



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 October 2017
EMA/690754/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: fish oil / olive oil / soybean oil / triglycerides medium-chain

Procedure no.: PSUSA/00010223/201702



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
SMOFlipid	SE/H/0421/001	76/123/05-C	FRESENIUS KABI AB	CZ
SMOFlipid 200 mg/ml infuusioneste, emulsio	SE/H/0421/001	19351	FRESENIUS KABI AB	FI
SMOFlipid 200 mg/ml innrennslyf, fleyti.	SE/H/0421/001	IS/1/04/027/01	FRESENIUS KABI AB	IS
SMOFlipid, 200 mg/ml, emulsja do infuzji	SE/H/0421/001	11377	FRESENIUS KABI AB	PL
SMOFlipid infúzna emulzia	SE/H/0421/001	76/0070/05-S	FRESENIUS KABI AB	SK
SMOFlipid 20% emulsija infūzijām	SE/H/0421/001	05-0116	FRESENIUS KABI AB	LV
SMOFlipid 20% infuzine emulsija	SE/H/0421/001	LT/1/05/0194/001	FRESENIUS KABI AB	LT
SMOFlipid 200 g/1000 ml emulsie perfuzabilă	not available	6105/2014/01	FRESENIUS KABI AB	RO
SMOFlipid 200 mg/ml emulsión para perfusión	SE/H/0421/001	66.581	FRESENIUS KABI AB	ES
SMOFlipid 200 mg/ml infusionsvätska, emulsion	SE/H/0421/001	18854	FRESENIUS KABI AB	SE
SMOFlipid, 20% infusiooniemulsioon	SE/H/0421/001	468905	FRESENIUS KABI AB	EE
SMOFlipid 200 mg/ml Emulsion zur Infusion	SE/H/0421/001	1-25645	FRESENIUS KABI AUSTRIA GMBH	AT
SMOFlipid	SE/H/0421/001	0452/0510069	FRESENIUS KABI DEUTSCHLAND GMBH	LU
SMOFlipid 200 mg/ml Emulsion zur Infusion	SE/H/0421/001	60028.00.00	FRESENIUS KABI DEUTSCHLAND GMBH	DE

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SMOFlipid 200 mg/ml γαλάκτωμα για έγχυση.	SE/H/0421/001	48238/8-7-2010	FRESENIUS KABI HELLAS A.E.	GR
SMOFlipid, 200mg/ml, γαλάκτωμα για έγχυση	SE/H/0421/001	20184	FRESENIUS KABI HELLAS A.E.	CY
SMOFlipid 200 mg/ml emulsion for infusion	SE/H/0421/001	PL 08828/0166	FRESENIUS KABI LIMITED	UK
SMOFlipid 200 mg/ml emulsion for infusion	SE/H/0421/001	PA 566/35/1	FRESENIUS KABI LIMITED	IE
SMOFlipid 200 mg/ml	SE/H/0421/001	RVG 30787	FRESENIUS KABI NEDERLAND B.V.	NL
SMOFlipid 200 mg/ml, émulsion pour perfusion	SE/H/0421/001	BE277487	FRESENIUS KABI NV/SA	BE
SMOFlipid 200 mg/ml, Emulsion zur Infusion	SE/H/0421/001	BE277487	FRESENIUS KABI NV/SA	BE
SMOFlipid 200 mg/ml, emulsie voor infusie	SE/H/0421/001	BE277487	FRESENIUS KABI NV/SA	BE
SMOFlipid 200 mg/ml infusjonsvæske, emulsjon	SE/H/0421/001	04-2640	FRESENIUS KABI NORGE AS	NO
SMOFlipid 200 mg/ml, emulsão para perfusão	SE/H/0421/001	5609789	FRESENIUS KABI PHARMA PORTUGAL LDA.	PT
SMOFlipid 20% emulzija za infuziju	not available	UP/I-530-09/11-02/319	FRESENIUS KABI D.O.O.	HR
SMOFlipid 200 g/1000 ml emulsie perfuzabilă	not available	6105/2014/02	FRESENIUS KABI AB	RO
SMOFlipid 200 g/1000 ml emulsie perfuzabilă	not available	6105/2014/03	FRESENIUS KABI AB	RO
SMOFlipid 200 g/1000 ml emulsie perfuzabilă	not available	6105/2014/04	FRESENIUS KABI AB	RO

