



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 September 2016
EMA/270645/2015
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: hydromorphone

Procedure no.: PSUSA/00001686/201511



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
Hidromorfona Aristo	DE/H/3761/001 \$ DE/H/3761/002 \$ DE/H/3761/003 \$ DE/H/3761/004	79781 \$ 79782 \$ 79783 \$ 79784	Aristo Pharma Iberia, S.L.	Spain
Hydal	DE/H/1540/001 \$ DE/H/1540/002 \$ DE/H/1540/003 \$ DE/H/1540/004	1-28305 \$ 1-28306 \$ 1-28307 \$ 1-28308	Mundipharma Gesellschaft M.B.H.	Austria
Hydromorphon Aristo	AT/H/0494/001 \$ AT/H/0494/002 \$ AT/H/0494/003 \$ AT/H/0494/004	1-31113 \$ 1-31114 \$ 1-31115 \$ 1-31116	Aristo Pharma Gmbh	Austria
Hydromorphon Aristo	AT/H/0494/001 \$ AT/H/0494/002 \$ AT/H/0494/003 \$ AT/H/0494/004	90469.00.00 \$ 90470.00.00 \$ 90471.00.00 \$ 90472.00.00	Aristo Pharma Gmbh	Germany
Hydromorphon Aristo Long	DE/H/3761/001/DC \$ DE/H/3761/002/DC \$ DE/H/3761/003/DC \$ DE/H/3761/004/DC	89245.00.00 \$ 89246.00.00 \$ 89247.00.00 \$ 89248.00.00	Aristo Pharma Gmbh (Art 57)	Germany
Hydromorphon Awd	DE/H/2246/001 \$ DE/H/2246/002 \$ DE/H/2246/003	76825.00.00 \$ 76826.00.00 \$ 76827.00.00	Teva Gmbh	Germany
Hydromorphon Develco	DE/H/3737/001/DC	89001.00.00	Develco Pharma Gmbh	Germany
Hydromorphon Develco	DE/H/3737/002/DC	89002.00.00	Develco Pharma Gmbh	Germany

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Hydromorphon Develco	DE/H/3737/003/DC	89003.00.00	Develco Pharma Gmbh	Germany
Hydromorphon Develco	DE/H/3737/004/DC	89004.00.00	Develco Pharma Gmbh	Germany
Hydromorphon HCl- Hormosan	DE/H/2246/001 \$ DE/H/2246/002 \$ DE/H/2246/003 \$ DE/H/2246/004	76825.00.00 \$ 76826.00.00 \$ 76827.00.00 \$ 76828.00.00	Hormosan Pharma Gmbh	Germany
Hydromorphon Hexal	DE/H/2248/001 \$ DE/H/2248/002 \$ DE/H/2248/003 \$ DE/H/2248/004	1-29429 \$ 1-29430 \$ 1-29431 \$ 1-29432	Hexal Pharma Gmbh	Austria
Hydromorphon Hexal Retard	DE/H/2431/001 \$ DE/H/2431/002 \$ DE/H/2431/003 \$ DE/H/2431/004 \$ DE/H/2431/005	78090.00.00 \$ 78091.00.00 \$ 78092.00.00 \$ 78093.00.00 \$ 78094.00.00	Hexal Ag	Germany
Hydromorphon Neuraxpharm	DE/H/3762/001/DC \$ DE/H/3762/002/DC \$ DE/H/3762/003/DC \$ DE/H/3762/004/DC	89249.00.00 \$ 89250.00.00 \$ 89251.00.00 \$ 89252.00.00	Aristo Pharma GmbH	Germany
Hydromorphon Ratiopharm	DE/H/2245/001 \$ DE/H/2245/002 \$ DE/H/2245/003 \$ DE/H/2245/004	76821.00.00 \$ 76822.00.00 \$ 76823.00.00 \$ 76824.00.00	Ratiopharm Gmbh	Germany

