodispersible tablets	not available	PL 36687/0319	TORRENT PHARMA (UK) LTD.	XI
Mirtazapine 15mg Film-coated Tablets	not available	PL 20075/0614	ACCORD HEALTHCARE LIMITED	XI
Mirtazapine 30 mg film-coated tablets	not available	PL 44041/0024	NOUMED LIFE SCIENCES	XI
Mirtazapine 30 mg orodispersible tablets	not available	PL 36687/0320	TORRENT PHARMA (UK) LTD.	XI

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
Mirtazapine 30mg Film-coated Tablets	not available	PL 20075/0616	ACCORD HEALTHCARE LIMITED	XI
Mirtazapine 45 mg film-coated tablets	not available	PL 44041/0025	NOUMED LIFE SCIENCES	XI
Mirtazapine 45 mg orodispersible tablets	not available	PL 36687/0321	TORRENT PHARMA (UK) LTD.	XI
Mirtazapine 45mg Film-coated Tablets	not available	PL 20075/0618	ACCORD HEALTHCARE LIMITED	XI
MIRTAZAPINE EG 15 mg, comprimé pelliculé	not available	NL30913	EG LABO LABORATOIRES EUROGENERICS	FR
Mirtazapine Mylan 15 mg, filmomhulde tabletten	DE/H/4373/001	RVG 30732	MYLAN PHARMACEUTICALS LIMITED	NL
Mirtazapine Mylan 30 mg, filmomhulde tabletten	DE/H/4373/002	RVG 30733	MYLAN PHARMACEUTICALS LIMITED	NL
Mirtazapine Mylan 45 mg, filmomhulde tabletten	DE/H/4373/003	RVG 30734	MYLAN PHARMACEUTICALS LIMITED	NL
Mirtazapine Viatrix 15 mg filmomhulde tabletten	DE/H/4373/001	BE266147	VIATRIS GX	BE

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
Mirtazapine Viatris 15 mg filmomhulde tabletten	DE/H/4373/001	BE266165	VIATRIS GX	BE
Mirtazapine Viatris 15 mg Filmtabletten	DE/H/4373/001	BE266147	VIATRIS GX	BE
Mirtazapine Viatris 15 mg Filmtabletten	DE/H/4373/001	BE266165	VIATRIS GX	BE
Mirtazapine Viatris 15mg comprimés pelliculés	DE/H/4373/001	BE266147	VIATRIS GX	BE
Mirtazapine Viatris 15mg comprimés pelliculés	DE/H/4373/001	BE266165	VIATRIS GX	BE
Mirtazapine Viatris 45 mg filmomhulde tabletten	DE/H/4373/003	BE266192	VIATRIS GX	BE
Mirtazapine Viatris 45 mg filmomhulde tabletten	DE/H/4373/003	BE266201	VIATRIS GX	BE
Mirtazapine Viatris 45 mg Filmtabletten	DE/H/4373/003	BE266192	VIATRIS GX	BE
Mirtazapine Viatris 45 mg Filmtabletten	DE/H/4373/003	BE266201	VIATRIS GX	BE

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
Mirtazapine Viatris 45mg comprimés pelliculés	DE/H/4373/003	BE266192	VIATRIS GX	BE
Mirtazapine Viatris 45mg comprimés pelliculés	DE/H/4373/003	BE266201	VIATRIS GX	BE
MIRTAZAPINE/MYLAN 30 mg Επικαλυμμένα με λεπτό υμένιο δισκία	DE/H/4373/002	17512 / 15 / 02-06-2016	MYLAN IRELAND LIMITED	GR
MIRTAZAPINE/MYLAN 45 mg Επικαλυμμένα με λεπτό υμένιο δισκία	DE/H/4373/003	18662/ 15 / 02-06-2016	MYLAN IRELAND LIMITED	GR
NORSET 15 mg, comprimé pelliculé	NL/H/0132/006	34009 344 541 2 7	ORGANON_FRANCE	FR
NORSET 15 mg, comprimé pelliculé	NL/H/0132/006	34009 344 542 9 5	ORGANON_FRANCE	FR
NORSET 15 mg, comprimé pelliculé	NL/H/0132/006	34009 344 543 5 6	ORGANON_FRANCE	FR
REMERGIL SolTab® 15 mg Schmelztabletten	NL/H/0132/003	52428.00.00	ORGANONHEALTHCARE GMBH	DE
REMERGIL SolTab® 30 mg Schmelztabletten	NL/H/0132/004	52428.01.00	ORGANONHEALTHCARE 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
REMERGIL SolTab® 45 mg Schmelztabletten	NL/H/0132/005	52428.02.00	ORGANONHEALTHCARE GMBH	DE
REMERGON SolTab 15 mg comprimés orodispersibles	NL/H/0132/003	2002090040	ORGANONBELGIUM	LU
REMERGON SolTab® 15 mg Schmelztabletten Mirtazapin	NL/H/0132/003	BE239346	ORGANONBELGIUM	BE
REMERGON SolTab® 30 mg Schmelztabletten Mirtazapin	NL/H/0132/004	BE239355	ORGANONBELGIUM	BE
REMERGON SolTab® 15 mg comprimés orodispersibles	NL/H/0132/003	BE239346	ORGANONBELGIUM	BE
REMERGON SolTab® 15 mg orodispergeerbare tabletten	NL/H/0132/003	BE239346	ORGANONBELGIUM	BE
REMERGON SolTab® 30 mg comprimés orodispersibles	NL/H/0132/004	BE239355	ORGANONBELGIUM	BE
REMERGON SolTab® 30 mg comprimés orodispersibles	NL/H/0132/004	2002090041	ORGANONBELGIUM	LU
REMERGON SolTab® 30 mg orodispergeerbare tabletten	NL/H/0132/004	BE239355	ORGANONBELGIUM	BE

