24 July 2025
EMADOC-1700519818-2424948
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): hydromorphone

EURD list No. PSUSA/00001686/202411

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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
Edunix 4 mg comprimidos de liberación prolongada	DE/H/3761/001	79783	ARISTO PHARMA GMBH (ART 57)	ES
Edunix 16 mg comprimidos de liberación prolongada	DE/H/3761/003	79781	ARISTO PHARMA GMBH (ART 57)	ES
Edunix 16 mg comprimidos de libertação prolongada	DE/H/3762/003	5810148	ARISTO PHARMA GMBH (ART 57)	PT
Edunix 16 mg comprimidos de libertação prolongada	DE/H/3762/003	5810148	ARISTO PHARMA GMBH (ART 57)	PT
Edunix 32 mg comprimidos de liberación prolongada	DE/H/3761/004	79782	ARISTO PHARMA GMBH (ART 57)	ES
Edunix 32 mg comprimidos de libertação prolongada	DE/H/3762/004	5810155	ARISTO PHARMA GMBH (ART 57)	PT
Edunix 32 mg comprimidos de libertação prolongada	DE/H/3762/004	5810155	ARISTO PHARMA GMBH (ART 57)	PT
Edunix 32 mg comprimidos de libertação prolongada	DE/H/3762/004	5810155	ARISTO PHARMA GMBH (ART 57)	PT
Edunix 4 mg comprimidos de libertação prolongada	DE/H/3762/001	5810114	ARISTO PHARMA GMBH (ART 57)	PT
Edunix 4 mg comprimidos de libertação prolongada	DE/H/3762/001	5810122	ARISTO PHARMA GMBH (ART 57)	PT
Edunix 4 mg comprimidos de libertação prolongada	DE/H/3762/001	5810114	ARISTO PHARMA GMBH (ART 57)	PT
Edunix 4 mg comprimidos de	DE/H/3762/001	5810122	ARISTO PHARMA GMBH (ART 57)	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
libertação prolongada				
Edunix 4 mg comprimidos de libertação prolongada	DE/H/3762/001	5810114	ARISTO PHARMA GMBH (ART 57)	PT
Edunix 4 mg comprimidos de libertação prolongada	DE/H/3762/001	5810122	ARISTO PHARMA GMBH (ART 57)	PT
Edunix 8 mg comprimidos de liberación prolongada	DE/H/3761/002	79784	ARISTO PHARMA GMBH (ART 57)	ES
Edunix 8 mg comprimidos de libertação prolongada	DE/H/3762/002	5810130	ARISTO PHARMA GMBH (ART 57)	PT
Edunix 8 mg comprimidos de libertação prolongada	DE/H/3762/002	5810130	ARISTO PHARMA GMBH (ART 57)	PT
Edunix 8 mg comprimidos de libertação prolongada	DE/H/3762/002	5810130	ARISTO PHARMA GMBH (ART 57)	PT
HYDAGELAN 10 mg/mL, solution injectable / pour perfusion	not available	34009 302 622 6 9	G.L. PHARMA GMBH	FR
HYDAGELAN 10 mg/mL, solution injectable / pour perfusion	not available	34009 550 918 3 7	G.L. PHARMA GMBH	FR
HYDAGELAN 10 mg/mL, solution injectable / pour perfusion	not available	34009 550 918 4 4	G.L. PHARMA GMBH	FR
Hydagelan 16 mg Retardtabletten	DE/H/7719/003	7011484.00.00	G.L. PHARMA GMBH	DE
HYDAGELAN 20 mg/mL, solution injectable / pour perfusion	not available	34009 302 622 7 6	G.L. PHARMA GMBH	FR
Hydagelan 24 mg Retardtabletten	DE/H/7719/004	7011485.00.00	G.L. PHARMA GMBH	DE
Hydagelan 4 mg	DE/H/7719/001	7011482.00.00	G.L. PHARMA GMBH	DE

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Retardtabletten				
