



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 January 2016
EMA/230161/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: fentanyl (transdermal patches, solution for injection)

Procedure no.: PSUSA/00001370/201504



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
Durogesic		0162/08059771	Janssen-Cilag Nv	Luxembourg
Durogesic		0162/08059772	Janssen-Cilag Nv	Luxembourg
Durogesic		0162/08059773	Janssen-Cilag Nv	Luxembourg
Durogesic		0162/08059774	Janssen-Cilag Nv	Luxembourg
Durogesic		0162/08059775	Janssen-Cilag Nv	Luxembourg
Durogesic		029212053	Janssen-Cilag Spa	Italy
Durogesic		029212065	Janssen-Cilag Spa	Italy
Durogesic		029212077	Janssen-Cilag Spa	Italy
Durogesic		029212089	Janssen-Cilag Spa	Italy
Durogesic		04-2767	Janssen-Cilag A/S	Norway
Durogesic		1-21365	Janssen-Cilag Pharma Gmbh	Austria
Durogesic		1-21366	Janssen-Cilag Pharma Gmbh	Austria
Durogesic		1-21367	Janssen-Cilag Pharma Gmbh	Austria
Durogesic		1-21376	Janssen-Cilag Pharma Gmbh	Austria
Durogesic		1-26080	Janssen-Cilag Pharma Gmbh	Austria
Durogesic		11791	Janssen-Cilag Oy	Finland
Durogesic		11792	Janssen-Cilag Oy	Finland
Durogesic		11793	Janssen-Cilag Oy	Finland
Durogesic		11794	Janssen-Cilag Oy	Finland
Durogesic		12483	Janssen-Cilag Ab	Sweden

Durogesic		12484	Janssen-Cilag Ab	Sweden
Durogesic		12485	Janssen-Cilag Ab	Sweden
Durogesic		12486	Janssen-Cilag Ab	Sweden
Durogesic		12949	Janssen-Cilag International Nv	Poland
Durogesic		2810-15451-93	Janssen-Cilag A/S	Denmark
Durogesic		2810-15452-93	Janssen-Cilag A/S	Denmark
Durogesic		2810-15453-93	Janssen-Cilag A/S	Denmark
Durogesic		2810-15454-93	Janssen-Cilag A/S	Denmark
Durogesic		17985	Janssen-Cilag International Nv	Cyprus
Durogesic		17986	Janssen-Cilag International Nv	Cyprus
Durogesic		17987	Janssen-Cilag International Nv	Cyprus
Durogesic		19678	Janssen-Cilag Oy	Finland
Durogesic		21308	Janssen-Cilag Ab	Sweden
Durogesic		2505287	Janssen Farmacêutica Portugal, Lda	Portugal
Durogesic		2505386	Janssen Farmacêutica Portugal, Lda	Portugal
Durogesic		2505485	Janssen Farmacêutica Portugal, Lda	Portugal
Durogesic		2505584	Janssen Farmacêutica Portugal, Lda	Portugal
Durogesic		2810-37604-04	Janssen-Cilag A/S	Denmark
Durogesic		342 383.0	Janssen-Cilag	France
Durogesic		342 384.7	Janssen-Cilag	France

