21 July 2022
EMA/270645/2015
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: hydromorphone

Procedure no.: PSUSA/00001686/202111

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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 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 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 4 mg comprimidos de liberación prolongada	DE/H/3761/001	79783	ARISTO PHARMA GMBH (ART 57)	ES
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
Hydal 1.3 mg Kapseln	not available	1-21972	MUNDIPHARMA GES.M.B.H	AT
Hydal 10 mg/ml Injektionslösung	DE/H/1540/002	1-28306	MUNDIPHARMA GES.M.B.H	AT
Hydal 2 mg/ml Injektions-/Infusionslösung	DE/H/1540/001	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/1540/003	1-28307	MUNDIPHARMA GES.M.B.H	AT
Hydal 50 mg/ml Injektionslösung	DE/H/1540/004	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	not available	1-21973	MUNDIPHARMA GES.M.B.H	AT

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
Kapseln				
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 Pharma 4 mg Hartkapseln, retardiert	not available	84815.00.00	1 A PHARMA GMBH	DE
Hydromorphon Aristo 16 mg Retardtabletten	DE/H/6507/003	90471.00.00	ARISTO PHARMA GMBH (ART 57)	DE
Hydromorphon Aristo 24 mg Retardtabletten	DE/H/6507/004	90472.00.00	ARISTO PHARMA GMBH (ART 57)	DE
Hydromorphon Aristo 4 mg Retardtabletten	DE/H/6507/001	90469.00.00	ARISTO PHARMA GMBH (ART 57)	DE
Hydromorphon Aristo 8 mg Retardtabletten	DE/H/6507/002	90470.00.00	ARISTO PHARMA GMBH (ART 57)	DE
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

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
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 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 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 Hexal 16 mg - Retardtabletten	DE/H/2248/003	1-29431	HEXAL PHARMA GMBH	AT
Hydromorphon Hexal 24 mg - Retardtabletten	DE/H/2248/004	1-29432	HEXAL PHARMA GMBH	AT
Hydromorphon Hexal 4 mg - Retardtabletten	DE/H/2248/001	1-29429	HEXAL PHARMA GMBH	AT
Hydromorphon Hexal 8 mg - Retardtabletten	DE/H/2248/002	1-29430	HEXAL PHARMA GMBH	AT
Hydromorphon Krugmann 1,3 mg Hartkapseln	DE/H/7284/001-002/DC	2204999.00.00	KRUGMANN GMBH (GERMANY)	DE
Hydromorphon Krugmann	DE/H/7284/001-002/DC	2205000.00.00	KRUGMANN 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
2,6 mg Hartkapseln			(GERMANY)	
Hydromorphon ratiopharm 16 mg Retardtabletten	DE/H/2245/003	1-29274	TEVA B.V	AT
Hydromorphon ratiopharm 24 mg Retardtabletten	DE/H/2245/004	1-29275	TEVA B.V	AT
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

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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 Hartkapseln, retardiert	DE/H/2432/005	78099.00.00	PUREN PHARMA GMBH & CO. KG	DE
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 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 Krugmann 16 mg, Hartkapseln, retardiert	not available	2203922.00.00	KRUGMANN GMBH (GERMANY)	DE
Hydromorphon-HCl Krugmann 16 mg, Hartkapseln, retardiert	not available	2203922.00.00	KRUGMANN GMBH (GERMANY)	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
Hydromorphon-HCl Krugmann 24 mg, Hartkapseln, retardiert	not available	2203923.00.00	KRUGMANN GMBH (GERMANY)	DE
Hydromorphon-HCl Krugmann 24 mg, Hartkapseln, retardiert	not available	2203923.00.00	KRUGMANN GMBH (GERMANY)	DE
Hydromorphon-HCl Krugmann 4 mg, Hartkapseln, retardiert	not available	2203920.00.00	KRUGMANN GMBH (GERMANY)	DE
Hydromorphon-HCl Krugmann 4 mg, Hartkapseln, retardiert	not available	2203920.00.00	KRUGMANN GMBH (GERMANY)	DE
Hydromorphon-HCl Krugmann 8 mg, Hartkapseln, retardiert	not available	2203921.00.00	KRUGMANN GMBH (GERMANY)	DE
Hydromorphon-HCl Krugmann 8 mg, Hartkapseln, retardiert	not available	2203921.00.00	KRUGMANN GMBH (GERMANY)	DE
Hydromorphon-HCl-ratiopharm® 16 mg Hartkapseln, retardiert	not available	84822.00.00	RATIOPHARM GMBH	DE
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,	DE/H/2431/004	78093.00.00	HEXAL AG	DE