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Hydromorphon Ratiopharm	DE/H/2245/001 \$ DE/H/2245/002	1-29272 \$ 1-29273	Ratiopharm Arzneimittel Vertriebs-GmbH	Austria
Hydromorphon Ratiopharm	DE/H/2245/003 \$ DE/H/2245/004	1-29274 \$ 1-29275	Ratiopharm Arzneimittel Vertriebs-GmbH	Austria
Hydromorphon Hexal Retard	DE/H/2248/001 \$ DE/H/2248/002 \$ DE/H/2248/003 \$ DE/H/2248/004	76833.00.00 \$ 76834.00.00 \$ 76835.00.00 \$ 76836.00.00	Hexal Ag	Germany
Hydromorphon Winthrop	DE/H/2247/001 \$ DE/H/2247/002 \$ DE/H/2247/003 \$ DE/H/2247/004	76829.00.00 \$ 76830.00.00 \$ 76831.00.00 \$ 76832.00.00	Winthrop Arzneimittel GmbH	Germany
Hydromorphon-Awd	DE-H-2246-001-004	76825.00.00 \$ 76826.00.00 \$ 76827.00.00	Teva GmbH	Germany
Hydromorphon-Hcl 1 A Pharma		84814.00.00 \$ 84815.00.00 \$ 84817.00.00 \$ 84818.00.00	1 A Pharma GmbH	Germany
Hydromorphone-HCL- Acino		85909.00.00 \$ 85910.00.00 \$ 85911.00.00 \$ 85912.00.00 \$ 85913.00.00	Acino Ag	Germany
Hydromorphon-Hcl Ratiopharm		84819.00.00 \$ 84821.00.00 \$ 84823.00.00	Ratiopharm GmbH	Germany
Hydromorphon-Hcl Ratiopharm		84820.00.00 \$ 84822.00.00	Ratiopharm GmbH	Germany

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Hydromorphone Hcl Ratiopharm		84819.00.00 \$ 84820.00.00 \$ 84821.00.00 \$ 84822.00.00 \$ 84823.00.00	Ratiopharm Gmbh	Germany
Hydromorphone Hcl Ratiopharm	DE-H-2245-001-004	1-29272 \$ 1-29273 \$ 1-29274 \$ 1-29275	Ratiopharm Arzneimittel Vertriebs-Gmbh	Austria
Hydromorphone Hcl Ratiopharm	DE-H-2245-001-004	76821.00.00 \$ 76822.00.00 \$ 76823.00.00 \$ 76824.00.00	Ratiopharm Gmbh	Germany
Hydromorphone Hydrochloride		PA 361/18/1 \$ PA 361/18/2	Martindale Pharmaceuticals Ltd	Ireland
Jurnista		58351	Janssen-Cilag Ag	Liechtenstein

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Jurnista	DK/H/0869/001 \$ DK/H/0869/002 \$ DK/H/0869/003 \$ DK/H/0869/004 \$ DK/H/0869/005	037396013 \$ 037396025 \$ 037396049 \$ 037396064 \$ 037396076 \$ 037396088 \$ 037396090 \$ 037396102/M \$ 037396114 \$ 037396126 \$ 037396138 \$ 037396140 \$ 037396165 \$ 037396189 \$ 037396191 \$ 037396203 \$ 037396215 \$ 037396227 \$ 037396239 \$ 037396241 \$ 037396254 \$ 037396266 \$ 037396280 \$ 037396304 \$ 037396328 \$ 037396330 \$ 037396342 \$ 037396355 \$ 037396367 \$ 037396379 \$ 037396381 \$ 037396405 \$ 037396429 \$ 037396431 \$ 037396443 \$ 037396456 \$ 037396468 \$ 037396470 \$ 037396482 \$ 037396494 \$ 037396506 \$ 037396520 \$ 037396544 \$ 037396557 \$ 037396569 \$ 037396571 \$ 037396583 \$ 037396595 \$ 037396607	Janssen-Cilag Spa	Italy

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Jurnista	DK/H/0869/001 \$ DK/H/0869/002 \$ DK/H/0869/003 \$ DK/H/0869/004 \$ DK/H/0869/005	037396037 \$ 037396052 \$ 037396153 \$ 037396177 \$ 037396278 \$ 037396292 \$ 037396393 \$ 037396417 \$ 037396518 \$ 037396532 \$ 037396316	Janssen-Cilag Spa	Italy
Jurnista	DK/H/0869/001 \$ DK/H/0869/002 \$ DK/H/0869/003 \$ DK/H/0869/004 \$ DK/H/0869/005	32344 \$ 32345 \$ 32346 \$ 32347 \$ 40775	Janssen-Cilag A/S	Denmark
Jurnista	DK/H/0869/001 \$ DK/H/0869/002 \$ DK/H/0869/003 \$ DK/H/0869/004 \$ DK/H/0869/005	63501.00.00 \$ 63502.00.00 \$ 63503.00.00 \$ 63504.00.00 \$ 68242.00.00	Janssen-Cilag Gmbh	Germany

