



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 October 2017
EMA/722339/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

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

Procedure no.: PSUSA/00001635/201702



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® 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
Octaplas LG 45-70 mg/ml Infusionslösung	UK/H/0355/001	236510	OCTAPHARMA PHARMAZEUTIKA PRODUKTIONSGESMBH	AT
octaplasLG, solution pour perfusion	UK/H/0355/001	BE222713	OCTAPHARMA BENELUX S.A./N.V.	BE
octaplasLG, 45–70 mg/ml solution for infusion	UK/H/0355/001	20150313	OCTAPHARMA (IP)-LTD.	BG
octaplasLG	UK/H/0355/001	75/266/16-C	OCTAPHARMA (IP)-LTD.	CZ
Octaplas	not available	75/038/03-C	OCTAPHARMA (IP)-LTD.	CZ
Octaplas® LG	not available	PEI.H.02698.01.1	OCTAPHARMA GMBH	DE
OctaplasLG, infusionsvæske, opløsning	UK/H/0355/001	58093	OCTAPHARMA AB	DK
OctaplasLG, infusionsvæske, opløsning	UK/H/0355/001	58094	OCTAPHARMA AB	DK
OctaplasLG, infusionsvæske, opløsning	UK/H/0355/001	58095	OCTAPHARMA AB	DK
OctaplasLG, infusionsvæske, opløsning	UK/H/0355/001	58096	OCTAPHARMA AB	DK
OctaplasLG, 45...70 mg/ml, infusiooñilahus	UK/H/0355/001	888615	OCTAPHARMA (IP)-LTD.	EE
OctaplasmaLG (0) 45 - 70 mg/ml solución para perfusión	UK/H/0355/001	80563	OCTAPHARMA S.A.	ES
OctaplasmaLG (A) 45 - 70 mg/ml solución para perfusión	UK/H/0355/001	81078	OCTAPHARMA S.A.	ES

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OctaplasmaLG (B) 45 - 70 mg/ml solución para perfusión	UK/H/0355/001	81079	OCTAPHARMA S.A.	ES
OctaplasmaLG (AB) 45 - 70 mg/ml solución para perfusión	UK/H/0355/001	81080	OCTAPHARMA S.A.	ES
octaplasLG	UK/H/0355/001	15619	OCTAPHARMA AB	FI
OCTAPLASLG, solution pour perfusion	UK/H/0355/001	34009 550 030 9 0	OCTAPHARMA FRANCE	FR
OCTAPLASLG, solution pour perfusion	UK/H/0355/001	34009 550 031 0 6	OCTAPHARMA FRANCE	FR
OCTAPLASLG, solution pour perfusion	UK/H/0355/001	34009 550 031 1 3	OCTAPHARMA FRANCE	FR
OCTAPLASLG, solution pour perfusion	UK/H/0355/001	34009 550 031 2 0	OCTAPHARMA FRANCE	FR
octaplasLG 45-70 mg/ml otopina za infuziju	UK/H/0355/001	HR-H-098600779	OCTAPHARMA (IP)-LTD.	HR
OctaplasLG 45-75 mg/ml oldatos infúzió	UK/H/0355/001	OGYI-T-20223/05	OCTAPHARMA (IP)-LTD.	HU
Octaplas fagyasztott oldatos infúzió	not available	OGYI-T-20223/02	OCTAPHARMA (IP)-LTD.	HU
Octaplas fagyasztott oldatos infúzió	not available	OGYI-T-20223/03	OCTAPHARMA (IP)-LTD.	HU
Octaplas fagyasztott oldatos infúzió	not available	OGYI-T-20223/04	OCTAPHARMA (IP)-LTD.	HU
Octaplas fagyasztott oldatos infúzió	not available	OGYI-T-20223/01	OCTAPHARMA (IP)-LTD.	HU
LG-octaplas solution for infusion	UK/H/0355/001	PA 521/4/2	OCTAPHARMA-LTD	IE
PLASMAGRADE soluzione per infusione	not available	041868011	KEDRION S.P.A.	IT
PLASMASAFE soluzione per infusione	not available	033369012	KEDRION S.P.A.	IT
Octaplas	not available	AIC N. 034540017; AIC N. 533	OCTAPHARMA PHARMAZEUTIKA PRODUKTIONSGESMBH	IT
octaplasma infuzinis tirpalas	UK/H/0355/001	LT/1/15/3801/001	OCTAPHARMA (IP)-LTD.	LT
octaplasLG	UK/H/0355/001	0345205 (NATIONAL); 1196/09050311 (AMM)	OCTAPHARMA BENELUX S.A./N.V.	LU

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octaplasma □ķīdums infūzijām	UK/H/0355/001	15-0256	OCTAPHARMA (IP)-LTD.	LV
octaplasLG, solution for infusion	UK/H/0355/001	MA754/00901	OCTAPHARMA (IP)-LTD.	MT
Omniplasma	UK/H/0355/001	RVG 25407	OCTAPHARMA GMBH	NL
Octaplasma 45-70 mg/ml infusjonsvæske, oppløsning	UK/H/0355/001	14-10475	OCTAPHARMA AS	NO
octaplasLG, roztwór do infuzji	UK/H/0355/001	22806	OCTAPHARMA (IP)-LTD.	PL
Octaplas	not available	2830487	OCTAPHARMA PRODUTOS FARMACEUTICOS, LDA.	PT
Novoplas (AB Plasma)	not available	5319686	OCTAPHARMA PRODUTOS FARMACEUTICOS, LDA.	PT
OctaplasLG soluție perfuzabilă	UK/H/0355/001	8288/2015/01 (BLOOD GROUP A)	OCTAPHARMA (IP)-LTD.	RO
OctaplasLG soluție perfuzabilă	UK/H/0355/001	8288/2015/02 (BLOOD GROUP B)	OCTAPHARMA (IP)-LTD.	RO
OctaplasLG soluție perfuzabilă	UK/H/0355/001	8288/2015/03 (BLOOD GROUP AB)	OCTAPHARMA (IP)-LTD.	RO
OctaplasLG soluție perfuzabilă	UK/H/0355/001	8288/2015/04 (BLOOD GROUP O)	OCTAPHARMA (IP)-LTD.	RO
octaplasLG, infusionsvätska lösning	UK/H/0355/001	16273	OCTAPHARMA AB	SE
octaplasLG 45-70 mg/ml raztopina za infundiranje	UK/H/0355/001	H/16/02216/001	OCTAPHARMA (IP)-LTD.	SI
octaplasLG 45-70 mg/ml raztopina za infundiranje	UK/H/0355/001	H/16/02216/002	OCTAPHARMA (IP)-LTD.	SI
octaplasLG 45-70 mg/ml raztopina za infundiranje	UK/H/0355/001	H/16/02216/003	OCTAPHARMA (IP)-LTD.	SI
octaplasLG	UK/H/0355/001	H/16/02216/004	OCTAPHARMA (IP)-LTD.	SI
Octaplasma 45 – 70 mg/ml infúzný roztok	UK/H/0355/001	75/0190/16-S	OCTAPHARMA (IP)-LTD.	SK
octaplasLG, solution for infusion	UK/H/0355/001	PL 10673/0009	OCTAPHARMA-LTD	UK