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retardiert				
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, retardiert	DE/H/2431/003	78092.00.00	HEXAL AG	DE
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
Hydromorphonhydrochlori	DE/H/2430/002	78086.00.00	BETAPHARM ARZNEIMITTEL	DE

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d beta 4 mg Retardkapseln			GMBH	
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® 4 mg Retardtabletten	DE/H/2326/001	77417.00.00	STADAPHARM GMBH	DE
Hydromorphon-STADA® 8 mg Retardtabletten	DE/H/2326/002	77418.00.00	STADAPHARM GMBH	DE
Hydromorphon-Winthrop 16 mg Retardtabletten	DE/H/2247/003	76831.00.00	WINTHROP ARZNEIMITTEL GMBH	DE
Hydromorphon-Winthrop 24 mg Retardtabletten	DE/H/2247/004	76832.00.00	WINTHROP ARZNEIMITTEL GMBH	DE
Hydromorphon-Winthrop 4 mg Retardtabletten	DE/H/2247/001	76829.00.00	WINTHROP ARZNEIMITTEL GMBH	DE
Hydromorphon-Winthrop 8 mg Retardtabletten	DE/H/2247/002	76830.00.00	WINTHROP ARZNEIMITTEL GMBH	DE
JURNISTA 16 mg compresse a rilascio	DK/H/0869/002	037396165	JANSSEN-CILAG SPA	IT

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prolungato				
JURNISTA 16 mg compresse a rilascio prolungato	DK/H/0869/002	037396189	JANSSEN-CILAG SPA	IT
JURNISTA 16 mg compresse a rilascio prolungato	DK/H/0869/002	037396138	JANSSEN-CILAG SPA	IT
JURNISTA 16 mg compresse a rilascio prolungato	DK/H/0869/002	037396140	JANSSEN-CILAG SPA	IT
JURNISTA 16 mg compresse a rilascio prolungato	DK/H/0869/002	037396153	JANSSEN-CILAG SPA	IT
JURNISTA 16 mg compresse a rilascio prolungato	DK/H/0869/002	037396239	JANSSEN-CILAG SPA	IT
JURNISTA 16 mg compresse a rilascio prolungato	DK/H/0869/002	037396227	JANSSEN-CILAG SPA	IT
JURNISTA 16 mg compresse a rilascio prolungato	DK/H/0869/002	037396191	JANSSEN-CILAG SPA	IT
JURNISTA 16 mg compresse a rilascio prolungato	DK/H/0869/002	037396203	JANSSEN-CILAG SPA	IT
JURNISTA 16 mg compresse a rilascio prolungato	DK/H/0869/002	037396241	JANSSEN-CILAG SPA	IT
JURNISTA 16 mg compresse a rilascio prolungato	DK/H/0869/002	037396177	JANSSEN-CILAG SPA	IT
JURNISTA 16 mg compresse a rilascio prolungato	DK/H/0869/002	037396215	JANSSEN-CILAG SPA	IT
Jurnista 16 mg	DK/H/0869/002	68.019	JANSSEN-CILAG S.A.	ES