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Jurnista	DK/H/0869/001 \$ DK/H/0869/002 \$ DK/H/0869/003 \$ DK/H/0869/004 \$ DK/H/0869/005	OGYI-T-20162/01 \$ OGYI-T-20162/02 \$ OGYI-T-20162/03 \$ OGYI-T-20162/04 \$ OGYI-T-20162/05 \$ OGYI-T-20162/06 \$ OGYI-T-20162/07 \$ OGYI-T-20162/08 \$ OGYI-T-20162/09 \$ OGYI-T-20162/10 \$ OGYI-T-20162/11 \$ OGYI-T-20162/12 \$ OGYI-T-20162/13 \$ OGYI-T-20162/14 \$ OGYI-T-20162/15 \$ OGYI-T-20162/16 \$ OGYI-T-20162/17 \$ OGYI-T-20162/18 \$ OGYI-T-20162/19 \$ OGYI-T-20162/20 \$ OGYI-T-20162/21 \$ OGYI-T-20162/22 \$ OGYI-T-20162/23 \$ OGYI-T-20162/24 \$ OGYI-T-20162/25 \$ OGYI-T-20162/26 \$ OGYI-T-20162/27 \$ OGYI-T-20162/28 \$ OGYI-T-20162/29 \$ OGYI-T-20162/30 \$ OGYI-T-20162/31 \$ OGYI-T-20162/32 \$ OGYI-T-20162/33 \$ OGYI-T-20162/34 \$ OGYI-T-20162/35 \$ OGYI-T-20162/36 \$ OGYI-T-20162/37 \$ OGYI-T-20162/38 \$ OGYI-T-20162/39 \$ OGYI-T-20162/40 \$ OGYI-T-20162/41 \$ OGYI-T-20162/42 \$ OGYI-T-20162/43 \$ OGYI-T-20162/44 \$ OGYI-T-20162/45 \$ OGYI-T-20162/46 \$ OGYI-T-20162/47 \$ OGYI-T-20162/48 \$ OGYI-T-20162/49 \$ OGYI-T-20162/50 \$ OGYI-T-20162/51 \$ OGYI-T-20162/52 \$ OGYI-T-20162/53 \$ OGYI-T-20162/54 \$ OGYI-T-20162/55 \$ OGYI-T-20162/56 \$ OGYI-T-20162/57 \$ OGYI-T-20162/58 \$ OGYI-T-20162/59 \$ OGYI-T-20162/60 \$ OGYI-T-20162/61 \$ OGYI-T-20162/62 \$ OGYI-T-20162/63 \$ OGYI-T-20162/64 \$ OGYI-T-20162/65 \$ OGYI-T-20162/66 \$ OGYI-T-20162/67 \$ OGYI-T-20162/68 \$ OGYI-T-20162/69 \$ OGYI-T-20162/70 \$ OGYI-T-20162/71 \$ OGYI-T-20162/72 \$ OGYI-T-20162/73 \$ OGYI-T-20162/74 \$ OGYI-T-20162/75 \$ OGYI-T-20162/76 \$ OGYI-T-20162/77 \$ OGYI-T-20162/78 \$ OGYI-T-20162/79 \$ OGYI-T-20162/80 \$ OGYI-T-20162/81 \$ OGYI-T-20162/82 \$ OGYI-T-20162/83 \$ OGYI-T-20162/84 \$ OGYI-T-20162/85 \$ OGYI-T-20162/86 \$ OGYI-T-20162/87 \$ OGYI-T-20162/88 \$ OGYI-T-20162/89 \$ OGYI-T-20162/90 \$ OGYI-T-20162/91 \$ OGYI-T-20162/92 \$ OGYI-T-20162/93 \$ OGYI-T-20162/94 \$ OGYI-T-20162/95 \$ OGYI-T-20162/96 \$ OGYI-T-20162/97 \$ OGYI-T-20162/98 \$ OGYI-T-20162/99 \$ OGYI-T-20162/100 \$	Janssen-Cilag Kft.	Hungary

