



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 May 2019
EMA/281358/2019
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: asparaginase, crisantaspase, pegaspargase (nationally authorised products)

Procedure no.: PSUSA/00003161/201808

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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
Erwinase	not available	15666	JAZZ PHARMACEUTICALS FRANCE	DK
ERWINASE	not available	8248	JAZZ PHARMACEUTICALS FRANCE	NO
Erwinase 10,000 Units. Powder for solution for injection	not available	PA 1020/002/001	JAZZ PHARMACEUTICALS FRANCE	IE
Erwinase 10.000 I.E./Durchstechflasche Pulver zur Herstellung einer Injektionslösung	not available	1-23357	JAZZ PHARMACEUTICALS FRANCE	AT
ERWINASE 10000 UI/flacon, poudre pour solution pour injection	not available	34009 550 041 6 5	JAZZ PHARMACEUTICALS FRANCE	FR
Erwinase pulver till injektionsvätska, lösning	not available	12644	JAZZ PHARMACEUTICALS FRANCE	SE
Erwinase, 10000 U.I. Pó para solução injetável	not available	5080742	JAZZ PHARMACEUTICALS FRANCE	PT
Erwinase, poeder voor oplossing voor injectie, 10.000 IE/injectieflacon	not available	RVG 16986	JAZZ PHARMACEUTICALS FRANCE	NL
ERWINASE® , 10,000 Units/vial, Lyophilisate for solution for injection	not available	PL 44403/0002	PORTON BIOPHARMA LIMITED	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
KIDROLASE 10 000 U.I., poudre et solvant pour solution injectable	not available	34009 311 810 4 0	JAZZ PHARMACEUTICALS FRANCE	FR
Pegaspargase Shire 750 I.E./ ml Injektionslösung	not available	30204.00.00	LES LABORATOIRES SERVIER (SURESNES)	DE
Pegaspargase Shire 750 I.E./ ml Injektionslösung	not available	30204.00.00	LES LABORATOIRES SERVIER (SURESNES)	DE
Pegaspargase, 750 j.m./ml, roztwór do wstrzykiwań i infuzji	not available	9508	BAXALTA INNOVATIONS GMBH	PL
Pegaspargase, 750 j.m./ml, roztwór do wstrzykiwań i infuzji	not available	9508	BAXALTA INNOVATIONS GMBH	PL
КИДРОЛАЗА 10 000 I.U. прах за инжекционен разтвор	not available	20040130	JAZZ PHARMACEUTICALS FRANCE	BG