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comprimidos de liberación prolongada				
JURNISTA 16 mg comprimidos de libertação prolongada	DK/H/0869/002	5841788	JANSSEN-CILAG FARMACÊUTICA, LDA.	PT
JURNISTA 16 mg comprimidos de libertação prolongada	DK/H/0869/002	5841689	JANSSEN-CILAG FARMACÊUTICA, LDA.	PT
JURNISTA 16 mg Retardtabletten	DK/H/0869/ 002	63502.00.00	JANSSEN-CILAG GMBH	DE
JURNISTA 32 mg compresse a rilascio prolungato	DK/H/0869/003	037396316	JANSSEN-CILAG SPA	IT
JURNISTA 32 mg compresse a rilascio prolungato	DK/H/0869/003	037396278	JANSSEN-CILAG SPA	IT
JURNISTA 32 mg compresse a rilascio prolungato	DK/H/0869/003	037396280	JANSSEN-CILAG SPA	IT
JURNISTA 32 mg compresse a rilascio prolungato	DK/H/0869/003	037396254	JANSSEN-CILAG SPA	IT
JURNISTA 32 mg compresse a rilascio prolungato	DK/H/0869/003	037396266	JANSSEN-CILAG SPA	IT
JURNISTA 32 mg compresse a rilascio prolungato	DK/H/0869/003	037396304	JANSSEN-CILAG SPA	IT
JURNISTA 32 mg compresse a rilascio prolungato	DK/H/0869/003	037396292	JANSSEN-CILAG SPA	IT
JURNISTA 32 mg compresse a rilascio prolungato	DK/H/0869/003	037396330	JANSSEN-CILAG SPA	IT
JURNISTA 32 mg	DK/H/0869/003	037396367	JANSSEN-CILAG SPA	IT

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compresse a rilascio prolungato				
JURNISTA 32 mg compresse a rilascio prolungato	DK/H/0869/003	037396328	JANSSEN-CILAG SPA	IT
JURNISTA 32 mg compresse a rilascio prolungato	DK/H/0869/003	037396342	JANSSEN-CILAG SPA	IT
JURNISTA 32 mg compresse a rilascio prolungato	DK/H/0869/003	037396355	JANSSEN-CILAG SPA	IT
Jurnista 32 mg comprimidos de liberación prolongada	DK/H/0869/003	68.020	JANSSEN-CILAG S.A.	ES
JURNISTA 32 mg comprimidos de libertação prolongada	DK/H/0869/003	5841887	JANSSEN-CILAG FARMACÊUTICA, LDA.	PT
JURNISTA 32 mg comprimidos de libertação prolongada	DK/H/0869/003	5841986	JANSSEN-CILAG FARMACÊUTICA, LDA.	PT
JURNISTA 32 mg Retardtabletten	DK/H/0869/ 003	63503.00.00	JANSSEN-CILAG GMBH	DE
JURNISTA 4 mg compresse a rilascio prolungato	DK/H/0869/005	037396532	JANSSEN-CILAG SPA	IT
JURNISTA 4 mg compresse a rilascio prolungato	DK/H/0869/005	037396494	JANSSEN-CILAG SPA	IT
JURNISTA 4 mg compresse a rilascio prolungato	DK/H/0869/005	037396595	JANSSEN-CILAG SPA	IT
JURNISTA 4 mg compresse a rilascio prolungato	DK/H/0869/005	037396557	JANSSEN-CILAG SPA	IT
JURNISTA 4 mg	DK/H/0869/005	037396571	JANSSEN-CILAG SPA	IT

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compresse a rilascio prolungato				
JURNISTA 4 mg compresse a rilascio prolungato	DK/H/0869/005	037396520	JANSSEN-CILAG SPA	IT
JURNISTA 4 mg compresse a rilascio prolungato	DK/H/0869/005	037396583	JANSSEN-CILAG SPA	IT
JURNISTA 4 mg compresse a rilascio prolungato	DK/H/0869/005	037396518	JANSSEN-CILAG SPA	IT
JURNISTA 4 mg compresse a rilascio prolungato	DK/H/0869/005	037396569	JANSSEN-CILAG SPA	IT
JURNISTA 4 mg compresse a rilascio prolungato	DK/H/0869/005	037396544	JANSSEN-CILAG SPA	IT
JURNISTA 4 mg compresse a rilascio prolungato	DK/H/0869/005	037396506	JANSSEN-CILAG SPA	IT
JURNISTA 4 mg compresse a rilascio prolungato	DK/H/0869/005	037396607	JANSSEN-CILAG SPA	IT
Jurnista 4 mg comprimidos de liberación prolongada	DK/H/0869/005	69.710	JANSSEN-CILAG S.A.	ES
JURNISTA 4 mg comprimidos de libertação prolongada	DK/H/0869/005	5286257	JANSSEN-CILAG FARMACÊUTICA, LDA.	PT
JURNISTA 4 mg comprimidos de libertação prolongada	DK/H/0869/005	5079033	JANSSEN-CILAG FARMACÊUTICA, LDA.	PT
JURNISTA 4 mg comprimidos de libertação prolongada	DK/H/0869/005	5296173	JANSSEN-CILAG FARMACÊUTICA, LDA.	PT