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SMOFlipid 200 g/1000 ml emulsie perfuzabilă	not available	6105/2014/05	FRESENIUS KABI AB	RO
SMOFlipid 200 g/1000 ml emulsie perfuzabilă	not available	6105/2014/06	FRESENIUS KABI AB	RO
SMOFlipid 200 mg/ml, emulsie voor infusie	SE/H/0421/001	BE277496	FRESENIUS KABI NV/SA	BE
SMOFlipid 200 mg/ml, emulsie voor infusie	SE/H/0421/001	BE277505	FRESENIUS KABI NV/SA	BE
SMOFlipid 200 mg/ml, emulsie voor infusie	SE/H/0421/001	BE270751	FRESENIUS KABI NV/SA	BE
SMOFlipid 200 mg/ml, emulsie voor infusie	SE/H/0421/001	BE270767	FRESENIUS KABI NV/SA	BE
SMOFlipid 200 mg/ml, emulsie voor infusie	SE/H/0421/001	BE270776	FRESENIUS KABI NV/SA	BE
SMOFlipid 200 mg/ml, émulsion pour perfusion	SE/H/0421/001	BE277496	FRESENIUS KABI NV/SA	BE
SMOFlipid 200 mg/ml, émulsion pour perfusion	SE/H/0421/001	BE277505	FRESENIUS KABI NV/SA	BE
SMOFlipid 200 mg/ml, émulsion pour perfusion	SE/H/0421/001	BE270751	FRESENIUS KABI NV/SA	BE
SMOFlipid 200 mg/ml, émulsion pour perfusion	SE/H/0421/001	BE270767	FRESENIUS KABI NV/SA	BE
SMOFlipid 200 mg/ml, émulsion pour perfusion	SE/H/0421/001	BE270776	FRESENIUS KABI NV/SA	BE
SMOFlipid 200 mg/ml, Emulsion zur Infusion	SE/H/0421/001	BE277496	FRESENIUS KABI NV/SA	BE
SMOFlipid 200 mg/ml, Emulsion zur Infusion	SE/H/0421/001	BE277505	FRESENIUS KABI NV/SA	BE

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SMOFlipid 200 mg/ml, Emulsion zur Infusion	SE/H/0421/001	BE270751	FRESENIUS KABI NV/SA	BE
SMOFlipid 200 mg/ml, Emulsion zur Infusion	SE/H/0421/001	BE270767	FRESENIUS KABI NV/SA	BE
SMOFlipid 200 mg/ml, Emulsion zur Infusion	SE/H/0421/001	BE270776	FRESENIUS KABI NV/SA	BE
SMOFlipid 200 mg/ml, emuls 7Jo para perfus 7Jo	SE/H/0421/001	5171889	FRESENIUS KABI PHARMA PORTUGAL LDA.	PT
SMOFlipid 200 mg/ml, emuls 7Jo para perfus 7Jo	SE/H/0421/001	5171681	FRESENIUS KABI PHARMA PORTUGAL LDA.	PT
SMOFlipid 200 mg/ml, emuls 7Jo para perfus 7Jo	SE/H/0421/001	5171780	FRESENIUS KABI PHARMA PORTUGAL LDA.	PT
SMOFlipid 200 mg/ml, emuls 7Jo para perfus 7Jo	SE/H/0421/001	5610282	FRESENIUS KABI PHARMA PORTUGAL LDA.	PT
SMOFlipid 200 mg/ml, emuls 7Jo para perfus 7Jo	SE/H/0421/001	5610183	FRESENIUS KABI PHARMA PORTUGAL LDA.	PT
SMOFlipid 200 mg/ml, emuls 7Jo para perfus 7Jo	SE/H/0421/001	5610084	FRESENIUS KABI PHARMA PORTUGAL LDA.	PT
SMOFlipid 200 mg/ml, emuls 7Jo para perfus 7Jo	SE/H/0421/001	5609987	FRESENIUS KABI PHARMA PORTUGAL LDA.	PT
SMOFlipid 200 mg/ml, emuls 7Jo para perfus 7Jo	SE/H/0421/001	5609888	FRESENIUS KABI PHARMA PORTUGAL LDA.	PT
SMOFlipid 200 mg/ml emulsion for infusion	SE/H/0421/001	PA 566/35/2	FRESENIUS KABI LIMITED	IE
SMOFlipid 20% infuzine emulsija	SE/H/0421/001	LT/1/05/0194/002	FRESENIUS KABI AB	LT
SMOFlipid 20% infuzine emulsija	SE/H/0421/001	LT/1/05/0194/003	FRESENIUS KABI AB	LT