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Jurnista	DK/H/0869/001 \$ DK/H/0869/002 \$ DK/H/0869/003 \$ DK/H/0869/004 \$ DK/H/0869/005 \$ DK/H/0869/005	5079033 \$ 5079041 \$ 5100318 \$ 5100326 \$ 5286240 \$ 5286257 \$ 5296173 \$ 5841481 \$ 5841580 \$ 5841689 \$ 5841788 \$ 5841887 \$ 5841986 \$ 5842083 \$ 5842182	Janssen-Cilag Farmacêutica, Lda.	Portugal
Jurnista	DK/H/0869/001 \$ DK/H/0869/002 \$ DK/H/0869/003 \$ DK/H/0869/005	65/187/06-C \$ 65/188/06-C \$ 65/189/06-C \$ 65/723/07-C	Janssen-Cilag S.R.O	Czech Republic
Jurnista	DK/H/0869/001 \$ DK/H/0869/002 \$ DK/H/0869/003 \$ DK/H/0869/005	68.018 \$ 68.019 \$ 68.020 \$ 69.710	Janssen-Cilag S.A.	Spain
Palladon		16714 \$ 16715 \$ 16716 \$ 16717	Norpharma A/S	Denmark
Palladon		32124 \$ 32125	Norpharma A/S	Denmark
Palladon		32273 \$ 32342 \$ 32343	Norpharma A/S	Denmark
Palladone	DE/H/1540/001 \$ DE/H/1540/002 \$ DE/H/1540/003 \$ DE/H/1540/004	BE342702 \$ BE342711 \$ BE342727 \$ BE342736	Mundipharma Comm Va	Belgium
Palladone Immediate Release		BE 256952 \$ BE256961	Mundipharma Comm Va	Belgium

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Palladon	DE/H/1540/001 \$ DE/H/1540/002 \$ DE/H/1540/003 \$ DE/H/1540/004	43149 \$ 43150 \$ 43151 \$ 43152	Norpharma A/S	Denmark
Palladon	DE/H/1540/001 \$ DE/H/1540/002 \$ DE/H/1540/003 \$ DE/H/1540/004	IS/1/08/079/01 \$ IS/1/08/079/02 \$ IS/1/08/079/03 \$ IS/1/08/079/04	Norpharma A/S	Iceland
Palladon		IS/1/00/056/01 \$ IS/1/00/056/02	Norpharma A/S	Iceland
Palladon		980415 (IS) \$ 9800416 (IS) \$ 980417 (IS) \$ 980418 (IS)	Norpharma A/S	Iceland
Palladone Slow Release		BE 217131 \$ BE 217156 \$ BE 217174 \$ BE 217192	Mundipharma Comm Va	Belgium
Palladon		11978 \$ 11979 \$ 11980 \$ 11981 \$ 12924 \$ 12925	Mundipharma Oy	Finland
Palladon	DE/H/1540/001 \$ DE/H/1540/002 \$ DE/H/1540/003 \$ DE/H/1540/004	24917 \$ 24918 \$ 24919 \$ 24920	Mundipharma Oy	Finland
Sophidone L.P		34009 348 906 5 9 \$ 34009 348 907 1 0 \$ 34009 561 203 8 3 \$ 34009 561 204 4 4	Mundipharma	France

