



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 April 2016
EMA/282906/2016
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: dalteparin sodium

Procedure no.: PSUSA/00000922/201508



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
Fragmin		1-18731	Pfizer Corporation Austria Gesellschaft M.B.H.	Austria
Fragmin		1-18732	Pfizer Corporation Austria Gesellschaft M.B.H.	Austria
Fragmin		1-18733 \$ 1-26354 \$ 1-26355 \$ 1-26356 \$ 1-26357 \$ 1-26358	Pfizer Corporation Austria Gesellschaft M.B.H.	Austria
Fragmin		1-18734	Pfizer Corporation Austria Gesellschaft M.B.H.	Austria
Fragmin		1-22340	Pfizer Corporation Austria Gesellschaft M.B.H.	Austria
Fragmin		BE153447 \$ BE153492 \$ BE153517 \$ BE172627 \$ BE189436 \$ BE196271 \$ BE196655 \$ BE196664 \$ BE196673	Pfizer S.A. (Belgium)	Belgium
Fragmin		BE153501	Pfizer S.A. (Belgium)	Belgium
Fragmin		BE175926 \$ BE192245 \$ BE209361 \$ BE209377	Pfizer S.A. (Belgium)	Belgium
фрагмин		20060638 \$ 20060639 \$ 20060640 \$ 20060641 \$ 20060642 \$ 20060643 \$ 9900346 \$ 9900347 \$ 9900348	Pfizer Enterprises Sarl	Bulgaria
Fragmin		UP/I-530-09/13-02/299 \$ UP/I-530-09/13-02/300 \$ UP/I-530-09/13-02/301 \$ UP/I-530-09/13-	Pfizer Croatia D.O.O.	Croatia

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
		02/304 \$ UP/I-530-09/13-02/305 \$ UP/I-530-09/13-02/306		
Fragmin		UP/I-530-09/13-02/302	Pfizer Croatia D.O.O.	Croatia
Fragmin		UP/I-530-09/13-02/303 \$ UP/I-530-09/13-02/307	Pfizer Croatia D.O.O.	Croatia
Fragmin		16/274/07-C \$ 16/400/92-C/C \$ 16/400/92-D/C \$ 16/400/92-E/C	Pfizer, Spol. S R.O.	Czech Republic
Fragmin		12949 \$ 12950	Pfizer Aps	Denmark
Fragmin		17534	Pfizer Aps	Denmark
Fragmin		54981 \$ 54983 \$ 54985 \$ 54986 \$ 54987 \$ 54988 \$ 54989	Pfizer Aps	Denmark
Fragmin		55916 \$ 55917 \$ 55918 \$ 55919 \$ 55920	Pfizer Aps	Denmark
Fragmin		54982 \$ 54984	Pfizer Aps	Denmark
Fragmin		128396 \$ 128496 \$ 363601 \$ 363801	Pfizer Enterprises Sarl	Estonia
Fragmin		10145 \$ 9860	Pfizer Oy	Finland
Fragmin		9861 \$ 9862	Pfizer Oy	Finland
Fragmin Cum Conservans		11036	Pfizer Oy	Finland

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Fragmin		NL 14 780 \$ NL 14783 \$ NL 18491 \$ NL 18492 \$ NL 35983 \$ NL 35984 \$ NL 35985 \$ NL 35986 \$ NL 35987 \$ NL 35988	Pfizer Holding France (S.C.A.)	France
Fragmin		36131.00.00	Pharmacia Gmbh	Germany
Fragmin		36131.01.00	Pharmacia Gmbh	Germany
Fragmin		6050.00.00	Pharmacia Gmbh	Germany
Fragmin D		69423.00.00 \$ 69424.00.00 \$ 69425.00.00 \$ 69426.00.00 \$ 69427.00.00	Pharmacia Gmbh	Germany
Fragmin Multidose		7389.00.00	Pharmacia Gmbh	Germany
Fragmin P		69428.00.00	Pharmacia Gmbh	Germany
Fragmin P Forte		8157.00.00	Pharmacia Gmbh	Germany
Fragmin		8157.01.00	Pharmacia Gmbh	Germany
Fragmin		78543/13/3-2-2014 \$ 78544/13/3-2-2014 \$ 78545/13/3-2-2014 \$ 91693/13/3-2-2014	Pfizer Hellas, A.E.	Greece
Fragmin		OGYI-T-4428/01 \$ OGYI-T-4428/02 \$ OGYI-T-4428/03 \$ OGYI-T-4428/04 \$ OGYI-T-4428/05 \$ OGYI-T-4428/06 \$ OGYI-T-4428/07 \$ OGYI-T-4428/08 \$ OGYI-T-4428/09	Pfizer Kft.	Hungary