Durogesic		342 385.3	Janssen-Cilag	France
Durogesic		342 387.6	Janssen-Cilag	France
Durogesic		369 851.5	Janssen-Cilag	France
Durogesic		39724	Janssen-Cilag Pharmaceutical S.A.C.I.	Greece
Durogesic		39726	Janssen-Cilag Pharmaceutical S.A.C.I.	Greece
Durogesic		39727	Janssen-Cilag Pharmaceutical S.A.C.I.	Greece
Durogesic		39729	Janssen-Cilag Pharmaceutical S.A.C.I.	Greece
Durogesic		39731	Janssen-Cilag Pharmaceutical S.A.C.I.	Greece
Durogesic		5363-I-2119/11	Johnson & Johnson Prodaja Medicinskih In Farmaceutskih Izdelkov, D.O.O.	Slovenia
Durogesic		5363-I-2120/11	Johnson & Johnson Prodaja Medicinskih In Farmaceutskih Izdelkov, D.O.O.	Slovenia
Durogesic		5363-I-2121/11	Johnson & Johnson Prodaja Medicinskih In Farmaceutskih Izdelkov, D.O.O.	Slovenia
Durogesic		5363-I-2122/11	Johnson & Johnson Prodaja Medicinskih In Farmaceutskih Izdelkov, D.O.O.	Slovenia
Durogesic		5363-I-2123/11	Johnson & Johnson Prodaja Medicinskih In Farmaceutskih Izdelkov, D.O.O.	Slovenia
Durogesic		5738398	Janssen Farmacêutica Portugal, Lda	Portugal
Durogesic		65/059/06-C	Janssen-Cilag S.R.O	Czech Republic
Durogesic		65/716/97-C	Janssen-Cilag S.R.O	Czech Republic
Durogesic		65/717/97-C	Janssen-Cilag S.R.O	Czech Republic

Durogesic		65/718/97-C	Janssen-Cilag S.R.O	Czech Republic
Durogesic		65/719/97-C	Janssen-Cilag S.R.O	Czech Republic
Durogesic		7654	Janssen-Cilag International Nv	Poland
Durogesic		7655	Janssen-Cilag International Nv	Poland
Durogesic		7656	Janssen-Cilag International Nv	Poland
Durogesic		7657	Janssen-Cilag International Nv	Poland
Durogesic		8097	Janssen-Cilag A/S	Norway
Durogesic		8098	Janssen-Cilag A/S	Norway
Durogesic		8099	Janssen-Cilag A/S	Norway
Durogesic		8100	Janssen-Cilag A/S	Norway
Durogesic		930066	Janssen-Cilag Ab	Iceland
Durogesic		930067	Janssen-Cilag Ab	Iceland
Durogesic		930068	Janssen-Cilag Ab	Iceland
Durogesic		930069	Janssen-Cilag Ab	Iceland
Durogesic		BE 177834	Janssen-Cilag Nv	Belgium
Durogesic		BE 177886	Janssen-Cilag Nv	Belgium
Durogesic		BE 177895	Janssen-Cilag Nv	Belgium
Durogesic		BE 177904	Janssen-Cilag Nv	Belgium
Durogesic		BE 274181	Janssen-Cilag Nv	Belgium
Durogesic		IS/1/05/107/01	Janssen-Cilag Ab	Iceland

Durogesic		OGYI-T-4530/01	Janssen-Cilag Kft.	Hungary
Durogesic		OGYI-T-4530/02	Janssen-Cilag Kft.	Hungary
Durogesic		OGYI-T-4530/03	Janssen-Cilag Kft.	Hungary
Durogesic		OGYI-T-4530/04	Janssen-Cilag Kft.	Hungary
Durogesic		OGYI-T-4530/05	Janssen-Cilag Kft.	Hungary
Durogesic		RVG 16845	Janssen-Cilag Bv	Netherlands
Durogesic		RVG 16846	Janssen-Cilag Bv	Netherlands
Durogesic		RVG 16847	Janssen-Cilag Bv	Netherlands
Durogesic		RVG 16848	Janssen-Cilag Bv	Netherlands
Durogesic		RVG 31418	Janssen-Cilag Bv	Netherlands
Durogesic		UP/I-530-09/11-02/154	Johnson & Johnson S.E. D.O.O.	Croatia
Durogesic		UP/I-530-09/11-02/155	Johnson & Johnson S.E. D.O.O.	Croatia
Durogesic		UP/I-530-09/11-02/156	Johnson & Johnson S.E. D.O.O.	Croatia
Durogesic		UP/I-530-09/11-02/157	Johnson & Johnson S.E. D.O.O.	Croatia
Durogesic		UP/I-530-09/11-02/158	Johnson & Johnson S.E. D.O.O.	Croatia
Durogesic Dtrans		AA018/02901	Janssen-Cilag International Nv	Malta
Durogesic Dtrans		AA018/02902	Janssen-Cilag International Nv	Malta
Durogesic Dtrans		AA018/02903	Janssen-Cilag International Nv	Malta
Durogesic Dtrans		AA018/02904	Janssen-Cilag International Nv	Malta
Durogesic Dtrans		AA018/02905	Janssen-Cilag International Nv	Malta