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Sophidone L.P.		34009 348 901 3 0 \$ 34009 348 904 2 0 \$ 34009 348 908 8 8	Mundipharma	France
Sophidone L.P.		NL 23993 \$ NL 23994 \$ NL 23995 \$ NL 23996	Mundipharma SAS	France
Sophidone L.P.		34009 348 903 6 9 \$ 34009 348 905 9 8 \$ 34009 348 909 4 9 \$ 34009 561 199 0 5 \$ 34009 561 200 9 3 \$ 34009 561 201 5 4 \$ 34009 561 202 1 5 \$ 34009 561 205 0 5 \$ 34009 561 206 7 3	Mundipharma Sas	France
Palladon Injekt		59109.00.00 \$ 59110.00.00 \$ 59111.00.00	Mundipharma Gmbh	Germany
Palladone		5363-I-1202/09 \$ 5363-I-1204/09 \$ 5363-I-1206/09 \$ 5363-I- 1207/09 \$ 5363-I-1208/09 \$ 5363- I-1210/09 \$ 5363-I-1211/09 \$ 5363-I-1212/09 \$ 5363-I-1214/09 \$ 5363-I-1215/09 \$ 5363-I- 1216/09 \$ 5363-I-1218/09 \$ 5363- I-1220/09	Medis, D.O.O.	Slovenia
Palladone		PL16950/0163 \$ PL16950/0164 \$ PL16950/0165	Napp Pharmaceuticals Ltd	United Kingdom
Palladone		PL16950/0166	Napp Pharmaceuticals Ltd	United Kingdom

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Palladone SR		PL16950/0051 \$ PL16950/0052 \$ PL16950/0053 \$ PL16950/0054 \$ PL169/0055	Napp Pharmaceuticals Ltd	United Kingdom
Palladone		PL16950/0049 \$ PL16950/0050	Napp Pharmaceuticals Ltd	United Kingdom
Palladon Injekt	DE/H/1540/001 \$ DE/H/1540/002 \$ DE/H/1540/003 \$ DE/H/1540/004	72196.00.00 \$ 72197.00.00 \$ 72198.00.00 \$ 72199.00.00	Mundipharma Gmbh	Germany
Palladon retard		33162.00.00 \$ 33162.01.00 \$ 33162.02.00 \$ 33162.03.00	Mundipharma Gmbh	Germany
Palladon	IE/H/0131/005/MR \$ IE/H/0131/006/MR	59112.00.00 \$ 59112.01.00	Mundipharma Gmbh	Germany
Palladone	IE/H/0131/005 \$ IE/H/0131/006	PA 1688/007/001 \$ PA 1688/007/002	Mundipharma Pharmaceuticals Limited	Ireland
Palladone Sr	IE/H/0131/001 \$ IE/H/0131/002 \$ IE/H/0131/003 \$ IE/H/0131/004	PA 1688/007/007 \$ PA 1688/007/008 \$ PA 1688/007/009 \$ PA 1688/007/010 \$ PA 1688/007/011	Mundipharma Pharmaceuticals Limited	Ireland
Palladone	DE/H/1540/001 \$ DE/H/1540/002 \$ DE/H/1540/003 \$ DE/H/1540/004	1495/09120028 \$ 1495/09120029 \$ 1495/09120030 \$ 1495/09120031	Mundipharma Comm Va	Luxembourg

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Palladone Immediate Release		1495/04030125 \$ 1495/04030126	Mundipharma Comm Va	Luxembourg
Palladone Slow Release		1495/01070020 \$ 1495/01070021 \$ 1495/01070022 \$ 1495/01070023	Mundipharma Comm Va	Luxembourg
Palladon Injectie		RVG 104833 \$ RVG 104836 \$ RVG 104837 \$ RVG 104838	Mundipharma Pharmaceuticals Bv	Netherlands
Palladon-Ir		RVG 26549 \$ RVG 26550	Mundipharma Pharmaceuticals Bv	Netherlands
Palladon-Sr Capsules		RVG 22162 \$ RVG 22163 \$ RVG 22164 \$ RVG 22165 \$ RVG 29655	Mundipharma Pharmaceuticals Bv	Netherlands
Palladon	DE/H/1540/001 \$ DE/H/1540/002 \$ DE/H/1540/003 \$ DE/H/1540/004	08-5876 \$ 08-5877 \$ 08-5878 \$ 08-5879	Mundipharma As.	Norway
Palladon	IE/H/0131/001 \$ IE/H/0131/002 \$ IE/H/0131/003 \$ IE/H/0131/004	03-2293 \$ 03-2294 \$ 03-2295 \$ 03-2296	Mundipharma As.	Norway
Palladon	IE/H/0131/005 \$ IE/H/0131/006	03-2290 \$ 03-2291	Mundipharma As.	Norway
Palladone-Sr		65/0248/03-S \$ 65/0249/03-S \$ 65/0250/03-S \$ 65/0251/03-S	Mundipharma Ges.M.B.H	Slovakia