HYDAGELAN 50 mg/mL, solution injectable / pour perfusion	not available	34009 550 918 5 1	G.L. PHARMA GMBH	FR
Hydagelan 8 mg Retardtabletten	DE/H/7719/002	7011483.00.00	G.L. PHARMA GMBH	DE
HYDAGELAN LP 16 mg, comprimé sécable à libération prolongée	DE/H/7719/003	34009 302 857 0 1	G.L. PHARMA GMBH	FR
HYDAGELAN LP 16 mg, comprimé sécable à libération prolongée	DE/H/7719/003	34009 302 857 2 5	G.L. PHARMA GMBH	FR
HYDAGELAN LP 16 mg, comprimé sécable à libération prolongée	DE/H/7719/003	34009 550 994 8 2	G.L. PHARMA GMBH	FR
HYDAGELAN LP 24 mg, comprimé sécable à libération prolongée	DE/H/7719/004	34009 302 857 9 4	G.L. PHARMA GMBH	FR
HYDAGELAN LP 24 mg, comprimé sécable à libération prolongée	DE/H/7719/004	34009 302 858 0 0	G.L. PHARMA GMBH	FR
HYDAGELAN LP 24 mg, comprimé sécable à libération prolongée	DE/H/7719/004	34009 550 995 1 2	G.L. PHARMA GMBH	FR
HYDAGELAN LP 4 mg, comprimé sécable à libération prolongée	DE/H/7719/001	34009 302 856 3 3	G.L. PHARMA GMBH	FR
HYDAGELAN LP 4 mg, comprimé sécable à libération prolongée	DE/H/7719/001	34009 302 856 4 0	G.L. PHARMA GMBH	FR
HYDAGELAN LP 4 mg, comprimé sécable à libération prolongée	DE/H/7719/001	34009 550 994 1 3	G.L. PHARMA GMBH	FR
HYDAGELAN LP 8 mg, comprimé sécable à libération prolongée	DE/H/7719/002	34009 302 856 6 4	G.L. PHARMA GMBH	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
HYDAGELAN LP 8 mg, comprimé sécable à libération prolongée	DE/H/7719/002	34009 302 856 7 1	G.L. PHARMA GMBH	FR
HYDAGELAN LP 8 mg, comprimé sécable à libération prolongée	DE/H/7719/002	34009 550 994 7 5	G.L. PHARMA GMBH	FR
Hydal 1.3 mg Kapseln	not available	1-21972	MUNDIPHARMA GES.M.B.H	AT
Hydal 10 mg/ml Injektionslösung	DE/H/1540/001-004	1-28306	MUNDIPHARMA GES.M.B.H	AT
Hydal 2 mg/ml Injektionslösung	DE/H/1540/001-004	1-28305	MUNDIPHARMA GES.M.B.H	AT
Hydal 2.6 mg Kapseln	not available	1-21974	MUNDIPHARMA GES.M.B.H	AT
Hydal 20 mg/ml Injektionslösung	DE/H/1540/001-004	1-28307	MUNDIPHARMA GES.M.B.H	AT
Hydal 50 mg/ml Injektionslösung	DE/H/1540/001-004	1-28308	MUNDIPHARMA GES.M.B.H	AT
Hydal retard 16 mg Kapseln	not available	1-21977	MUNDIPHARMA GES.M.B.H	AT
Hydal retard 2 mg Kapseln	not available	1-21973	MUNDIPHARMA GES.M.B.H	AT
Hydal retard 24 mg Kapseln	not available	1-21978	MUNDIPHARMA GES.M.B.H	AT
Hydal retard 4 mg Kapseln	not available	1-21975	MUNDIPHARMA GES.M.B.H	AT
Hydal retard 8 mg Kapseln	not available	1-21976	MUNDIPHARMA GES.M.B.H	AT
Hydromorphon - 1 A Pharma 16 mg Hartkapseln, retardiert	not available	84817.00.00	1 A PHARMA GMBH	DE
Hydromorphon - 1 A Pharma 2 mg Hartkapseln, retardiert	not available	84814.00.00	1 A PHARMA GMBH	DE
Hydromorphon - 1 A Pharma 24 mg Hartkapseln, retardiert	not available	84818.00.00	1 A PHARMA GMBH	DE
Hydromorphon - 1 A	not available	84815.00.00	1 A PHARMA GMBH	DE

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Pharma 4 mg Hartkapseln, retardiert				