Durogesic Dtrans		PA 748/2/1	Janssen-Cilag Limited	Ireland
Durogesic Dtrans		PA 748/2/2	Janssen-Cilag Limited	Ireland
Durogesic Dtrans		PA 748/2/3	Janssen-Cilag Limited	Ireland
Durogesic Dtrans		PA 748/2/4	Janssen-Cilag Limited	Ireland
Durogesic Dtrans		PA 748/2/5	Janssen-Cilag Limited	Ireland
Durogesic Dtrans		PL 00242/0192	Janssen-Cilag Limited	United Kingdom
Durogesic Dtrans		PL 00242/0193	Janssen-Cilag Limited	United Kingdom
Durogesic Dtrans		PL 00242/0194	Janssen-Cilag Limited	United Kingdom
Durogesic Dtrans		PL 00242/0195	Janssen-Cilag Limited	United Kingdom
Durogesic Dtrans		PL 00242/0409	Janssen-Cilag Limited	United Kingdom
Durogesic Matrix		61.959	Janssen-Cilag S.A.	Spain
Durogesic Matrix		61.960	Janssen-Cilag S.A.	Spain
Durogesic Matrix		61.961	Janssen-Cilag S.A.	Spain
Durogesic Matrix		65.032	Janssen-Cilag S.A.	Spain
Durogesic Matrix		67.029	Janssen-Cilag S.A.	Spain
Durogesic Smat		18411.00.00	Janssen-Cilag Gmbh	Germany
Durogesic Smat		18411.01.00	Janssen-Cilag Gmbh	Germany
Durogesic Smat		18411.02.00	Janssen-Cilag Gmbh	Germany
Durogesic Smat		18411.03.00	Janssen-Cilag Gmbh	Germany
Durogesic Smat		60415.00.00	Janssen-Cilag Gmbh	Germany

Epufen	DE/H/1049/002	5363-I-749/14 \$ 5363-I-750/14	Lek Pharmaceuticals D.D. Ljubljana	Slovenia
Fentalis	DE/H/0765/001	65/417/07-C	Sandoz S.R.O.	Czech Republic
FentaMat Sandoz	DE/H/1147/003	69440.00.00	HEXAL AG	Germany
Fentanest		020473029	Pfizer Italia S.R.L.	Italy
Fentanest		3129681 \$ 3283983 \$ 8176321 \$ 8176339	Janssen Farmacêutica Portugal, Lda	Portugal
Fentanest		41.764	Kern Pharma, S.L.	Spain
Fentanilo Pharmakern	PT/H/0346/001	5323142 \$ 5323159 \$ 5323167 \$ 5323175 \$ 5323209 \$ 5323217 \$ 5358239 \$ 5358247 \$ 5358254	Pharmakern Portugal - Produtos Farmaceuticos, Sociedade Unipessoal, Lda	Portugal
Fentanyl		0162/89011501 \$ 162/89011500	Janssen-Cilag Nv	Luxembourg
Fentanyl		90/218/70-C	Janssen-Cilag S.R.O	Czech Republic
Fentanyl		BE091996 \$ BE115412	Janssen-Cilag Nv	Belgium
Fentanyl		UP/I-530-09/11-02/602	Johnson & Johnson S.E. D.O.O.	Croatia
Fentanyl 1a Pharma	2167846 \$ 2169837	67846.00.00 \$ 69837.00.00	1 A Pharma Gmbh	Germany
Fentanyl 1a Pharma	DE/H/1048/001 \$ DE/H/1048/002	1-27661 \$ 1-27662	1a Pharma Gmbh	Austria
Fentanyl Hexal	2167844	67844.00.00	Hexal Ag	Germany
Fentanyl Hexal	DE/H/1047/001 \$ DE/H/1047/002	0495815 \$ 0495829 \$ 0495832 \$ 0495846 \$ 0495863 \$ 0495877 \$ 0495881 \$ 0495894 \$ 0495913 \$ 0495927 \$ 0495931 \$ 0495944 \$ 0715/08110047 \$ 0715/08110048	Hexal Ag	Luxembourg
Fentanyl Hexal	DE/H/1047/001 \$ DE/H/1047/002	1-27663 \$ 1-27664	Hexal Pharma Gmbh	Austria
Fentanyl Janssen		16.948 \$ 17.049	Janssen-Cilag Pharma Gmbh	Austria
Fentanyl Janssen		558 784-3 \$ 556 137-0 \$ 558 783-7	Janssen-Cilag	France

