5 May 2017
EMA/303127/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: esketamine

Procedure no.: PSUSA/00001266/201608

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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
Esketamine Pfizer 25 mg/ml šķīdums injekcijām/infūzijām	FI/H/0115/002	13-0280	PFIZER EUROPE MA EEIG	LV
ESKETAMINE PFIZER 25 mg/ml, solution injectable/pour perfusion	FI/H/0115/002	34009 585 681 7 6	PFIZER HOLDING FRANCE (S.C.A.)	FR
ESKETAMINE PFIZER 25 mg/ml, solution injectable/pour perfusion	FI/H/0115/002	34009 585 682 3 7	PFIZER HOLDING FRANCE (S.C.A.)	FR
Esketamine Pfizer 5 mg/ml šķīdums injekcijām/infūzijām	FI/H/0115/001	13-0279	PFIZER EUROPE MA EEIG	LV
ESKETAMINE PFIZER 5 mg/ml, solution injectable / pour perfusion	FI/H/0115/001	34009 585 678 6 5	PFIZER HOLDING FRANCE (S.C.A.)	FR
ESKETAMINE PFIZER 5 mg/ml, solution injectable / pour perfusion	FI/H/0115/001	34009 585 679 2 6	PFIZER HOLDING FRANCE (S.C.A.)	FR
Esketamine Pfizer, 25 mg/ml süste- või infusioonilahus	FI/H/0115/002	821413	PFIZER EUROPE MA EEIG	EE
Esketamine Pfizer, 5 mg/ml süste- või infusioonilahus	FI/H/0115/001	821313	PFIZER EUROPE MA EEIG	EE

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
Ketanest 25 mg/ml injeksjonsvæske/infusjonsvæske, oppløsning	FI/H/0115/002	13-9423	PFIZER AS	NO
Ketanest 25 mg/ml injektions-/infusionsvätska, lösning	FI/H/0115/002	49021	PFIZER AB	SE
Ketanest 25 mg/ml raztopina za injiciranje/infundiranje	FI/H/0115/002	H/13/00837/003	PFIZER LUXEMBOURG SARL	SI
Ketanest 25 mg/ml raztopina za injiciranje/infundiranje	FI/H/0115/002	H/13/00837/004	PFIZER LUXEMBOURG SARL	SI
Ketanest 5 mg/ml injeksjonsvæske/infusjonsvæske, oppløsning	FI/H/0115/001	13-9422	PFIZER AS	NO
Ketanest 5 mg/ml injektions-/infusionsvätska, lösning	FI/H/0115/001	49020	PFIZER AB	SE
Ketanest 5 mg/ml raztopina za injiciranje/infundiranje	FI/H/0115/001	H/13/00837/001	PFIZER LUXEMBOURG SARL	SI
Ketanest 5 mg/ml raztopina za injiciranje/infundiranje	FI/H/0115/001	H/13/00837/002	PFIZER LUXEMBOURG SARL	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
Ketanest® S 25 mg/ml - Ampullen	not available	1-22525	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Ketanest® S 25 mg/ml (10 ml), Injektionslösung, Ampullen	not available	39946.00.00	PFIZER PHARMA PFE GMBH	DE
Ketanest® S 25 mg/ml (2 ml), Injektionslösung, Ampullen	not available	37087.00.00	PFIZER PHARMA PFE GMBH	DE
Ketanest® S 25 mg/ml, Injektionslösung, Injektionsflaschen	not available	39945.00.00	PFIZER PHARMA PFE GMBH	DE
Ketanest® S 5 mg/ml - Ampullen	not available	1-22524	PFIZER CORPORATION AUSTRIA GESELLSCHAFT M.B.H.	AT
Ketanest® S 5 mg/ml (20 ml), Injektionslösung, Injektionsflaschen	not available	39944.00.00	PFIZER PHARMA PFE GMBH	DE
Ketanest® S 5 mg/ml (5 ml), Injektionslösung, Ampullen	not available	37086.00.00	PFIZER PHARMA PFE GMBH	DE
Ketanest-S 25 mg/ml injektio-/infuusioneste, liuos	FI/H/0115/002	13384	PFIZER OY	FI

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
Ketanest-S 25 mg/ml injektions-/infusionsvätska, lösning	FI/H/0115/002	13384	PFIZER OY	FI
Ketanest-S 5 mg/ml injektio-/infuusioneste, liuos	FI/H/0115/001	13383	PFIZER OY	FI
Ketanest-S 5 mg/ml injektions-/infusionsvätska, lösning	FI/H/0115/001	13383	PFIZER OY	FI
Ketanest-S® 25 Multi-dose, oplossing voor injectie 25 mg/ ml	not available	RVG 24775	EUROCEPT B.V.	NL
Ketanest-S® 5 Multi-dose, oplossing voor injectie 5 mg/ ml	not available	RVG 24775	EUROCEPT B.V.	NL
Ketanest-S® 5, oplossing voor injectie 5 mg/ml	not available	RVG 22550	EUROCEPT B.V.	NL
S-ketamin "Pfizer" injektionsvæske, opløsning	not available	19569	PFIZER APS	DK
S-ketamin "Pfizer" injektionsvæske, opløsning	not available	19568	PFIZER APS	DK

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
S-Ketamin „Pfizer“ 25 mg/ml stungulyf, lausn	not available	IS/1/04/165/02	PFIZER APS	IS
S-Ketamin „Pfizer“ 5 mg/ml stungulyf, lausn	not available	IS/1/04/165/01	PFIZER APS	IS
Vesierra 25 mg/ml solution for injection/infusion	FI/H/0115/002	PL 00057/1497	PFIZER LIMITED	UK
Vesierra 25 mg/ml solution injectable/pour perfusion	FI/H/0115/002	BE466800	PFIZER S.A. (BELGIUM)	BE
Vesierra 25 mg/ml solution injectable/pour perfusion	FI/H/0115/002	2015040102	PFIZER S.A. (BELGIUM)	LU
Vesierra 5 mg/ml solution for injection/infusion	FI/H/0115/001	PL 00057/1496	PFIZER LIMITED	UK
Vesierra 5 mg/ml solution injectable/pour perfusion	FI/H/0115/001	BE466782	PFIZER S.A. (BELGIUM)	BE
Vesierra 5 mg/ml solution injectable/pour perfusion	FI/H/0115/001	2015040101	PFIZER S.A. (BELGIUM)	LU