Hydromorphon Aristo long 16 mg Retardtabletten	DE/H/3761/003	89247.00.00	ARISTO PHARMA GMBH (ART 57)	DE
Hydromorphon Aristo long 32 mg Retardtabletten	DE/H/3761/004	89248.00.00	ARISTO PHARMA GMBH (ART 57)	DE
Hydromorphon Aristo long 4 mg Retardtabletten	DE/H/3761/001	89245.00.00	ARISTO PHARMA GMBH (ART 57)	DE
Hydromorphon Aristo long 8 mg Retardtabletten	DE/H/3761/002	89246.00.00	ARISTO PHARMA GMBH (ART 57)	DE
Hydromorphon beta 16 mg Retardtabletten	DE/H/7605/003	7010473.00.00	BETAPHARM ARZNEIMITTEL GMBH	DE
Hydromorphon beta 24 mg Retardtabletten	DE/H/7605/004	7010474.00.00	BETAPHARM ARZNEIMITTEL GMBH	DE
Hydromorphon beta 4 mg Retardtabletten	DE/H/7605/001	7010471.00.00	BETAPHARM ARZNEIMITTEL GMBH	DE
Hydromorphon beta 8 mg Retardtabletten	DE/H/7605/002	7010472.00.00	BETAPHARM ARZNEIMITTEL GMBH	DE
Hydromorphon esparma 1 x täglich 16 mg Retardtabletten	DE/H/3762/003	89251.00.00	ARISTO PHARMA GMBH (ART 57)	DE
Hydromorphon esparma 1 x täglich 16 mg Retardtabletten	DE/H/3762/003	89251.00.00	ARISTO PHARMA GMBH (ART 57)	DE
Hydromorphon esparma 1 x täglich 32 mg Retardtabletten	DE/H/3762/004	89252.00.00	ARISTO PHARMA GMBH (ART 57)	DE
Hydromorphon esparma 1 x täglich 32 mg Retardtabletten	DE/H/3762/004	89252.00.00	ARISTO PHARMA GMBH (ART 57)	DE
Hydromorphon esparma 1 x täglich 32 mg	DE/H/3762/004	89252.00.00	ARISTO PHARMA GMBH (ART 57)	DE

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Retardtabletten				
Hydromorphon esparma 1 x täglich 4 mg Retardtabletten	DE/H/3762/001	89249.00.00	ARISTO PHARMA GMBH (ART 57)	DE
Hydromorphon esparma 1 x täglich 4 mg Retardtabletten	DE/H/3762/001	89249.00.00	ARISTO PHARMA GMBH (ART 57)	DE
Hydromorphon esparma 1 x täglich 4 mg Retardtabletten	DE/H/3762/001	89249.00.00	ARISTO PHARMA GMBH (ART 57)	DE
Hydromorphon esparma 1 x täglich 8 mg Retardtabletten	DE/H/3762/002	89250.00.00	ARISTO PHARMA GMBH (ART 57)	DE
Hydromorphon esparma 1 x täglich 8 mg Retardtabletten	DE/H/3762/002	89250.00.00	ARISTO PHARMA GMBH (ART 57)	DE
Hydromorphon esparma 1 x täglich 8 mg Retardtabletten	DE/H/3762/002	89250.00.00	ARISTO PHARMA GMBH (ART 57)	DE
Hydromorphon HCl Hormosan 16 mg Retardtabletten	DE/H/2246/003	76827.00.00	HORMOSAN PHARMA GMBH	DE
Hydromorphon HCl Hormosan 24 mg Retardtabletten	DE/H/2246/004	76828.00.00	HORMOSAN PHARMA GMBH	DE
Hydromorphon HCl Hormosan 4 mg Retardtabletten	DE/H/2246/001	76825.00.00	HORMOSAN PHARMA GMBH	DE
Hydromorphon HCl Hormosan 8 mg Retardtabletten	DE/H/2246/002	76826.00.00	HORMOSAN PHARMA GMBH	DE
Hydromorphon ratiopharm 16 mg Retardtabletten	DE/H/2245/003	1-29274	TEVA B.V	AT
Hydromorphon ratiopharm 24 mg	DE/H/2245/004	1-29275	TEVA B.V	AT

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Retardtabletten				
Hydromorphon ratiopharm 4 mg Retardtabletten	DE/H/2245/001	1-29272	TEVA B.V	AT
Hydromorphon ratiopharm 8 mg Retardtabletten	DE/H/2245/002	1-29273	TEVA B.V	AT
