



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

06 April 2017
EMA/238496/2017
Procedure Management and Committees Support

List of nationally authorised medicinal products

Active substance: buserelin

Procedure no.: PSUSA/00000462/201608



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
Suprefact oldatos injekció	not available	OGYI-T-4400/03	SANOFI-AVENTIS ZRT	HU
SUPRECUR 0,15 MG NASALE SPRUHLÖSUNG	not available	1-18846	SANOFI-AVENTIS GMBH ÖSTERREICH	AT
SUPRECUR NASAL SPRAY 150MICROGRAMS	not available	PA 540/73/2	SANOFI-AVENTIS IRELAND LTD	IE
PROFACT NASAL	not available	4739.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
PROFACT DEPOT 6,3 MG 2-MONATSIMPLANTAT	not available	35484.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
SUPRECUR 0,15 MG NASALE SPRUHLÖSUNG	not available	1-18846	SANOFI-AVENTIS GMBH ÖSTERREICH	AT
SUPREFACT NASAL SPRAY 100 MICROGRAMS	not available	PA 540/74/4	SANOFI-AVENTIS IRELAND LTD	IE
SUPREFACT 1 MG/ML-DURCHSTICHFLASCHE	not available	1-18261	SANOFI-AVENTIS GMBH ÖSTERREICH	AT
SUPREFACT 1 MG/ML-DURCHSTICHFLASCHE	not available	1-18261	SANOFI-AVENTIS GMBH ÖSTERREICH	AT
SUPREFACT 1MG/ML SOLUTION FOR INJECTION	not available	PA 540/74/1	SANOFI-AVENTIS IRELAND LTD	IE
PROFACT NASAL	not available	4739.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
PROFACT PRO INJECTIONE	not available	4738.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
SUPREFACT DEPOT 3 MONTHS	not available	20010642	SANOFI-AVENTIS BULGARIA EOOD	BG
SUPREFACT 1MG/ML SOLUTION FOR INJECTION	not available	PA 540/74/1	SANOFI-AVENTIS IRELAND LTD	IE
SUPREFACT DEPOT 6,3 MG IMPLANTAT	not available	11730	SANOFI AB	SE
Suprefact Nasal 0,1 mg solution pour pulvérisation nasale	not available	BE131826	SANOFI BELGIUM	BE
PROFACT PRO INJECTIONE	not available	4738.00.00	SANOFI-AVENTIS DEUTSCHLAND 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
SUPREFACT 1 MG/ML INJEKTIONSVATSKA, LOSNING	not available	10763	SANOFI AB	SE
Suprefact Nasal 0,1 mg solution pour pulvérisation nasale	not available	BE131826	SANOFI BELGIUM	BE
SUPREFACT	not available	10250	SANOFI-AVENTIS CYPRUS LTD	CY
SUPREFACT INJECTION	not available	PL 04425/0268	AVENTIS PHARMA LTD	UK
SUPREFACT NASAL SPRAY	not available	PL 04425/0279	AVENTIS PHARMA LTD	UK
Suprefact 100 microgramos/pulsación solución para pulverización nasal	not available	57.037	SANOFI-AVENTIS, S.A.	ES
Suprefact Depot 6,3 mg implante en jeringa precargada	not available	60980	SANOFI-AVENTIS, S.A.	ES
SUPREFACT NASAL	not available	0111870	SANOFI BELGIUM	LU
SUPREFACT NASAL	not available	0158197	SANOFI BELGIUM	LU
Suprefact 1 mg/ml solución inyectable	not available	57011	SANOFI-AVENTIS, S.A.	ES
SUPRECUR NASAL SPRAY 0,15 MG/DOSE	not available	IS/1/10/132/01	SANOFI-AVENTIS NORGE AS	IS
SUPRECUR NASAL SPRAY 0,15 MG/DOSE	not available	8054	SANOFI-AVENTIS NORGE AS	NO
PROFACT DEPOT 9,45 MG 3-MONATSIMPLANTAT	SE/H/0144/001	43912.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
PROFACT DEPOT 9,45 MG 3-MONATSIMPLANTAT	SE/H/0144/001	43912.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
SUPRECUR INJECTION	not available	PL 04425/0278	AVENTIS PHARMA LTD	UK
SUPRECUR 150 MICROGRAMS NASAL SPRAY SOLUTION	not available	PL 04425/0277	AVENTIS PHARMA LTD	UK

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
SUPREFACT 1 MG/ML, SOLUTION INJECTABLE PAR VOIE SOUS-CUTANÉE	not available	328 505-5	SANOFI-AVENTIS FRANCE	FR
Suprefact Nasal 0,1 mg neusspray oplossing	not available	BE131826	SANOFI BELGIUM	BE
Suprefact Nasal 0,1 mg neusspray oplossing	not available	BE131826	SANOFI BELGIUM	BE
Profact® Depot 6,3 mg 2-Monatsimplantat Wirkstoff: Buserelin	not available	35484.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
SUPRECUR	not available	14176	SANOFI-AVENTIS DENMARK A/S	DK
SUPRECUR	not available	14176	SANOFI-AVENTIS DENMARK A/S	DK
SUPRECUR	not available	11729	SANOFI AB	SE
SUPREFACT DEPOT 3 MONTHS	not available	19372	SANOFI-AVENTIS CYPRUS LTD	CY
SUPRECUR 0,15 MG/ANNOS NENASUMUTE, LIUOS	not available	10784	SANOFI OY	FI
SUPREFACT	not available	191390202	SANOFI-AVENTIS AEBE	GR
Profact® Depot 9,45 mg 3-Monatsimplantat	SE/H/0144/001	43912.00.00	SANOFI-AVENTIS DEUTSCHLAND GMBH	DE
METRELEF 0,15 mg Nasenspray, Lösung	not available	27000.00.00	FERRING ARZNEIMITTEL GMBH	DE
SUPREFACT DEPOT 9,45 MG IMPLANTAATTI	SE/H/0144/001	13683	SANOFI OY	FI
SUPREFACT DEPOT 9,45 MG IMPLANTAATTI	SE/H/0144/001	13683	SANOFI OY	FI
Suprefact Depot Implantat für 3 Monate	SE/H/0144/001	1-22727	SANOFI-AVENTIS GMBH OSTERREICH	AT
SUPREFACT DEPOT 3	SE/H/0144/001	RVG 21170	SANOFI-AVENTIS	NL

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
MONTHS			NETHERLANDS B.V.	
SUPREFACT DEPOT 9,45 MG IMPLANTE	SE/H/0144/001	62477	SANOFI-AVENTIS, S.A.	ES
SUPREFACT DEPOT 3 MESI	SE/H/0144/001	025540042	SANOFI SPA	IT
SUPREFACT DEPOT 9,45 MG IMPLANTAT	SE/H/0144/001	13372	SANOFI AB	SE
SUPREFACT DEPOT	SE/H/0144/001	2807287	SANOFI - PRODUTOS FARMACEUTICOS LDA	PT
SUPREFACT	not available	RVG 10873	SANOFI-AVENTIS NETHERLANDS B.V.	NL
SUPREFACT	not available	RVG 10873	SANOFI-AVENTIS NETHERLANDS B.V.	NL