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SMOFlipid 20% infuzine emulsija	SE/H/0421/001	LT/1/05/0194/004	FRESENIUS KABI AB	LT
SMOFlipid 20% infuzine emulsija	SE/H/0421/001	LT/1/05/0194/006	FRESENIUS KABI AB	LT
SMOFlipid 20% infuzine emulsija	SE/H/0421/001	LT/1/05/0194/007	FRESENIUS KABI AB	LT
SMOFlipid 20% infuzine emulsija	SE/H/0421/001	LT/1/05/0194/008	FRESENIUS KABI AB	LT
SMOFlipid 20% infuzine emulsija	SE/H/0421/001	LT/1/05/0194/009	FRESENIUS KABI AB	LT
SMOFlipid 20% infuzine emulsija	SE/H/0421/001	LT/1/05/0194/010	FRESENIUS KABI AB	LT
SMOFlipid 20% infuzine emulsija	SE/H/0421/001	LT/1/05/0194/011	FRESENIUS KABI AB	LT
SMOFlipid 20% infuzine emulsija	SE/H/0421/001	LT/1/05/0194/012	FRESENIUS KABI AB	LT
SMOFlipid 200 mg/ml emulziós infúzió	SE/H/0421/001	OGYI-T-10 109/02	FRESENIUS KABI AB	HU
SMOFlipid 200 mg/ml emulziós infúzió	SE/H/0421/001	OGYI-T-10 109/03	FRESENIUS KABI AB	HU
SMOFlipid 200 mg/ml emulziós infúzió	SE/H/0421/001	OGYI-T-10 109/04	FRESENIUS KABI AB	HU
SMOFlipid 200 mg/ml emulziós infúzió	SE/H/0421/001	OGYI-T-10 109/05	FRESENIUS KABI AB	HU
SMOFlipid 200 mg/ml emulziós infúzió	SE/H/0421/001	OGYI-T-10 109/06	FRESENIUS KABI AB	HU
SMOFlipid 200 mg/ml, émulsion pour perfusion	SE/H/0557/001	34009 385 113 5 2	FRESENIUS KABI FRANCE S.A.S.	FR

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
SMOFlipid 200 mg/ml emulzija za infundiranje	SE/H/0421/001	H/05/01433/001	MEDIAS INTERNATIONAL D.O.O.	SI
SMOFlipid 200 mg/ml emulzija za infundiranje	SE/H/0421/001	H/05/01433/003	MEDIAS INTERNATIONAL D.O.O.	SI
SMOFlipid 200 mg/ml emulzija za infundiranje	SE/H/0421/001	H/05/01433/002	MEDIAS INTERNATIONAL D.O.O.	SI
SMOFlipid 200 mg/ml emulzija za infundiranje	SE/H/0421/001	H/05/01433/006	MEDIAS INTERNATIONAL D.O.O.	SI
SMOFlipid 200 mg/ml emulzija za infundiranje	SE/H/0421/001	H/05/01433/005	MEDIAS INTERNATIONAL D.O.O.	SI
SMOFlipid 200 mg/ml emulzija za infundiranje	SE/H/0421/001	H/05/01433/004	MEDIAS INTERNATIONAL D.O.O.	SI
SMOFlipid 200 mg/ml emulzija za infundiranje	SE/H/0421/001	H/05/01433/007	MEDIAS INTERNATIONAL D.O.O.	SI
SMOFlipid 200 mg/ml emulzija za infundiranje	SE/H/0421/001	H/05/01433/008	MEDIAS INTERNATIONAL D.O.O.	SI
SMOFlipid 200 mg/ml emulzija za infundiranje	SE/H/0421/001	H/05/01433/009	MEDIAS INTERNATIONAL D.O.O.	SI
SMOFlipid 200 mg/ml emulzija za infundiranje	SE/H/0421/001	H/05/01433/010	MEDIAS INTERNATIONAL D.O.O.	SI
SMOFlipid 200 mg/ml emulzija za infundiranje	SE/H/0421/001	H/05/01433/011	MEDIAS INTERNATIONAL D.O.O.	SI
SMOFlipid 200 mg/ml emulzija za infundiranje	SE/H/0421/001	H/05/01433/012	MEDIAS INTERNATIONAL D.O.O.	SI
SMOFlipid 200 mg/ml, émulsion pour perfusion	SE/H/0421/001	34009 300 381 2 3	FRESENIUS KABI FRANCE S.A.S.	FR
SMOFlipid 200 mg/ml, émulsion pour perfusion	SE/H/0421/001	34009 300 381 3 0	FRESENIUS KABI FRANCE S.A.S.	FR

