



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 October 2023
EMA/299600/2023
Human Medicines Division

List of nationally authorised medicinal products

Active substance(s): human plasma (pooled and treated for virus inactivation)

Procedure No. PSUSA/00001635/202302



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
Octaplas LG 45-70 mg/ml Infusionslösung	SE/H/1866/001	236510	OCTAPHARMA PHARMAZEUTIKA PRODUKTIONSGESMBH	AT
OCTAPLAS® SD* Blutgruppe A zur Infusion	not available	2-00137	OCTAPHARMA PHARMAZEUTIKA PRODUKTIONSGESMBH	AT
OCTAPLAS® SD* Blutgruppe B zur Infusion	not available	2-00138	OCTAPHARMA PHARMAZEUTIKA PRODUKTIONSGESMBH	AT
OCTAPLAS® SD* Blutgruppe AB zur Infusion	not available	2-00139	OCTAPHARMA PHARMAZEUTIKA PRODUKTIONSGESMBH	AT
OCTAPLAS® SD* Blutgruppe 0 zur Infusion	not available	2-00140	OCTAPHARMA PHARMAZEUTIKA PRODUKTIONSGESMBH	AT
octaplasLG, solution pour perfusion	SE/H/1866/01	BE 222713	OCTAPHARMA BENELUX S.A.	BE
октаплаcLG, 45-70 mg/ml инфузионен разтвор	SE/H/1866/01	20150313	OCTAPHARMA (IP) SPRL	BG
Octaplas LG infuzní roztok	SE/H/1866/01	75/266/16-C	OCTAPHARMA (IP) SPRL	CZ
Octaplas® LG	not available	PEI.H.02698.01.1	OCTAPHARMA GMBH	DE
OctaplasLG, infusionsvæske, opløsning	SE/H/1866/01	58093	OCTAPHARMA AB	DK
OctaplasLG, infusionsvæske, opløsning	SE/H/1866/001	58094	OCTAPHARMA AB	DK
OctaplasLG, infusionsvæske, opløsning	SE/H/1866/01	58095	OCTAPHARMA AB	DK
OctaplasLG, infusionsvæske, opløsning	SE/H/1866/01	58096	OCTAPHARMA AB	DK

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OctaplasLG, 45...70 mg/ml, infusiooñilahu.	SE/H/1866/001	888615	OCTAPHARMA (IP) SPRL	EE
OctaplasmaLG (0) 45-70 mg/ml solución para perfusión	SE/H/1866/01	80563	OCTAPHARMA S.A.	ES
OctaplasmaLG (A) 45-70 mg/ml solución para perfusión	SE/H/1866/01	81078	OCTAPHARMA S.A.	ES
OctaplasmaLG (B) 45-70 mg/ml solución para perfusión	SE/H/1866/01	81079	OCTAPHARMA S.A.	ES
OctaplasmaLG (AB) 45-70 mg/ml solución para perfusión	SE/H/1866/01	81080	OCTAPHARMA S.A.	ES
octaplasLG infuusioneste, liuos	SE/H/1866/001	15619	OCTAPHARMA AB	FI
OCTAPLASLG, solution pour perfusion	SE/H/1866/01	34009 550 030 9 0	OCTAPHARMA FRANCE	FR
OCTAPLASLG, solution pour perfusion	SE/H/1866/01	34009 550 031 0 6	OCTAPHARMA FRANCE	FR
OCTAPLASLG, solution pour perfusion	SE/H/1866/01	34009 550 031 1 3	OCTAPHARMA FRANCE	FR
OCTAPLASLG, solution pour perfusion	SE/H/1866/01	34009 550 031 2 0	OCTAPHARMA FRANCE	FR
octaplasLG 45-70 mg/ml otopina za infuziju	SE/H/1866/01	HR-H-098600779	OCTAPHARMA (IP) SPRL	HR
OctaplasLG 45-70 mg/ml oldatos infúzió	SE/H/1866/01	OGYI-T-20223/05	OCTAPHARMA (IP) SPRL	HU
OctaplasLG 45-70 mg/ml oldatos infúzió	SE/H/1866/01	OGYI-T-20223/06	OCTAPHARMA (IP) SPRL	HU
OctaplasLG 45-70 mg/ml oldatos infúzió	SE/H/1866/01	OGYI-T-20223/07	OCTAPHARMA (IP) SPRL	HU
OctaplasLG 45-70 mg/ml oldatos infúzió	SE/H/1866/01	OGYI-T-20223/08	OCTAPHARMA (IP) SPRL	HU
LG-octaplas solution for infusion	SE/H/1866/01	PA2219/002/001	OCTAPHARMA (IP) SPRL	IE
OCTAPLAS soluzione per infusione	not available	034540017	OCTAPHARMA PHARMAZEUTIKA	IT