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JURNISTA 4 mg comprimidos de libertação prolongada	DK/H/0869/005	5079041	JANSSEN-CILAG FARMACÊUTICA, LDA.	PT
JURNISTA 4 mg comprimidos de libertação prolongada	DK/H/0869/005	5286240	JANSSEN-CILAG FARMACÊUTICA, LDA.	PT
JURNISTA 4 mg Retardtabletten	DK/H/0869/ 005	68242.00.00	JANSSEN-CILAG GMBH	DE
JURNISTA 64 mg compresse a rilascio prolungato	DK/H/0869/004	037396468	JANSSEN-CILAG SPA	IT
JURNISTA 64 mg compresse a rilascio prolungato	DK/H/0869/004	037396431	JANSSEN-CILAG SPA	IT
JURNISTA 64 mg compresse a rilascio prolungato	DK/H/0869/004	037396443	JANSSEN-CILAG SPA	IT
JURNISTA 64 mg compresse a rilascio prolungato	DK/H/0869/004	037396470	JANSSEN-CILAG SPA	IT
JURNISTA 64 mg compresse a rilascio prolungato	DK/H/0869/004	037396482	JANSSEN-CILAG SPA	IT
JURNISTA 64 mg compresse a rilascio prolungato	DK/H/0869/004	037396381	JANSSEN-CILAG SPA	IT
JURNISTA 64 mg compresse a rilascio prolungato	DK/H/0869/004	037396393	JANSSEN-CILAG SPA	IT
JURNISTA 64 mg compresse a rilascio prolungato	DK/H/0869/004	037396456	JANSSEN-CILAG SPA	IT
JURNISTA 64 mg compresse a rilascio prolungato	DK/H/0869/004	037396379	JANSSEN-CILAG SPA	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
JURNISTA 64 mg compresse a rilascio prolungato	DK/H/0869/004	037396417	JANSSEN-CILAG SPA	IT
JURNISTA 64 mg compresse a rilascio prolungato	DK/H/0869/004	037396405	JANSSEN-CILAG SPA	IT
JURNISTA 64 mg compresse a rilascio prolungato	DK/H/0869/004	037396429	JANSSEN-CILAG SPA	IT
JURNISTA 64 mg comprimidos de libertação prolongada	DK/H/0869/004	5842182	JANSSEN-CILAG FARMACÊUTICA, LDA.	PT
JURNISTA 64 mg comprimidos de libertação prolongada	DK/H/0869/004	5842083	JANSSEN-CILAG FARMACÊUTICA, LDA.	PT
JURNISTA 64 mg Retardtabletten	DK/H/0869/ 004	63504.00.00	JANSSEN-CILAG GMBH	DE
JURNISTA 8 mg compresse a rilascio prolungato	DK/H/0869/001	037396049	JANSSEN-CILAG SPA	IT
JURNISTA 8 mg compresse a rilascio prolungato	DK/H/0869/001	037396090	JANSSEN-CILAG SPA	IT
JURNISTA 8 mg compresse a rilascio prolungato	DK/H/0869/001	037396102/M	JANSSEN-CILAG SPA	IT
JURNISTA 8 mg compresse a rilascio prolungato	DK/H/0869/001	037396013	JANSSEN-CILAG SPA	IT
JURNISTA 8 mg compresse a rilascio prolungato	DK/H/0869/001	037396114	JANSSEN-CILAG SPA	IT
JURNISTA 8 mg compresse a rilascio prolungato	DK/H/0869/001	037396126	JANSSEN-CILAG SPA	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
JURNISTA 8 mg compresse a rilascio prolungato	DK/H/0869/001	037396025	JANSSEN-CILAG SPA	IT
JURNISTA 8 mg compresse a rilascio prolungato	DK/H/0869/001	037396052	JANSSEN-CILAG SPA	IT
JURNISTA 8 mg compresse a rilascio prolungato	DK/H/0869/001	037396088	JANSSEN-CILAG SPA	IT
JURNISTA 8 mg compresse a rilascio prolungato	DK/H/0869/001	037396076	JANSSEN-CILAG SPA	IT
JURNISTA 8 mg compresse a rilascio prolungato	DK/H/0869/001	037396037	JANSSEN-CILAG SPA	IT
JURNISTA 8 mg compresse a rilascio prolungato	DK/H/0869/001	037396064	JANSSEN-CILAG SPA	IT
Jurnista 8 mg comprimidos de liberación prolongada	DK/H/0869/001	68.018	JANSSEN-CILAG S.A.	ES
JURNISTA 8 mg comprimidos de libertação prolongada	DK/H/0869/001	5841580	JANSSEN-CILAG FARMACÊUTICA, LDA.	PT
JURNISTA 8 mg comprimidos de libertação prolongada	DK/H/0869/001	5100318	JANSSEN-CILAG FARMACÊUTICA, LDA.	PT
JURNISTA 8 mg comprimidos de libertação prolongada	DK/H/0869/001	5100326	JANSSEN-CILAG FARMACÊUTICA, LDA.	PT
JURNISTA 8 mg comprimidos de libertação prolongada	DK/H/0869/001	5841481	JANSSEN-CILAG FARMACÊUTICA, LDA.	PT
JURNISTA 8 mg Retardtabletten	DK/H/0869/ 001	63501.00.00	JANSSEN-CILAG 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
Jurnista, depottabletter	DK/H/0869/002	32345	JANSSEN-CILAG A/S	DK
Jurnista, depottabletter	DK/H/0869/004	32347	JANSSEN-CILAG A/S	DK
Jurnista, depottabletter	DK/H/0869/003	32346	JANSSEN-CILAG A/S	DK
Jurnista, depottabletter	DK/H/0869/001	32344	JANSSEN-CILAG A/S	DK
Jurnista, depottabletter	DK/H/0869/005	40775	JANSSEN-CILAG A/S	DK