Hydromorphon STADA 16 mg Retardtabletten	DE/H/2326/003	1-29530	STADA ARZNEIMITTEL GMBH	AT
Hydromorphon STADA 24 mg Retardtabletten	DE/H/2326/004	1-29531	STADA ARZNEIMITTEL GMBH	AT
Hydromorphon STADA 4 mg Retardtabletten	DE/H/2326/001	1-29528	STADA ARZNEIMITTEL GMBH	AT
Hydromorphon STADA 8 mg Retardtabletten	DE/H/2326/002	1-29529	STADA ARZNEIMITTEL GMBH	AT
Hydromorphon-AL 16 mg Retardtabletten	DE/H/2327/003	77423.00.00	ALIUD PHARMA GMBH	DE
Hydromorphon-AL 24 mg Retardtabletten	DE/H/2327/004	77424.00.00	ALIUD PHARMA GMBH	DE
Hydromorphon-AL 4 mg Retardtabletten	DE/H/2327/001	77421.00.00	ALIUD PHARMA GMBH	DE
Hydromorphon-AL 8 mg Retardtabletten	DE/H/2327/002	77422.00.00	ALIUD PHARMA GMBH	DE
Hydromorphon-dura 16 mg Retardtabletten	DE/H/2428/003	78115.02.00	MYLAN GERMANY GMBH	DE
Hydromorphon-dura 24 mg Retardtabletten	DE/H/2428/004	78115.03.00	MYLAN GERMANY GMBH	DE
Hydromorphon-dura 4 mg Retardtabletten	DE/H/2428/001	78115.00.00	MYLAN GERMANY GMBH	DE
Hydromorphon-dura 8 mg Retardtabletten	DE/H/2428/002	78115.01.00	MYLAN GERMANY GMBH	DE
Hydromorphon-HCl PUREN 16 mg Hartkapseln, retardiert	DE/H/2432/004	78098.00.00	PUREN PHARMA GMBH & CO. KG	DE
Hydromorphon-HCl PUREN 24 mg	DE/H/2432/005	78099.00.00	PUREN PHARMA GMBH & CO. KG	DE

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Hartkapseln, retardiert				
Hydromorphon-HCl PUREN 4 mg Hartkapseln, retardiert	DE/H/2432/002	78096.00.00	PUREN PHARMA GMBH & CO. KG	DE
Hydromorphon-HCl PUREN 8 mg Hartkapseln, retardiert	DE/H/2432/003	78097.00.00	PUREN PHARMA GMBH & CO. KG	DE
Hydromorphon-HCl PUREN 8 mg Hartkapseln, retardiert	DE/H/2432/003	78097.00.00	PUREN PHARMA GMBH & CO. KG	DE
Hydromorphon-HCl AbZ 16 mg Hartkapseln, retardiert	not available	84813.00.00	ABZ-PHARMA GMBH	DE
Hydromorphon-HCl AbZ 4 mg Hartkapseln, retardiert	not available	84811.00.00	ABZ-PHARMA GMBH	DE
Hydromorphon-HCl AbZ 8 mg Hartkapseln, retardiert	not available	84812.00.00	ABZ-PHARMA GMBH	DE
Hydromorphon-HCl Heumann 16 mg Hartkapseln, retardiert	not available	85917.00.00	HEUMANN PHARMA GMBH & CO. GENERICA KG	DE
Hydromorphon-HCl Heumann 2 mg Hartkapseln, retardiert	not available	85914.00.00	HEUMANN PHARMA GMBH & CO. GENERICA KG	DE
Hydromorphon-HCl Heumann 24 mg Hartkapseln, retardiert	not available	85918.00.00	HEUMANN PHARMA GMBH & CO. GENERICA KG	DE
Hydromorphon-HCl Heumann 4 mg Hartkapseln, retardiert	not available	85915.00.00	HEUMANN PHARMA GMBH & CO. GENERICA KG	DE
Hydromorphon-HCl Heumann 8 mg Hartkapseln, retardiert	not available	85916.00.00	HEUMANN PHARMA GMBH & CO. GENERICA KG	DE
Hydromorphon-HCl-ratiopharm® 16 mg	not available	84822.00.00	RATIOPHARM GMBH	DE

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Hartkapseln, retardiert				
Hydromorphon-HCl-ratiopharm® 2 mg Hartkapseln, retardiert	not available	84819.00.00	RATIOPHARM GMBH	DE
