



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 October 2023
EMA/542082/2023
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: omega-3-acid ethyl esters

Procedure no.: PSUSA/00010312/202301

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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
ESAPENT 1000 mg Capsule molli	not available	027617024	PFIZER ITALIA S.R.L.	IT
OMACOR 1000 mg, capsule molle	FR/H/0105/001	34009 339 435 3 0	BASF AS	FR
OMACOR 1000 mg, capsule molle	FR/H/0105/001	34009 563 901 4 4	BASF AS	FR
Omacor 1000 mg Weichkapseln	FR/H/0105/001	1-21530	BASF AS	AT
OMACOR 1000 mg capsules molles	FR/H/0105/001	BE253066	BASF AS	BE
OMACOR® 1000 mg, καψάκια, μαλακά	FR/H/0105/001	20055	BASF AS	CY
Omacor, 1000 mg pehmekapslid	FR/H/0105/001	430203	BASF AS	EE
Omacor 1000 mg lágy kapszula	FR/H/0105/001	OGYI-T-9691/01	BASF AS	HU
Omacor 1000 mg Soft Capsules	FR/H/0105/001	PA 1099/1/1	BASF AS	IE

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Omacor 1000 mg mīkstās kapsulas	FR/H/0105/001	05-0465	BASF AS	LV
Omacor 1000 mg minkštosios kapsulės	FR/H/0105/001	LT/1/05/0319/003	BASF AS	LT
Omacor 1000 mg minkštosios kapsulės	FR/H/0105/001	LT/1/05/0319/001	BASF AS	LT
Omacor 1000 mg minkštosios kapsulės	FR/H/0105/001	LT/1/05/0319/004	BASF AS	LT
Omacor 1000 mg minkštosios kapsules	FR/H/0105/001	LT/1/05/0319/002	BASF AS	LT
Omacor 1000 mg minkštosios kapsulės	FR/H/0105/001	LT/1/05/0319/005	BASF AS	LT
OMACOR 1000 mg capsules molles	FR/H/0105/001	2011071232	BASF AS	LU
Omacor 1000 mg, capsules, soft	FR/H/0105/001	517/00101	BASF AS	MT
Omacor, zachte capsules, 460 mg/380 mg	FR/H/0105/001	RVG 28822	BASF AS	NL

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Omacor, 1000 mg, kapsułki miękkie	FR/H/0105/001	12303	BASF AS	PL
Omacor 1000 mg, cápsulas moles	FR/H/0105/001	5336888	BASF AS	PT
Omacor 1000 mg, cápsulas moles	FR/H/0105/001	4452884	BASF AS	PT
Omacor 1000 mg, cápsulas moles	FR/H/0105/001	5336987	BASF AS	PT
Omacor 1000 mg, cápsulas moles	FR/H/0105/001	4452983	BASF AS	PT
Omacor 1000 mg, cápsulas moles	FR/H/0105/001	4453080	BASF AS	PT
Omacor 1000 mg mehke kapsule	FR/H/0105/001	H/05/01172/001	BASF AS	SI
OMACOR 1000 mg zachte capsules	FR/H/0105/001	BE253066	BASF AS	BE
Omacor 1000 mg Weichkapseln	FR/H/0105/001	BE253066	BASF AS	BE

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Omacor 1000 mg Weichkapseln	FR/H/0105/001	2011071232	BASF AS	LU
OMACOR 1000 mg, capsule molle	FR/H/0105/001	34009 300 105 3 2	BASF AS	FR
OMACOR 1000 mg, capsule molle	FR/H/0105/001	34009 300 105 4 9	BASF AS	FR
OMACOR 1000 mg, capsule molle	FR/H/0105/001	34009 300 198 1 8	BASF AS	FR
Omacor 1000 mg, capsules, soft	FR/H/0105/001	PL 15905/0001	BASF AS	XI
Omacor 1000 mg cápsulas blandas	FR/H/0105/001	65.476	BASF AS	ES
Omacor® 1000 mg Weichkapseln Wirkstoff: Omega - 3 - Säurenethylester 90	FR/H/0105/001	37312.00.00	BASF AS	DE
OMACOR 1000 mg, capsule molle	FR/H/0105/001	34009 357 025 8 6	BASF AS	FR
Omacor 1000 mg mehke kapsule	FR/H/0105/001	H/05/01172/002	BASF AS	SI