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
REMERGON SolTab® 45 mg comprimés orodispersibles	NL/H/0132/005	BE239364	ORGANONBELGIUM	BE
REMERGON SolTab® 45 mg comprimés orodispersibles	NL/H/0132/005	2002090042	ORGANONBELGIUM	LU
REMERGON SolTab® 45 mg orodispergeerbare tabletten	NL/H/0132/005	BE239364	ORGANONBELGIUM	BE
REMERGON SolTab® 45 mg Schmelztabletten Mirtazapin	NL/H/0132/005	BE239364	ORGANONBELGIUM	BE
Remeron 15 mg compresse orodispersibili	NL/H/0132/003	029444116	ORGANON ITALIA S.R.L.	IT
Remeron 15 mg compresse orodispersibili	NL/H/0132/003	029444128	ORGANON ITALIA S.R.L.	IT
Remeron 15 mg compresse orodispersibili	NL/H/0132/003	029444130	ORGANON ITALIA S.R.L.	IT
Remeron 15 mg compresse orodispersibili	NL/H/0132/003	029444142	ORGANON ITALIA S.R.L.	IT
Remeron 15 mg compresse orodispersibili	NL/H/0132/003	029444155	ORGANON ITALIA S.R.L.	IT

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Remeron 15 mg filmomhulde tabletten	NL/H/0132/006	RVG 16685	N.V. ORGANON	NL
Remeron 30 mg compresse orodispersibili	NL/H/0132/004	029444167	ORGANON ITALIA S.R.L.	IT
Remeron 30 mg compresse orodispersibili	NL/H/0132/004	029444179	ORGANON ITALIA S.R.L.	IT
Remeron 30 mg compresse orodispersibili	NL/H/0132/004	029444181	ORGANON ITALIA S.R.L.	IT
Remeron 30 mg compresse orodispersibili	NL/H/0132/004	029444193	ORGANON ITALIA S.R.L.	IT
Remeron 30 mg compresse orodispersibili	NL/H/0132/004	029444205	ORGANON ITALIA S.R.L.	IT
Remeron 30 mg filmdrasjerte tabletter	NL/H/0132/007	97-3657	N.V. ORGANON	NO
Remeron 30 mg filmomhulde tabletten	NL/H/0132/007	RVG 16686	N.V. ORGANON	NL
Remeron 30 mg szájban diszpergálódó tableta	NL/H/0132/004	OGYI-T-6022/03	ORGANON HUNGARY KFT.	HU

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
Remeron 30 mg szájban diszpergálódó tabletta	NL/H/0132/004	OGYI-T-6022/04	ORGANON HUNGARY KFT.	HU
Remeron 30 mg επικαλυμμένα με λεπτό υμένιο δισκία	NL/H/0132/007	17755	N.V. ORGANON	CY
Remeron 30 mg επικαλυμμένα με λεπτό υμένιο δισκία	NL/H/0132/007	30721/6-4-2016	N.V. ORGANON	GR
Remeron 45 mg filmomhulde tabletten	NL/H/0132/001	RVG 18217	N.V. ORGANON	NL
Remeron 45 mg szájban diszpergálódó tabletta	NL/H/0132/005	OGYI-T-6022/05	ORGANON HUNGARY KFT.	HU
Remeron SolTab 15 mg comprimidos orodispersíveis	NL/H/0132/003	3862380	ORGANONPORTUGAL, SOCIEDADE UNIPessoal LDA.	PT
Remeron SolTab 15 mg comprimidos orodispersíveis	NL/H/0132/003	3862489	ORGANONPORTUGAL, SOCIEDADE UNIPessoal LDA.	PT
Remeron SolTab 15 mg comprimidos orodispersíveis	NL/H/0132/003	4060281	ORGANONPORTUGAL, SOCIEDADE UNIPessoal LDA.	PT
Remeron SolTab 15 mg comprimidos orodispersíveis	NL/H/0132/003	4060588	ORGANONPORTUGAL, SOCIEDADE UNIPessoal LDA.	PT