Hydromorphon-HCl-ratiopharm® 24 mg Hartkapseln, retardiert	not available	84823.00.00	RATIOPHARM GMBH	DE
Hydromorphon-HCl-ratiopharm® 4 mg Hartkapseln, retardiert	not available	84820.00.00	RATIOPHARM GMBH	DE
Hydromorphon-HCl-ratiopharm® 8 mg Hartkapseln, retardiert	not available	84821.00.00	RATIOPHARM GMBH	DE
Hydromorphon-HEXAL retard 16 mg Hartkapseln, retardiert	DE/H/2431/004	78093.00.00	HEXAL AG	DE
Hydromorphon-HEXAL retard 16 mg Retardtabletten	DE/H/2248/003	76835.00.00	HEXAL AG	DE
Hydromorphon-HEXAL retard 2 mg Hartkapseln, retardiert	DE/H/2431/001	78090.00.00	HEXAL AG	DE
Hydromorphon-HEXAL retard 24 mg Hartkapseln, retardiert	DE/H/2431/005	78094.00.00	HEXAL AG	DE
Hydromorphon-HEXAL retard 24 mg Retardtabletten	DE/H/2248/004	76836.00.00	HEXAL AG	DE
Hydromorphon-HEXAL retard 4 mg Hartkapseln, retardiert	DE/H/2431/002	78091.00.00	HEXAL AG	DE
Hydromorphon-HEXAL retard 4 mg Retardtabletten	DE/H/2248/001	76833.00.00	HEXAL AG	DE
Hydromorphon-HEXAL retard 8 mg Hartkapseln,	DE/H/2431/003	78092.00.00	HEXAL AG	DE

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retardiert				
Hydromorphon-HEXAL retard 8 mg Retardtabletten	DE/H/2248/002	76834.00.00	HEXAL AG	DE
Hydromorphonhydrochlorid beta 16 mg Retardkapseln	DE/H/2430/004	78088.00.00	BETAPHARM ARZNEIMITTEL GMBH	DE
Hydromorphonhydrochlorid beta 2 mg Retardkapseln	DE/H/2430/001	78085.00.00	BETAPHARM ARZNEIMITTEL GMBH	DE
Hydromorphonhydrochlorid beta 24 mg Retardkapseln	DE/H/2430/005	78089.00.00	BETAPHARM ARZNEIMITTEL GMBH	DE
Hydromorphonhydrochlorid beta 4 mg Retardkapseln	DE/H/2430/002	78086.00.00	BETAPHARM ARZNEIMITTEL GMBH	DE
Hydromorphonhydrochlorid beta 8 mg Retardkapseln	DE/H/2430/003	78087.00.00	BETAPHARM ARZNEIMITTEL GMBH	DE
Hydromorphon-ratiopharm® Retardtabletten	DE/H/2245/001	76821.00.00	RATIOPHARM GMBH	DE
Hydromorphon-ratiopharm® Retardtabletten	DE/H/2245/002	76822.00.00	RATIOPHARM GMBH	DE
Hydromorphon-ratiopharm® Retardtabletten	DE/H/2245/004	76824.00.00	RATIOPHARM GMBH	DE
Hydromorphon-ratiopharm® Retardtabletten	DE/H/2245/003	76823.00.00	RATIOPHARM GMBH	DE
Hydromorphon-STADA 16 mg Retardtabletten	DE/H/2326/003	77419.00.00	STADAPHARM GMBH	DE
Hydromorphon-STADA 24 mg Retardtabletten	DE/H/2326/004	77420.00.00	STADAPHARM GMBH	DE
Hydromorphon-STADA 8	DE/H/2326/002	77418.00.00	STADAPHARM GMBH	DE

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mg Retardtabletten				
Hydromorphon-STADA® 4 mg Retardtabletten	DE/H/2326/001	77417.00.00	STADAPHARM GMBH	DE
Hydromorphon-Winthrop 16 mg Retardtabletten	DE/H/2247/003	76831.00.00	ZENTIVA PHARMA GMBH	DE
Hydromorphon-Winthrop 24 mg Retardtabletten	DE/H/2247/004	76832.00.00	ZENTIVA PHARMA GMBH	DE
Hydromorphon-Winthrop 4 mg Retardtabletten	DE/H/2247/001	76829.00.00	ZENTIVA PHARMA GMBH	DE
Hydromorphon-Winthrop 8 mg Retardtabletten	DE/H/2247/002	76830.00.00	ZENTIVA PHARMA GMBH	DE
Medepidol 16 mg compresse a rilascio prolungato	DE/H/7719/003	050971074	G.L. PHARMA GMBH	IT