P ALLADONE-SR capsules 8 mg tvrde kapsuly s predfzenym uvol'novanim	not available	65/0250/03-S	MUNDIPHARMA GESELLSCHAFT M.B.H.	SK
Palladon 1,3 mg Hartkapseln	IE/H/0131/005	59112.00.00	MUNDIPHARMA GMBH	DE
Palladon 10 mg/ml injeksjons-/infusjonsvæske, oppløsning	DE/H/1540/002	08-5877	MUNDIPHARMA AS	NO
Palladon 10 mg/ml injektions-/infusionsvätska, lösning	DE/H/1540/002	26899	MUNDIPHARMA AB	SE
Palladon 2 mg/ml injeksjons-/infusjonsvæske, oppløsning	DE/H/1540/001	08-5876	MUNDIPHARMA AS	NO
Palladon 2 mg/ml injektions-/infusionsvätska, lösning	DE/H/1540/001	26898	MUNDIPHARMA AB	SE
Palladon 2,6 mg Hartkapseln	not available	59112.01.00	MUNDIPHARMA GMBH	DE
Palladon 20 mg/ml injeksjons-/infusjonsvæske, oppløsning	DE/H/1540/003	08-5878	MUNDIPHARMA AS	NO
Palladon 20 mg/ml injektions-/infusionsvätska, lösning	DE/H/1540/003	26900	MUNDIPHARMA AB	SE
Palladon 20 mg/ml stungulyf/innrennslislyf,	DE/H/1540/003	IS/1/08/079/03	MUNDIPHARMA A/S	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
lausn				
Palladon 24 mg depotkapseli, kova	not available	11981	MUNDIPHARMA OY	FI
Palladon 4 mg depotkapseli, kova	not available	11978	MUNDIPHARMA OY	FI
Palladon 50 mg/ml injeksjons-/infusjonsvæske, oppløsning	DE/H/1540/004	08-5879	MUNDIPHARMA AS	NO
Palladon 50 mg/ml injektions-/infusionsvätska, lösning	DE/H/1540/004	26901	MUNDIPHARMA AB	SE
Palladon 50 mg/ml stungulyf/innrennslislyf, lausn	DE/H/1540/004	IS/1/08/079/04	MUNDIPHARMA A/S	IS
Palladon 50 mg/ml, injektio-/infuusioneste, liuos	DE/H/1540/004	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 20 mg/ml, oplossing voor injectie of infusie	not available	RVG 104837	MUNDIPHARMA PHARMACEUTICALS BV	NL
Palladon injectie 50mg/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-	DE/H/1540/002	72197.00.00	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
/Infusionslösung Hydromorphonhydrochlorid				
Palladon injekt 10 mg/ml Injektions-/Infusionslösung Hydromorphonhydrochlorid	DE/H/1540/002	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 Hydromorphonhydrochlorid	DE/H/1540/001	72196.00.00	MUNDIPHARMA GMBH	DE
Palladon injekt 2 mg/ml Injektions-/Infusionslösung Hydromorphonhydrochlorid	DE/H/1540/001	72196.00.00	MUNDIPHARMA GMBH	DE
Palladon injekt 20 mg/ml Injektions-/Infusionslösung Hydromorphonhydrochlorid	DE/H/1540/003	72198.00.00	MUNDIPHARMA GMBH	DE
Palladon injekt 20 mg/ml Injektions-/Infusionslösung Hydromorphonhydrochlorid	DE/H/1540/003	72198.00.00	MUNDIPHARMA GMBH	DE
Palladon injekt 50 mg/ml Injektions-/Infusionslösung Hydromorphonhydrochlorid	DE/H/1540/004	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
Palladon injekt 50 mg/ml Injektions-/Infusionslösung Hydromorphonhydrochlorid	DE/H/1540/004	72199.00.00	MUNDIPHARMA GMBH	DE
Palladon, injektions- og infusionsvæske, opløsning	DE/H/1540/004	43152	MUNDIPHARMA A/S	DK
Palladon, injektions- og infusionsvæske, opløsning	DE/H/1540/003	43151	MUNDIPHARMA A/S	DK
Palladon® retard 16 mg	not available	33162.02.00	MUNDIPHARMA GMBH	DE
Palladon® retard 24 mg	not available	33162.03.00	MUNDIPHARMA GMBH	DE
Palladon® retard 4 mg	not available	33162.00.00	MUNDIPHARMA GMBH	DE
Palladon® retard 8 mg	not available	33162.01.00	MUNDIPHARMA GMBH	DE
Palladone 1.3 mg capsules	IE/H/0131/005	PA 1688/007/001	MUNDIPHARMA PHARMACEUTICALS LIMITED	IE
Palladone 10 mg/ml oplossing voor injectie of infusie	DE/H/1540/002	2009120029	MUNDIPHARMA COMM VA	LU
Palladone 10 mg/ml oplossing voor injectie of infusie.	DE/H/1540/002	BE342711	MUNDIPHARMA COMM VA	BE
Palladone 10 mg/ml solution injectable ou solution pour perfusion	DE/H/1540/002	BE342711	MUNDIPHARMA COMM VA	BE
PALLADONE 16 mg trde kapsule s podaljšanim sproščanjem	not available	H/02/01210/009	MUNDIPHARMA GES.M.B.H	SI
PALLADONE 16 mg trde kapsule s podaljšanim sproščanjem	not available	H/02/01210/010	MUNDIPHARMA GES.M.B.H	SI
PALLADONE 16 mg trde kapsule s podaljšanim sproščanjem	not available	H/02/01210/011	MUNDIPHARMA GES.M.B.H	SI
PALLADONE 2 mg trde kapsule s podaljšanim	not available	H/02/01210/001	MUNDIPHARMA GES.M.B.H	SI

