



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

7 April 2022
EMA/382258/2015
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: esketamine (except for centrally authorised products)

Procedure no.: PSUSA/00001266/202108

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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
Ketanest 25 mg/ml injeksjons-/infusjonsvæske, oppløsning	FI/H/0115/002	13-9423	PFIZER AS	NO
Ketanest 25 mg/ml injeksjons-/infusjonsvæske, oppløsning	FI/H/0115/002	13-9423	PFIZER AS	NO
Ketanest 25 mg/ml injeksjons-/infusionsvätska, lösning	FI/H/0115/002	49021	PFIZER AB	SE
Ketanest 25 mg/ml injeksjons-/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 25 mg/ml raztopina za injiciranje/infundiranje	FI/H/0115/002	H/13/00837/006	PFIZER LUXEMBOURG SARL	SI
Ketanest 25 mg/ml raztopina za injiciranje/infundiranje	FI/H/0115/002	H/13/00837/005	PFIZER LUXEMBOURG SARL	SI
Ketanest 25 mg/ml raztopina za injiciranje/infundiranje	FI/H/0115/002	H/13/00837/007	PFIZER LUXEMBOURG SARL	SI
Ketanest 5 mg/ml injeksjons-/infusjonsvæske, oppløsning	FI/H/0115/001	13-9422	PFIZER AS	NO
Ketanest 5 mg/ml	FI/H/0115/001	49020	PFIZER AB	SE