Medepidol 16 mg compresse a rilascio prolungato	DE/H/7719/003	050971086	G.L. PHARMA GMBH	IT
Medepidol 16 mg compresse a rilascio prolungato	DE/H/7719/003	050971098	G.L. PHARMA GMBH	IT
Medepidol 24 mg compresse a rilascio prolungato	DE/H/7719/004	050971100	G.L. PHARMA GMBH	IT
Medepidol 24 mg compresse a rilascio prolungato	DE/H/7719/004	050971112	G.L. PHARMA GMBH	IT
Medepidol 24 mg compresse a rilascio prolungato	DE/H/7719/004	050971124	G.L. PHARMA GMBH	IT
Medepidol 4 mg compresse a rilascio prolungato	DE/H/7719/001	050971011	G.L. PHARMA GMBH	IT
Medepidol 4 mg compresse a rilascio prolungato	DE/H/7719/001	050971023	G.L. PHARMA GMBH	IT
Medepidol 4 mg	DE/H/7719/001	050971035	G.L. PHARMA GMBH	IT

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compresse a rilascio prolungato				
Medepidol 8 mg compresse a rilascio prolungato	DE/H/7719/002	050971047	G.L. PHARMA GMBH	IT
Medepidol 8 mg compresse a rilascio prolungato	DE/H/7719/002	050971050	G.L. PHARMA GMBH	IT
Medepidol 8 mg compresse a rilascio prolungato	DE/H/7719/002	050971062	G.L. PHARMA GMBH	IT
Palladon 1,3 mg Hartkapseln	IE/H/0131/006;IE/H/0131/005	59112.00.00	MUNDIPHARMA GMBH	DE
Palladon 1,3 mg kapseli, kova	not available	12924	MUNDIPHARMA OY	FI
Palladon 10 mg/ml injektions-/infusionsvätska, lösning	DE/H/1540/001-004	26899	MUNDIPHARMA AB	SE
Palladon 16 mg depotkapseli, kova	not available	11980	MUNDIPHARMA OY	FI
Palladon 2 mg/ml injeksjons- eller infusjonsvæske, oppløsning	DE/H/1540/001-004	08-5876	MUNDIPHARMA AS	NO
Palladon 2 mg/ml injektions-/infusionsvätska, lösning	DE/H/1540/001-004	26898	MUNDIPHARMA AB	SE
Palladon 2,6 mg Hartkapseln	IE/H/0131/006;IE/H/0131/005	59112.01.00	MUNDIPHARMA GMBH	DE
Palladon 2,6 mg kapseli,kova	not available	12925	MUNDIPHARMA OY	FI
Palladon 20 mg/ml injektions-/infusionsvätska, lösning	DE/H/1540/001-004	26900	MUNDIPHARMA AB	SE
Palladon 24 mg depotkapseli, kova	not available	11981	MUNDIPHARMA OY	FI

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
Palladon 4 mg depotkapseli, kova	not available	11978	MUNDIPHARMA OY	FI
Palladon 50 mg/ml injeksjons- eller infusjonsvæske, oppløsning	DE/H/1540/001-004	08-5879	MUNDIPHARMA AS	NO
Palladon 50 mg/ml injektions-/infusionsvätska, lösning	DE/H/1540/001-004	26901	MUNDIPHARMA AB	SE
Palladon 50 mg/ml, injektio-/infuusioneste, liuos	DE/H/1540/001-004	24920	MUNDIPHARMA OY	FI
Palladon 8 mg depotkapseli, kova	not available	11979	MUNDIPHARMA OY	FI
Palladon injectie 10 mg/ml, oplossing voor injectie of infusie	not available	RVG 104836	MUNDIPHARMA PHARMACEUTICALS BV	NL
Palladon injectie 2 mg/ml, oplossing voor injectie of infusie	not available	RVG 104833	MUNDIPHARMA PHARMACEUTICALS BV	NL
Palladon injectie 50 mg/ml, oplossing voor injectie of infusie	not available	RVG 104838	MUNDIPHARMA PHARMACEUTICALS BV	NL
Palladon injekt 10 mg	not available	59110.00.00	MUNDIPHARMA GMBH	DE