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SMOFlipid 200 mg/ml, émulsion pour perfusion	SE/H/0421/001	34009 300 381 4 7	FRESENIUS KABI FRANCE S.A.S.	FR
SMOFlipid 200 mg/ml, émulsion pour perfusion	SE/H/0421/001	34009 300 381 5 4	FRESENIUS KABI FRANCE S.A.S.	FR
SMOFlipid 200 mg/ml, émulsion pour perfusion	SE/H/0421/001	34009 300 381 6 1	FRESENIUS KABI FRANCE S.A.S.	FR
SMOFlipid 200 mg/ml, émulsion pour perfusion	SE/H/0421/001	34009 300 381 7 8	FRESENIUS KABI FRANCE S.A.S.	FR
SMOFlipid 200 mg/ml, emulsão para perfusão	SE/H/0421/001	5691878	FRESENIUS KABI PHARMA PORTUGAL LDA.	PT
SMOFlipid 200 mg/ml, emulsão para perfusão	SE/H/0421/001	5691902	FRESENIUS KABI PHARMA PORTUGAL LDA.	PT
SMOFlipid 200 mg/ml, emulsão para perfusão	SE/H/0421/001	5691910	FRESENIUS KABI PHARMA PORTUGAL LDA.	PT
SMOFlipid 200 mg/ml, emulsão para perfusão	SE/H/0421/001	5691928	FRESENIUS KABI PHARMA PORTUGAL LDA.	PT
SMOFlipid 200 mg/ml, emulsão para perfusão	SE/H/0421/001	5691936	FRESENIUS KABI PHARMA PORTUGAL LDA.	PT
SMOFlipid 200 mg/ml, emulsão para perfusão	SE/H/0421/001	5691944	FRESENIUS KABI PHARMA PORTUGAL LDA.	PT
Optilipid 200 mg/ml infusionsvätska, emulsion	SE/H/0558/001	21832	FRESENIUS KABI AB	SE
SMOFlipid 200 mg/ml, emulsione per infusione.	SE/H/0558/001	037135011	FRESENIUS KABI ITALIA S.R.L.	IT
SMOFlipid 200 mg/ml, emulsione per infusione.	SE/H/0558/001	037135023	FRESENIUS KABI ITALIA S.R.L.	IT
SMOFlipid 200 mg/ml, emulsione per infusione.	SE/H/0558/001	037135035	FRESENIUS KABI ITALIA S.R.L.	IT