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
injektions- /infusionsvätska, lösning				
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
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 GMBH	DE
Ketanest® S 25 mg/ml (10 ml), Injektionslösung, Ampullen	not available	39946.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 25 mg/ml (10 ml), Injektionslösung, Ampullen	not available	39946.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 25 mg/ml (10 ml), Injektionslösung, Ampullen	not available	39946.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 25 mg/ml (10 ml), Injektionslösung, Ampullen	not available	39946.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 25 mg/ml (10 ml), Injektionslösung,	not available	39946.00.00	PFIZER PHARMA 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
Ampullen				
Ketanest® S 25 mg/ml (10 ml), Injektionslösung, Ampullen	not available	39946.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 25 mg/ml (2 ml), Injektionslösung, Ampullen	not available	37087.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 25 mg/ml (2 ml), Injektionslösung, Ampullen	not available	37087.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 25 mg/ml (2 ml), Injektionslösung, Ampullen	not available	37087.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 25 mg/ml (2 ml), Injektionslösung, Ampullen	not available	37087.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 25 mg/ml (2 ml), Injektionslösung, Ampullen	not available	37087.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 25 mg/ml (2 ml), Injektionslösung, Ampullen	not available	37087.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 25 mg/ml (2 ml), Injektionslösung, Ampullen	not available	37087.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 25 mg/ml, Injektionslösung, Injektionsflaschen	not available	39945.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 25 mg/ml, Injektionslösung, Injektionsflaschen	not available	39945.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 25 mg/ml, Injektionslösung,	not available	39945.00.00	PFIZER PHARMA 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
Injektionsflaschen				
Ketanest® S 25 mg/ml, Injektionslösung, Injektionsflaschen	not available	39945.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 25 mg/ml, Injektionslösung, Injektionsflaschen	not available	39945.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 25 mg/ml, Injektionslösung, Injektionsflaschen	not available	39945.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 25 mg/ml, Injektionslösung, Injektionsflaschen	not available	39945.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 25 mg/ml, Injektionslösung, Injektionsflaschen	not available	39945.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 25 mg/ml, Injektionslösung, Injektionsflaschen	not available	39945.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 25 mg/ml, Injektionslösung, Injektionsflaschen	not available	39945.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 25 mg/ml, Injektionslösung, Injektionsflaschen	not available	39945.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 25 mg/ml, Injektionslösung, Injektionsflaschen	not available	39945.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 25 mg/ml, Injektionslösung, Injektionsflaschen	not available	39945.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 25 mg/ml, Injektionslösung, Injektionsflaschen	not available	39945.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 25 mg/ml, Injektionslösung, Injektionsflaschen	not available	39945.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 25 mg/ml, Injektionslösung, Injektionsflaschen	not available	39945.00.00	PFIZER PHARMA 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
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 GMBH	DE
Ketanest® S 5 mg/ml (20 ml), Injektionslösung, Injektionsflaschen	not available	39944.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 5 mg/ml (20 ml), Injektionslösung, Injektionsflaschen	not available	39944.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 5 mg/ml (20 ml), Injektionslösung, Injektionsflaschen	not available	39944.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 5 mg/ml (20 ml), Injektionslösung, Injektionsflaschen	not available	39944.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 5 mg/ml (20 ml), Injektionslösung, Injektionsflaschen	not available	39944.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 5 mg/ml (20 ml), Injektionslösung, Injektionsflaschen	not available	39944.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 5 mg/ml (5 ml), Injektionslösung, Ampullen	not available	37086.00.00	PFIZER PHARMA 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
Ketanest® S 5 mg/ml (5 ml), Injektionslösung, Ampullen	not available	37086.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 5 mg/ml (5 ml), Injektionslösung, Ampullen	not available	37086.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 5 mg/ml (5 ml), Injektionslösung, Ampullen	not available	37086.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 5 mg/ml (5 ml), Injektionslösung, Ampullen	not available	37086.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 5 mg/ml (5 ml), Injektionslösung, Ampullen	not available	37086.00.00	PFIZER PHARMA GMBH	DE
Ketanest® S 5 mg/ml (5 ml), Injektionslösung, Ampullen	not available	37086.00.00	PFIZER PHARMA GMBH	DE
Ketanest-S 25 mg/ml injektions-/infusionsvätska, lösning	FI/H/0115/002	13384	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 24776	PFIZER B.V.	NL
Ketanest-S® 25 Multi-dose, oplossing voor injectie 25 mg/ml	not available	RVG 24776	PFIZER B.V.	NL
Ketanest-S® 25 Multi-dose, oplossing voor injectie 25 mg/ml	not available	RVG 24776	PFIZER B.V.	NL
Ketanest-S® 25 Multi-	not available	RVG 24776	PFIZER B.V.	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
dose, oplossing voor injectie 25 mg/ml				
Ketanest-S® 25 Multi-dose, oplossing voor injectie 25 mg/ml	not available	RVG 24776	PFIZER B.V.	NL
Ketanest-S® 25 Multi-dose, oplossing voor injectie 25 mg/ml	not available	RVG 24776	PFIZER B.V.	NL
Ketanest-S® 25 Multi-dose, oplossing voor injectie 25 mg/ml	not available	RVG 24776	PFIZER B.V.	NL
Ketanest-S® 5 Multi-dose, oplossing voor injectie 5 mg/ml	not available	RVG 24775	PFIZER B.V.	NL
Ketanest-S® 5 Multi-dose, oplossing voor injectie 5 mg/ml	not available	RVG 24775	PFIZER B.V.	NL
Ketanest-S® 5 Multi-dose, oplossing voor injectie 5 mg/ml	not available	RVG 24775	PFIZER B.V.	NL
Ketanest-S® 5 Multi-dose, oplossing voor injectie 5 mg/ml	not available	RVG 24775	PFIZER B.V.	NL
Ketanest-S® 5 Multi-dose, oplossing voor injectie 5 mg/ml	not available	RVG 24775	PFIZER B.V.	NL
Ketanest-S® 5 Multi-dose, oplossing voor injectie 5 mg/ml	not available	RVG 24775	PFIZER B.V.	NL
Ketanest-S® 5 Multi-dose, oplossing voor injectie 5 mg/ml	not available	RVG 24775	PFIZER B.V.	NL
Ketanest-S® 5, oplossing voor injectie 5	not available	RVG 22550	PFIZER B.V.	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
mg/ml				
Ketanest-S® 5, oplossing voor injectie 5 mg/ml	not available	RVG 22550	PFIZER B.V.	NL
Ketanest-S® 5, oplossing voor injectie 5 mg/ml	not available	RVG 22550	PFIZER B.V.	NL
Ketanest-S® 5, oplossing voor injectie 5 mg/ml	not available	RVG 22550	PFIZER B.V.	NL
Ketanest-S® 5, oplossing voor injectie 5 mg/ml	not available	RVG 22550	PFIZER B.V.	NL
Ketanest-S® 5, oplossing voor injectie 5 mg/ml	not available	RVG 22550	PFIZER B.V.	NL
Ketanest-S® 5, oplossing voor injectie 5 mg/ml	not available	RVG 22550	PFIZER B.V.	NL
Ketanest-S® 5, oplossing voor injectie 5 mg/ml	not available	RVG 22550	PFIZER B.V.	NL
Product full name (in authorisation country as per Art. 57 data)	MRP/DCP or CP Authorisation number (if not available then insert not available)	National Authorisation Number of product in the member state	MAH of product in the member state	Member State where product is authorised
S-ketamin "Pfizer" injektionsvæske, opløsning	not available	19569	PFIZER APS	DK
S-ketamin "Pfizer" injektionsvæske, opløsning	not available	19568	PFIZER APS	DK
S-ketamin „Pfizer“ 25 mg/ml stungulyf, lausn.	not available	IS/1/04/165/02	PFIZER APS	IS
S-ketamin „Pfizer“ 25 mg/ml stungulyf, lausn.	not available	IS/1/04/165/02	PFIZER APS	IS
S-ketamin „Pfizer“ 25	not available	IS/1/04/165/02	PFIZER APS	IS

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

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
perfusion				
Vesierra 25 mg/ml solution injectable/pour perfusion	FI/H/0115/002	BE516906	PFIZER S.A. (BELGIUM)	BE
Vesierra 5 mg/ml solution for injection/infusion	FI/H/0115/001	PL 00057/1496	PFIZER LIMITED	XI
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