Palladon injekt 10 mg/ml Injektions/Infusionslösung	DE/H/1540/001-004	72197.00.00	MUNDIPHARMA GMBH	DE
Palladon injekt 100 mg	not available	59111.00.00	MUNDIPHARMA GMBH	DE
Palladon injekt 2 mg	not available	59109.00.00	MUNDIPHARMA GMBH	DE
Palladon injekt 2 mg/ml Injektions/Infusionslösung	DE/H/1540/001-004	72196.00.00	MUNDIPHARMA GMBH	DE
Palladon injekt 20 mg/ml Injektions/Infusionslösung	DE/H/1540/001-004	72198.00.00	MUNDIPHARMA GMBH	DE
Palladon injekt 50 mg/ml	DE/H/1540/001-004	72199.00.00	MUNDIPHARMA 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
Injektions/Infusionslösung				
Palladon retard 16 mg, Hartkapseln, retardiert	not available	33162.02.00	MUNDIPHARMA GMBH	DE
Palladon retard 24 mg, Hartkapseln, retardiert	not available	33162.03.00	MUNDIPHARMA GMBH	DE
Palladon retard 4 mg, Hartkapseln, retardiert	not available	33162.00.00	MUNDIPHARMA GMBH	DE
Palladon retard 8 mg, Hartkapseln, retardiert	not available	33162.01.00	MUNDIPHARMA GMBH	DE
Palladon, injektions- og infusionsvæske, opløsning 50 mg/ml	DE/H/1540/001-004	43152	MUNDIPHARMA A/S	DK
PALLADONE - SR 16 mg	not available	65/120/03-C	MUNDIPHARMA GES.M.B.H	CZ
PALLADONE - SR 2 mg	not available	65/117/03-C	MUNDIPHARMA GES.M.B.H	CZ
PALLADONE - SR 4 mg	not available	65/118/03-C	MUNDIPHARMA GES.M.B.H	CZ
PALLADONE - SR 8 mg	not available	65/119/03-C	MUNDIPHARMA GES.M.B.H	CZ
Palladone 1.3 mg capsules	IE/H/0131/006;IE/H/0131/005	PA 1688/007/001	MUNDIPHARMA PHARMACEUTICALS LIMITED	IE
Palladone 2.6 mg Hard Capsules	IE/H/0131/006;IE/H/0131/005	PA 1688/007/002	MUNDIPHARMA PHARMACEUTICALS LIMITED	IE
Palladone Immediate Release 2,6 mg, capsules hard	not available	BE 256961	MUNDIPHARMA COMM VA	BE
Palladone Immediate Release 2,6 mg, harde capsules	not available	BE 256961	MUNDIPHARMA BV	BE
Palladone Immediate Release 2,6 mg, harde capsules	not available	2011041069	MUNDIPHARMA BV	LU
Palladone Slow Release 4 mg, capsules met verlengde afgifte, hard	not available	BE 217131	MUNDIPHARMA BV	BE
Palladone Slow Release	not available	BE 217131	MUNDIPHARMA BV	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
4 mg, gélules à libération prolongée				
Palladone Slow Release 4 mg, gélules à libération prolongée	not available	2001070020	MUNDIPHARMA BV	LU
Palladone Slow Release 8 mg, capsules met verlengde afgifte, hard	not available	BE 217156	MUNDIPHARMA BV	BE
Palladone Slow Release 8 mg, gélules à libération prolongée	not available	BE 217156	MUNDIPHARMA BV	BE
Palladone Slow Release 8 mg, gélules à libération prolongée	not available	2001070021	MUNDIPHARMA BV	LU
Palladone SR 2 mg prolonged release capsules	not available	PA 1688/007/007	MUNDIPHARMA PHARMACEUTICALS LIMITED	IE
PALLADONE SR 24 mg	not available	65/121/03-C	MUNDIPHARMA GES.M.B.H	CZ
Palladone SR 4 mg prolonged release capsules	IE/H/0131/004;IE/H/0131/003;IE/H/131/002;IE/H/0131	PA 1688/007/008	MUNDIPHARMA PHARMACEUTICALS LIMITED	IE