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		\$ OGYI-T-4428/10 \$ OGYI-T-4428/11 \$ OGYI-T-4428/12 \$ OGYI-T-4428/13 \$ OGYI-T-4428/14 \$ OGYI-T-4428/15 \$ OGYI-T-4428/16 \$ OGYI-T-4428/17		
Fragmin		910078 (IS) \$ 910079 (IS)	Pfizer Aps	Iceland
Fragmin		910080 (IS)	Pfizer Aps	Iceland
Fragmin		910081 (IS)	Pfizer Aps	Iceland
Fragmin		950136 (IS)	Pfizer Aps	Iceland
Fragmin		027276031 \$ 027276043 \$ 027276070 \$ 027276082 \$ 027276094 \$ 027276106 \$ 027276118 \$ 027276120	Pfizer Limited	Italy
Fragmin		00-0355 \$ 00-0358 \$ 05-0449 \$ 05-0450	Pfizer Europe Ma Eeig	Latvia
Fragmin		00-0356 \$ 00-0357	Pfizer Europe Ma Eeig	Latvia
Fragmin		LT/1/99/1505/001 \$ LT/1/99/1505/003	Pfizer Europe Ma Eeig	Lithuania
Fragmin		LT/1/99/1505/002	Pfizer Europe Ma Eeig	Lithuania
Fragmin		LT/1/99/1505/004 \$ LT/1/99/1505/008	Pfizer Europe Ma Eeig	Lithuania

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Fragmin		LT/1/99/1505/005	Pfizer Europe Ma Eeig	Lithuania
Fragmin		LT/1/99/1505/006	Pfizer Europe Ma Eeig	Lithuania
Fragmin		LT/1/99/1505/007	Pfizer Europe Ma Eeig	Lithuania
Fragmin		1996040180 \$ 1998054568 \$ 1998054570 \$ 1998054571 \$ 1998080007 \$ 1999030033 \$ 1999030034 \$ 1999030036	Pfizer S.A. (Belgium)	Luxembourg
Fragmin		1999030035	Pfizer S.A. (Belgium)	Luxembourg
Fragmin		1997030217 \$ 1998054569	Pfizer S.A. (Belgium)	Luxembourg
Fragmin		RVG 12786 \$ RVG 12787 \$ RVG 12788	Pfizer B.V.	Netherlands
Fragmin		RVG 20607 \$ RVG 21896 \$ RVG 21897 \$ RVG 21898 \$ RVG 21899	Pfizer B.V.	Netherlands
Fragmin		00-443	Pfizer As	Norway
Fragmin		7373 \$ 7374	Pfizer As	Norway
Fragmin		22693 \$ 22694	Pfizer Europe Ma Eeig	Poland
Fragmin		7764 \$ 7765 \$ 7766 \$ 7767 \$ 9494 \$ 9495 \$ 9496 \$ 9497 \$ 9588	Pfizer Europe Ma Eeig	Poland
Fragmin		2/87/88 \$ 99/H/56/001 \$ 99/H/36/001 \$ 99/H/36/002 \$ 99/H/36/003 \$ 99/H/36/004	Laboratórios Pfizer, Lda.	Portugal

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
Fragmin		7361/2015/01 \$ 7361/2015/02 \$ 7362/2015/01 \$ 7362/2015/02 \$ 7363/2015/01 \$ 7363/2015/02 \$ 7364/2015/01 \$ 7364/2015/02 \$ 7365/2015/01 \$ 7366/2015/01 \$ 7366/2015/02 \$ 7367/2015/01 \$ 7367/2015/02 \$ 7368/2015/01 \$ 7368/2015/02 \$ 7369/2015/01	Pfizer Europe Ma Eeig	Romania
Fragmin		16/0400/92-C/S	Pfizer Europe Ma Eeig	Slovakia
Fragmin		5363-I-1080/09 \$ 5363-I-1081/09 \$ 5363-I-1082/09 \$ 5363-I-659/11	Pfizer Luxembourg Sarl	Slovenia
Fragmin		5363-I-660/11 \$ 5363-I-661/11 \$ 5363-I-662/11 \$ 5363-I-663/11	Pfizer Luxembourg Sarl	Slovenia
Fragmin		58.536	Pfizer, S.L.	Spain
Fragmin		58.537	Pfizer, S.L.	Spain
Fragmin		61.523	Pfizer, S.L.	Spain
Fragmin		62.155 \$ 62.156 \$ 62.157 \$ 62.158	Pfizer, S.L.	Spain
Fragmin		62.567	Pfizer, S.L.	Spain
Fragmin Med Konserveringsmedel		10754 \$ 10944	Pfizer Ab	Sweden
Fragmin		10755 \$ 10756 \$ 19745 \$ 19746 \$ 19747 \$ 19748 \$ 19749	Pfizer Ab	Sweden

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Fragmin		11680 \$ 12690	Pfizer Ab	Sweden
Fragmin		PL 00057/0976 \$ PL 00057/0980 \$ PL 00057/0981 \$ PL 00057/0982	Pfizer Limited	United Kingdom
Fragmin		PL 00057/0978	Pfizer Limited	United Kingdom
Fragmin		PL 00057/0983	Pfizer Limited	United Kingdom
Fragmin		PL 00057/0984	Pfizer Limited	United Kingdom
Fragmin		PL 00057/0985	Pfizer Limited	United Kingdom
Fragmin Graduated Syringe		PL 00057/0977	Pfizer Limited	United Kingdom
Fragmin		PL 00057/0979	Pfizer Limited	United Kingdom
Fragmin		PL 00057/0986	Pfizer Limited	United Kingdom