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
Remeron SolTab 15 mg comprimidos orodispersíveis	NL/H/0132/003	4060885	ORGANONPORTUGAL, SOCIEDADE UNIPessoal LDA.	PT
Remeron SolTab 15 mg orodispergeerbare tabletten	NL/H/0132/003	RVG 25780	N.V. ORGANON	NL
Remeron SolTab 30 mg comprimato orodispersabile	NL/H/0132/004	5746/2013/01	ORGANON BIOSCIENCES S.R.L.	RO
Remeron SolTab 30 mg comprimato orodispersabile	NL/H/0132/004	5746/2013/02	ORGANON BIOSCIENCES S.R.L.	RO
Remeron SolTab 30 mg comprimato orodispersabile	NL/H/0132/004	5746/2013/03	ORGANON BIOSCIENCES S.R.L.	RO
Remeron SolTab 30 mg comprimato orodispersabile	NL/H/0132/004	5746/2013/04	ORGANON BIOSCIENCES S.R.L.	RO
Remeron SolTab 30 mg comprimato orodispersabile	NL/H/0132/004	5746/2013/05	ORGANON BIOSCIENCES S.R.L.	RO
Remeron SolTab 30 mg comprimidos orodispersíveis	NL/H/0132/004	3862786	ORGANONPORTUGAL, SOCIEDADE UNIPessoal LDA.	PT
Remeron SolTab 30 mg comprimidos orodispersíveis	NL/H/0132/004	3862885	ORGANONPORTUGAL, SOCIEDADE UNIPessoal LDA.	PT

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Remeron SolTab 30 mg comprimidos orodispersíveis	NL/H/0132/004	4060380	ORGANONPORTUGAL, SOCIEDADE UNIPessoal LDA.	PT
Remeron SolTab 30 mg comprimidos orodispersíveis	NL/H/0132/004	4060687	ORGANONPORTUGAL, SOCIEDADE UNIPessoal LDA.	PT
Remeron SolTab 30 mg comprimidos orodispersíveis	NL/H/0132/004	4060984	ORGANONPORTUGAL, SOCIEDADE UNIPessoal LDA.	PT
Remeron SolTab 30 mg orodispergeerbare tabletten	NL/H/0132/004	RVG 25781	N.V. ORGANON	NL
Remeron SolTab 45 mg comprimidos orodispersíveis	NL/H/0132/005	3863180	ORGANONPORTUGAL, SOCIEDADE UNIPessoal LDA.	PT
Remeron SolTab 45 mg comprimidos orodispersíveis	NL/H/0132/005	3863289	ORGANONPORTUGAL, SOCIEDADE UNIPessoal LDA.	PT
Remeron SolTab 45 mg comprimidos orodispersíveis	NL/H/0132/005	4060489	ORGANONPORTUGAL, SOCIEDADE UNIPessoal LDA.	PT
Remeron SolTab 45 mg comprimidos orodispersíveis	NL/H/0132/005	4060786	ORGANONPORTUGAL, SOCIEDADE UNIPessoal LDA.	PT
Remeron SolTab 45 mg comprimidos orodispersíveis	NL/H/0132/005	4061081	ORGANONPORTUGAL, SOCIEDADE UNIPessoal LDA.	PT

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Remeron SolTab 45 mg orodispergeerbare tabletten	NL/H/0132/005	RVG 25782	N.V. ORGANON	NL
Remeron-S 15 mg smeltetabletter	NL/H/0132/003	01-815	N.V. ORGANON	NO
Remeron-S 30 mg smeltetabletter	NL/H/0132/004	01-816	N.V. ORGANON	NO
Remeron-S 45 mg smeltetabletter	NL/H/0132/005	01-817	N.V. ORGANON	NO
Rexer 30 mg comprimidos recubiertos con película	NL/H/0132/007	61017	ORGANONSALUD, S.L.	ES
Rexer Flas 15 mg comprimidos bucodispersables	NL/H/0132/003	64819	ORGANONSALUD, S.L.	ES
Rexer Flas 30 mg comprimidos bucodispersables	NL/H/0132/004	64817	ORGANONSALUD, S.L.	ES
Zispin 15 mg film-coated tablets	NL/H/0132/006	PA23198/025/001	ORGANON PHARMA (IRELAND) LIMITED	IE
Zispin 30 mg film-coated tablets	NL/H/0132/007	PA23198/025/002	ORGANON PHARMA (IRELAND) LIMITED	IE

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Zispin SolTab 15 mg orodispersible tablets	NL/H/0132/003	PA23198/015/001	ORGANON PHARMA (IRELAND) LIMITED	IE
Zispin SolTab 30 mg orodispersible tablets	NL/H/0132/004	PA23198/015/002	ORGANON PHARMA (IRELAND) LIMITED	IE
Zispin SolTab 45 mg orodispersible tablets	NL/H/0132/005	PA23198/015/003	ORGANON PHARMA (IRELAND) LIMITED	IE
Zispin SolTab® 15 mg orodispersible tablets	NL/H/0132/003	PL 00025/0546	ORGANON PHARMA (UK) LIMITED	XI
Zispin SolTab® 30 mg orodispersible tablets	NL/H/0132/004	PL 00025/0547	ORGANON PHARMA (UK) LIMITED	XI
Zispin SolTab® 45 mg orodispersible tablets	NL/H/0132/005	PL 00025/0548	ORGANON PHARMA (UK) LIMITED	XI