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
sproščanjem				
PALLADONE 2 mg trde kapsule s podaljšanim sproščanjem	not available	H/02/01210/002	MUNDIPHARMA GES.M.B.H	SI
Palladone 2 mg/ml oplossing voor injectie of infusie	DE/H/1540/001	2009120028	MUNDIPHARMA COMM VA	LU
Palladone 2 mg/ml oplossing voor injectie of infusie.	DE/H/1540/001	BE342702	MUNDIPHARMA COMM VA	BE
Palladone 2 mg/ml solution injectable ou solution pour perfusion	DE/H/1540/001	BE342702	MUNDIPHARMA COMM VA	BE
Palladone 2.6 mg capsules.	IE/H/0131/006	PA 1688/007/002	MUNDIPHARMA PHARMACEUTICALS LIMITED	IE
Palladone 20 mg/ml oplossing voor injectie of infusie.	DE/H/1540/003	BE342727	MUNDIPHARMA COMM VA	BE
Palladone 20 mg/ml solution pour injection ou perfusion	DE/H/1540/003	2009120030	MUNDIPHARMA COMM VA	LU
PALLADONE 24 mg trde kapsule s podaljšanim sproščanjem	not available	H/02/01210/012	MUNDIPHARMA GES.M.B.H	SI
PALLADONE 24 mg trde kapsule s podaljšanim sproščanjem	not available	H/02/01210/013	MUNDIPHARMA GES.M.B.H	SI
PALLADONE 4 mg trde kapsule s podaljšanim sproščanjem	not available	H/02/01210/004	MUNDIPHARMA GES.M.B.H	SI
PALLADONE 4 mg trde kapsule s podaljšanim sproščanjem	not available	H/02/01210/003	MUNDIPHARMA GES.M.B.H	SI
PALLADONE 4 mg trde kapsule s podaljšanim	not available	H/02/01210/005	MUNDIPHARMA GES.M.B.H	SI