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			PRODUKTIONSGESMBH	
PLASMASAFE soluzione per infusione.	not available	033369012	KEDRION S.P.A.	IT
PLASMAGRADE soluzione per infusione	not available	041868011	KEDRION S.P.A.	IT
octaplasma infuzinis tirpalas	SE/H/1866/001	LT/1/15/3801/001	OCTAPHARMA (IP) SPRL	LT
octaplasLG, solution pour perfusion	SE/H/1866/01	0345205	OCTAPHARMA BENELUX S.A.	LU
octaplasma □kidums infuzijam	SE/H/1866/01	15-0256	OCTAPHARMA (IP) SPRL	LV
octaplasLG, solution for infusion	SE/H/1866/01	MA1219/00901	OCTAPHARMA (IP) SPRL	MT
Omniplasma 45-70 mg/ml oplossing voor infusie	SE/H/1866/01	RVG 25407	OCTAPHARMA GMBH	NL
Octaplasma 45-70 mg/ml infusjonsvæske, oppløsning	SE/H/1866/01	14-10475	OCTAPHARMA AS	NO
octaplasLG, roztwór do infuzji	SE/H/1866/01	22806	OCTAPHARMA (IP) SPRL	PL
Octaplas 45-70 mg/ml Solução para perfusão	not available	2830487	OCTAPHARMA PRODUTOS FARMACEUTICOS, LDA.	PT
OctaplasLG soluție perfuzabilă	SE/H/1866/01	13602/2020/01	OCTAPHARMA (IP) SPRL	RO
OctaplasLG soluție perfuzabilă	SE/H/1866/01	13602/2020/02	OCTAPHARMA (IP) SPRL	RO
OctaplasLG soluție perfuzabilă	SE/H/1866/01	13602/2020/03	OCTAPHARMA (IP) SPRL	RO
OctaplasLG soluție perfuzabilă	SE/H/1866/01	13602/2020/04	OCTAPHARMA (IP) SPRL	RO
octaplasLG, infusionsvätska lösning	SE/H/1866/01	16273	OCTAPHARMA AB	SE
octaplasLG 45□70 mg/ml raztopina za infundiranje	SE/H/1866/01	H/16/02216/001	OCTAPHARMA (IP) SPRL	SI
octaplasLG 45□70 mg/ml raztopina za	SE/H/1866/01	H/16/02216/002	OCTAPHARMA (IP) SPRL	SI

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infundiranje				
octaplasLG 45□70 mg/ml raztopina za infundiranje	SE/H/1866/01	H/16/02216/003	OCTAPHARMA (IP) SPRL	SI
octaplasLG 45□70 mg/ml raztopina za infundiranje	SE/H/1866/01	H/16/02216/004	OCTAPHARMA (IP) SPRL	SI
Octaplasma 45 – 70 mg/ml infúzny roztok	SE/H/1866/001	75/0190/16-S	OCTAPHARMA (IP) SPRL	SK
octaplasLG, solution for infusion	SE/H/1866/01	PL 10673/0009	OCTAPHARMA-LTD	XI