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Rexaphon		85919.00.00 \$ 85920.00.00 \$ 85921.00.00 \$ 85922.00.00 \$ 85923.00.00	Acino Ag	Germany
Palladone	DE/H/1540/001 \$ DE/H/1540/002 \$ DE/H/1540/003 \$ DE/H/1540/004	71471 \$ 71813 \$ 71814 \$ 71815	Mundipharma Pharmaceuticals SI	Spain
Palladone Continus		63.885 \$ 63.886 \$ 63.887 \$ 63.888	Mundipharma Pharmaceuticals SI	Spain
Palladon	DE/H/1540/001 \$ DE/H/1540/002 \$ DE/H/1540/003 \$ DE/H/1540/004	26898 \$ 26899 \$ 26900 \$ 26901	Mundipharma Ab	Sweden
HYDROMORPHON-HCI- ACTAVIS 4 MG HARTKAPSELN, RETARDIERT	DE/H/2432/002-005	78096.00.00	ACTAVIS GROUP PTC EHF.	Germany
HYDROMORPHON-HCI- ACTAVIS 8 MG HARTKAPSELN, RETARDIERT	DE/H/2432/002-005	78097.00.00	ACTAVIS GROUP PTC EHF.	Germany

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HYDROMORPHON-HCI- ACTAVIS 16 MG HARTKAPSELN, RETARDIERT	DE/H/2432/002-005	78098.00.00	ACTAVIS GROUP PTC EHF.	Germany
HYDROMORPHON-HCI- ACTAVIS 24 MG HARTKAPSELN, RETARDIERT	DE/H/2432/002-005	78099.00.00	ACTAVIS GROUP PTC EHF.	Germany
Palladon		13782 \$ 13783 \$ 13784 \$ 13785 \$ 13786 \$ 13787	Mundipharma Ab	Sweden
HYDROMORPHON- STADA® 24 MG RETARDTABLETTEN	DE/H/2326/004	77420.00.00	STADAPHARM GMBH	Germany
HYDROMORPHON STADA 8 MG RETARDTABLETTEN	DE/H/2326/002	1-29529	STADA ARZNEIMITTEL GMBH	Austria
HYDROMORPHON STADA 16 MG RETARDTABLETTEN	DE/H/2326/003	1-29530	STADA ARZNEIMITTEL GMBH	Austria
HYDROMORPHON- STADA® 16 MG RETARDTABLETTEN	DE/H/2326/003	77419.00.00	STADAPHARM GMBH	Germany
HYDROMORPHON STADA 4 MG RETARDTABLETTEN	DE/H/2326/001	1-29528	STADA ARZNEIMITTEL GMBH	Austria

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HYDROMORPHON STADA 24 MG RETARDTABLETTEN	DE/H/2326/004	1-29531	STADA ARZNEIMITTEL GMBH	Austria
HYDROMORPHON- STADA® 8 MG RETARDTABLETTEN	DE/H/2326/002	77418.00.00	STADAPHARM GMBH	Germany
HYDROMORPHON- STADA® 4 MG RETARDTABLETTEN	DE/H/2326/001	77417.00.00	STADAPHARM GMBH	Germany
HYDROMORPHON-AL 24 MG RETARDTABLETTEN	DE/H/2327/004	77424.00.00	ALIUD PHARMA GMBH	Germany
HYDROMORPHON-AL 8 MG RETARDTABLETTEN	DE/H/2327/002	77422.00.00	ALIUD PHARMA GMBH	Germany
HYDROMORPHON-AL 16 MG RETARDTABLETTEN	DE/H/2327/003	77423.00.00	ALIUD PHARMA GMBH	Germany
HYDROMORPHON-AL 4 MG RETARDTABLETTEN	DE/H/2327/001	77421.00.00	ALIUD PHARMA GMBH	Germany
Hydromorphon Develco		2014040022	Develco Pharma Gmbh	Luxembourg
Hydromorphon Develco		2014040023	Develco Pharma Gmbh	Luxembourg
Hydromorphon Develco		2014040024	Develco Pharma Gmbh	Luxembourg
Hydromorphon Develco		2014040025	Develco Pharma Gmbh	Luxembourg