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
sproščanjem				
PALLADONE 8 mg trde kapsule s podaljšanim sproščanjem	not available	H/02/01210/006	MUNDIPHARMA GES.M.B.H	SI
PALLADONE 8 mg trde kapsule s podaljšanim sproščanjem	not available	H/02/01210/007	MUNDIPHARMA GES.M.B.H	SI
PALLADONE 8 mg trde kapsule s podaljšanim sproščanjem	not available	H/02/01210/008	MUNDIPHARMA GES.M.B.H	SI
Palladone Immediate Release 1,3 mg, capsules hard	not available	BE 256952	MUNDIPHARMA COMM VA	BE
Palladone Immediate Release 1,3 mg, gélules	not available	BE256952	MUNDIPHARMA COMM VA	BE
Palladone Immediate Release 1,3 mg, gélules	not available	1495/04030125	MUNDIPHARMA COMM VA	LU
Palladone Immediate Release 2,6 mg, capsules hard	not available	BE 256961	MUNDIPHARMA COMM VA	BE
Palladone Immediate Release 2,6 mg, gélules	not available	BE256961	MUNDIPHARMA COMM VA	BE
Palladone Immediate Release 2,6 mg, gélules	not available	1495/04030126	MUNDIPHARMA COMM VA	LU
Palladone Slow Release 16 mg, capsules met verlengde afgifte, hard	not available	BE 217174	MUNDIPHARMA COMM VA	BE
Palladone Slow Release 16 mg, gélules à libération prolongée	not available	BE 217174	MUNDIPHARMA COMM VA	BE
Palladone Slow Release 16 mg, gélules à libération prolongée	not available	1495/01070022	MUNDIPHARMA COMM VA	LU
Palladone Slow Release 24 mg, capsules met	not available	BE 217192	MUNDIPHARMA COMM VA	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
verlengde afgifte, hard				
Palladone Slow Release 24 mg, gélules à libération prolongée	not available	BE 217192	MUNDIPHARMA COMM VA	BE
Palladone Slow Release 24 mg, gélules à libération prolongée	not available	1495/01070023	MUNDIPHARMA COMM VA	LU
Palladone Slow Release 4 mg, capsules met verlengde afgifte, hard	not available	BE 217131	MUNDIPHARMA COMM VA	BE
Palladone Slow Release 4 mg, gélules à libération prolongée	not available	BE 217131	MUNDIPHARMA COMM VA	BE
Palladone Slow Release 4 mg, gélules à libération prolongée	not available	1495/01070020	MUNDIPHARMA COMM VA	LU
Palladone Slow Release 8 mg, capsules met verlengde afgifte, hard	not available	BE 217156	MUNDIPHARMA COMM VA	BE
Palladone Slow Release 8 mg, gélules à libération prolongée	not available	BE 217156	MUNDIPHARMA COMM VA	BE
Palladone Slow Release 8 mg, gélules à libération prolongée	not available	1495/01070021	MUNDIPHARMA COMM VA	LU
Palladone SR 16 mg prolonged release capsules	IE/H/0131/003	PA 1688/007/010	MUNDIPHARMA PHARMACEUTICALS LIMITED	IE
Palladone SR 16 mg prolonged release capsules	IE/H/0131/003	PA 1688/007/010	MUNDIPHARMA PHARMACEUTICALS LIMITED	IE
Palladone SR 2 mg prolonged release capsules	not available	PA 1688/007/007	MUNDIPHARMA PHARMACEUTICALS LIMITED	IE
Palladone SR 2 mg	not available	PA 1688/007/007	MUNDIPHARMA	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
prolonged release capsules			PHARMACEUTICALS LIMITED	
Palladone SR 24 mg prolonged release capsules	IE/H/0131/004	PA 1688/007/011	MUNDIPHARMA PHARMACEUTICALS LIMITED	IE
Palladone SR 24 mg prolonged release capsules	IE/H/0131/004	PA 1688/007/011	MUNDIPHARMA PHARMACEUTICALS LIMITED	IE
Palladone SR 4 mg prolonged release capsules	IE/H/0131/001	PA 1688/007/008	MUNDIPHARMA PHARMACEUTICALS LIMITED	IE
Palladone SR 4 mg prolonged release capsules	IE/H/0131/001	PA 1688/007/008	MUNDIPHARMA PHARMACEUTICALS LIMITED	IE
Palladone SR 8 mg prolonged release capsules	IE/H/0131/002	PA 1688/007/009	MUNDIPHARMA PHARMACEUTICALS LIMITED	IE
Palladone SR 8 mg prolonged release capsules	IE/H/0131/002	PA 1688/007/009	MUNDIPHARMA PHARMACEUTICALS LIMITED	IE
PALLADONE-SR 4 mg tvrdé tobolky s prodlouženým uvolňováním	not available	65/118/03-C	MUNDIPHARMA GES.M.B.H	CZ
PALLADONE-SR 8 mg tvrdé tobolky s prodlouženým uvolňováním	not available	65/119/03-C	MUNDIPHARMA GES.M.B.H	CZ
PALLADONE-SR 16 mg tvrdé tobolky s prodlouženým uvolňováním	not available	65/120/03-C	MUNDIPHARMA GES.M.B.H	CZ
PALLADONE-SR 2 mg tvrdé tobolky s prodlouženým	not available	65/117/03-C	MUNDIPHARMA GES.M.B.H	CZ