Palladone SR 8 mg prolonged release capsules	IE/H/0131/004;IE/H/0131/003;IE/H/131/002;IE/H/0131	PA 1688/007/009	MUNDIPHARMA PHARMACEUTICALS LIMITED	IE
PALLADONE-SR capsules 16 mg tvrdé kapsuly s predĺženým uvoľňovaním	not available	65/0251/03-S	MUNDIPHARMA GESELLSCHAFT M.B.H.	SK
PALLADONE-SR capsules 2 mg tvrdé kapsuly s predĺženým uvoľňovaním	not available	65/0248/03-S	MUNDIPHARMA GESELLSCHAFT M.B.H.	SK
PALLADONE-SR capsules 4 mg tvrdé kapsuly s predĺženým uvoľňovaním	not available	65/0249/03-S	MUNDIPHARMA GESELLSCHAFT M.B.H.	SK
PALLADONE-SR capsules 8 mg tvrdé kapsuly s predĺženým uvoľňovaním	not available	65/0250/03-S	MUNDIPHARMA GESELLSCHAFT M.B.H.	SK

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
Palladon-IR capsules 1,3 mg	not available	RVG 26549	MUNDIPHARMA PHARMACEUTICALS BV	NL
Palladon-IR capsules 2,6 mg	not available	RVG 26550	MUNDIPHARMA PHARMACEUTICALS BV	NL
Palladon-SR capsules 4 mg, capsules met verlengde afgifte	not available	RVG 22162	MUNDIPHARMA PHARMACEUTICALS BV	NL
Palladon-SR capsules 8 mg, capsules met verlengde afgifte	not available	RVG 22163	MUNDIPHARMA PHARMACEUTICALS BV	NL
SOPHIDONE L.P. 16 mg, gélule à libération prolongée	not available	34009 561 204 4 4	MUNDIPHARMA SAS	FR
SOPHIDONE L.P. 16 mg, gélule à libération prolongée	not available	34009 561 203 8 3	MUNDIPHARMA SAS	FR
SOPHIDONE L.P. 16 mg, gélule à libération prolongée	not available	34009 348 907 1 0	MUNDIPHARMA SAS	FR
SOPHIDONE L.P. 16 mg, gélule à libération prolongée	not available	34009 348 906 5 9	MUNDIPHARMA SAS	FR
SOPHIDONE L.P. 24 mg, gélule à libération prolongée	not available	34009 348 908 8 8	MUNDIPHARMA SAS	FR
SOPHIDONE L.P. 24 mg, gélule à libération prolongée	not available	34009 561 206 7 3	MUNDIPHARMA SAS	FR
SOPHIDONE L.P. 24 mg, gélule à libération prolongée	not available	34009 348 909 4 9	MUNDIPHARMA SAS	FR
SOPHIDONE L.P. 24 mg, gélule à libération prolongée	not available	34009 561 205 0 5	MUNDIPHARMA SAS	FR
SOPHIDONE L.P. 4 mg, gélule à libération	not available	34009 561 200 9 3	MUNDIPHARMA SAS	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
prolongée				
SOPHIDONE L.P. 4 mg, gélule à libération prolongée	not available	34009 348 903 6 9	MUNDIPHARMA SAS	FR
SOPHIDONE L.P. 4 mg, gélule à libération prolongée	not available	34009 561 199 0 5	MUNDIPHARMA SAS	FR
SOPHIDONE L.P. 4 mg, gélule à libération prolongée	not available	34009 348 901 3 0	MUNDIPHARMA SAS	FR
SOPHIDONE L.P. 8 mg, gélule à libération prolongée	not available	34009 348 905 9 8	MUNDIPHARMA SAS	FR
SOPHIDONE L.P. 8 mg, gélule à libération prolongée	not available	34009 561 202 1 5	MUNDIPHARMA SAS	FR
SOPHIDONE L.P. 8 mg, gélule à libération prolongée	not available	34009 561 201 5 4	MUNDIPHARMA SAS	FR
SOPHIDONE L.P. 8 mg, gélule à libération prolongée	not available	34009 348 904 2 0	MUNDIPHARMA SAS	FR