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SMOFlipid 200 mg/ml, emulsione per infusione.	SE/H/0558/001	037135047	FRESENIUS KABI ITALIA S.R.L.	IT
SMOFlipid 200 mg/ml, emulsione per infusione.	SE/H/0558/001	037135050	FRESENIUS KABI ITALIA S.R.L.	IT
SMOFlipid 200 mg/ml, emulsione per infusione.	SE/H/0558/001	037135062	FRESENIUS KABI ITALIA S.R.L.	IT
SMOFlipid 200 mg/ml, emulsione per infusione.	SE/H/0558/001	037135074	FRESENIUS KABI ITALIA S.R.L.	IT
SMOFlipid 200 mg/ml, emulsione per infusione.	SE/H/0558/001	037135086	FRESENIUS KABI ITALIA S.R.L.	IT
SMOFlipid 200 mg/ml, emulsione per infusione.	SE/H/0558/001	037135098	FRESENIUS KABI ITALIA S.R.L.	IT
SMOFlipid 200 mg/ml, emulsione per infusione.	SE/H/0558/001	037135100	FRESENIUS KABI ITALIA S.R.L.	IT
SMOFlipid 200 mg/ml, emulsione per infusione.	SE/H/0558/001	037135112	FRESENIUS KABI ITALIA S.R.L.	IT
SMOFlipid 200 mg/ml, emulsione per infusione.	SE/H/0558/001	037135124	FRESENIUS KABI ITALIA S.R.L.	IT
SMOFlipid 200 mg/ml, emulsione per infusione.	SE/H/0558/001	037135136	FRESENIUS KABI ITALIA S.R.L.	IT
SMOFlipid 200 mg/ml, emulsione per infusione.	SE/H/0558/001	037135148	FRESENIUS KABI ITALIA S.R.L.	IT
SMOFlipid 200 mg/ml, emulsione per infusione.	SE/H/0558/001	037135151	FRESENIUS KABI ITALIA S.R.L.	IT
SMOFlipid 200 mg/ml, emulsione per infusione.	SE/H/0558/001	037135163	FRESENIUS KABI ITALIA S.R.L.	IT
SMOFlipid 200 mg/ml, emulsione per infusione.	SE/H/0558/001	037135175	FRESENIUS KABI ITALIA S.R.L.	IT

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SMOFlipid 200 mg/ml, emulsione per infusione.	SE/H/0558/001	037135187	FRESENIUS KABI ITALIA S.R.L.	IT
Kombilipid 200 mg/ml infusionsvätska, emulsion	SE/H/0557/001	21831	FRESENIUS KABI AB	SE
SMOFlipid 200 mg/ml, émulsion pour perfusion	SE/H/0557/001	34009 385 118 7 1	FRESENIUS KABI FRANCE S.A.S.	FR
SMOFlipid 200 mg/ml, émulsion pour perfusion	SE/H/0557/001	34009 376 001 3 2	FRESENIUS KABI FRANCE S.A.S.	FR
SMOFlipid 200 mg/ml, émulsion pour perfusion	SE/H/0557/001	34009 376 707 3 9	FRESENIUS KABI FRANCE S.A.S.	FR
SMOFlipid 200 mg/ml, émulsion pour perfusion	SE/H/0557/001	34009 376 705 0 0	FRESENIUS KABI FRANCE S.A.S.	FR
SMOFlipid 200 mg/ml, émulsion pour perfusion	SE/H/0557/001	34009 376 000 7 1	FRESENIUS KABI FRANCE S.A.S.	FR
SMOFlipid 200 mg/ml, émulsion pour perfusion	SE/H/0557/001	34009 376 706 7 8	FRESENIUS KABI FRANCE S.A.S.	FR
SMOFlipid 200 mg/ml, émulsion pour perfusion	SE/H/0557/001	34009 375 999 0 0	FRESENIUS KABI FRANCE S.A.S.	FR
SMOFlipid 200 mg/ml, émulsion pour perfusion	SE/H/0557/001	34009 385 117 0 3	FRESENIUS KABI FRANCE S.A.S.	FR
SMOFlipid 200 mg/ml, émulsion pour perfusion	SE/H/0557/001	34009 385 116 4 2	FRESENIUS KABI FRANCE S.A.S.	FR
SMOFlipid 200 mg/ml, émulsion pour perfusion	SE/H/0557/001	34009 385 115 8 1	FRESENIUS KABI FRANCE S.A.S.	FR
SMOFlipid 200 mg/ml, émulsion pour perfusion	SE/H/0557/001	34009 385 113 5 2	FRESENIUS KABI FRANCE S.A.S.	FR
SMOFlipid 200 mg/ml, émulsion pour perfusion	SE/H/0557/001	34009 385 114 1 3	FRESENIUS KABI FRANCE S.A.S.	FR