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
uvolňováním				
PALLADONE-SR 24 mg tvrdé tobolky s prodlouženým uvolňováním	not available	65/121/03-C	MUNDIPHARMA GES.M.B.H	CZ
PALLADONE-SR capsules 16 mg tvrde kapsuly s predfzenym uvol'novanim	not available	65/0251/03-S	MUNDIPHARMA GESELLSCHAFT M.B.H.	SK
PALLADONE-SR capsules 2 mg tvrde kapsuly s predlzenym uvol'novanim	not available	65/0248/03-S	MUNDIPHARMA GESELLSCHAFT M.B.H.	SK
PALLADONE-SR capsules 4 mg tvrde kapsuly s predfzenym uvol'novanim	not available	65/0249/03-S	MUNDIPHARMA GESELLSCHAFT M.B.H.	SK
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 16 mg, capsules met verlengde afgifte	not available	RVG 22164	MUNDIPHARMA PHARMACEUTICALS BV	NL
Palladon-SR capsules 2 mg, capsules met verlengde afgifte	not available	RVG 29655	MUNDIPHARMA PHARMACEUTICALS BV	NL
Palladon-SR capsules 24 mg, capsules met verlengde afgifte	not available	RVG 22165	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	not available	34009 561 204 4 4	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. 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 prolongée	not available	34009 561 200 9 3	MUNDIPHARMA SAS	FR
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,	not available	34009 348 905 9 8	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
gélule à libération prolongée				
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