Fentanyl Janssen-Cilag		933	Janssen-Cilag Oy	Finland
Fentanyl Janssen-Cilag Pharmaceutical		1358 \$ 1359	Janssen-Cilag Pharmaceutical S.A.C.I.	Greece
Fentanyl Kern Pharma	PT/H/0346/001	59673	Kern Pharma, S.L.	Greece
Fentanyl Mat Hexal	DE/H/1047/001-002	68534.00.00 \$ 68584.00.00	Hexal Ag	Germany
Fentanyl Matrix		RVG 32749	Janssen-Cilag Bv	Netherlands
Fentanyl Matrix		RVG 32750	Janssen-Cilag Bv	Netherlands
Fentanyl Matrix		RVG 32751	Janssen-Cilag Bv	Netherlands
Fentanyl Matrix		RVG 32752	Janssen-Cilag Bv	Netherlands
Fentanyl Matrix		RVG 32753	Janssen-Cilag Bv	Netherlands
Fentanyl Matrixplaster 1 A Pharma	DE/H/1048/001 \$ DE/H/1048/002	68480.00.00 \$ 68567.00.00	1 A Pharma Gmbh	Germany
Fentanyl S Hexal	DE/H/1146/003	69333.00.00	Hexal Ag	Germany
Fentanyl Sandoz	2167845	67845.00.00	Hexal Ag	Germany
Fentanyl Sandoz	DE/H/0765/004	65/0050/07-S	Sandoz Pharmaceuticals D.D.	Slovakia
Fentanyl Sandoz	DE/H/1049/002	68583.00.00	HEXAL AG	Germany
Fentanyl Sandoz	DE/H/1147/003	1-27936	Sandoz Gmbh	Austria
Fentanyl Sandoz	DE/H/1147/003	25589	Sandoz A/S	Sweden
Fentanyl Sandoz	DE/H/1147/003	RVG 100320	Sandoz B.V.	Netherlands
Fentanyl-Janssen		6762282.00.00 \$ 6762282.01.00	Janssen-Cilag Gmbh	Germany
Fentanyl-Janssen		RVG 04748	Janssen-Cilag Bv	Netherlands
Fetanex	DE/H/1146/003	PA0711/137/003	Rowex Ltd	Ireland

Haldid		04239+	Janssen-Cilag A/S	Denmark
Lefen	DE/H/1147/003	5363-I-902/14	Lek Pharmaceuticals D.D. Ljubljana	Slovenia
Leptanal		10813	Janssen-Cilag Ab	Sweden
Leptanal		7425	Janssen-Cilag A/S	Norway
Leptanal		880082	Janssen-Cilag Ab	Iceland
Mezolar Matrix	DE/H/1147/003	PL 04416/0846	Sandoz Ltd	United Kingdom
Sublimaze		PA 748/44/1	Janssen-Cilag Limited	Ireland
Sublimaze		PL 00242/5001R	Janssen-Cilag Limited	United Kingdom
Fentanyl-Richter		100095	Gedeon Richter Plc.	Estonia