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Omacor 1000 mg mehke kapsule	FR/H/0105/001	H/05/01172/003	BASF AS	SI
Omacor 1000 mg mehke kapsule	FR/H/0105/001	H/05/01172/004	BASF AS	SI
Omacor 1000 mg mehke kapsule	FR/H/0105/001	H/05/01172/005	BASF AS	SI
Omacor 1000 mg mehke kapsule	FR/H/0105/001	H/05/01172/006	BASF AS	SI
OMACOR® 1000 mg καψάκια, μαλακά	FR/H/0105/001	3196/13-1-2009	BGP PRODUCTS S.LTD	GR
Omacor 1000 mg capsule moi	not available	9639/2017/01	BASF AS	RO
Omacor 1000 mg capsule moi	not available	9639/2017/02	BASF AS	RO
Omacor 1000 mg capsule moi	not available	9639/2017/03	BASF AS	RO
Omacor 1000 mg capsule moi	not available	9639/2017/04	BASF AS	RO

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ESKIM 1000 mg capsule molli	not available	027618053	ALFASIGMA S.P.A.	IT
ESKIM 500 mg capsule molli	not available	027618038	ALFASIGMA S.P.A.	IT
ESKIM 1000 mg capsule molli	not available	027618040	ALFASIGMA S.P.A.	IT
Dualtis 1000 mg meke kapsule	not available	HR-H-550928853	MYLAN HRVATSKA D.O.O.	HR
SEACOR 1000 mg Capsule molli	not available	027616034	SPA – SOCIETÀ PRODOTTI ANTIBIOTICI S.P.A.	IT
SEACOR 1000 mg Capsule molli	not available	027616022	SPA – SOCIETÀ PRODOTTI ANTIBIOTICI S.P.A.	IT
SEACOR 500 mg Capsule molli	not available	027616010	SPA – SOCIETÀ PRODOTTI ANTIBIOTICI S.P.A.	IT
Zodin 1000 mg Weichkapseln	DE/H/6921/001/MR	1-26485	BASF AS	AT
Zodin® Omega-3 1000 mg Weichkapseln	DE/H/6921/001/MR	60885.00.00	BASF AS	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
ZODIN, 1000 mg cápsula mole	DE/H/6921/001/MR	5015839	BASF AS	PT
ZODIN, 1000 mg cápsula mole	DE/H/6921/001/MR	5409784	BASF AS	PT
ZODIN, 1000 mg cápsula mole	DE/H/6921/001/MR	5015847	BASF AS	PT
ZODIN, 1000 mg cápsula mole	DE/H/6921/001/MR	5409883	BASF AS	PT
ZODIN, 1000 mg cápsula mole	DE/H/6921/001/MR	5409982	BASF AS	PT
Zodin 1000 mg καψάκια, μαλακά	DE/H/6921/001	2661001	FERRER-GALENICA S.A.	GR
Омакор 1 000 mg меки капсули	not available	20040231	BASF AS	BG
Omacor 1000 mg meke kapsule	not available	HR-H-239310133	MYLAN HRVATSKA D.O.O.	HR
YSOMEGA 1g, capsule molle	not available	368 459-4	PIERRE FABRE MEDICAMENT	FR

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YSOMEGA 1g, capsule molle	not available	368 460-2	PIERRE FABRE MEDICAMENT	FR
YSOMEGA 1g, capsule molle	not available	368 461-9	PIERRE FABRE MEDICAMENT	FR
YSOMEGA 1g, capsule molle	not available	368 462-5	PIERRE FABRE MEDICAMENT	FR
Omacor 1000 mg kapsler, myke	not available	8041	BASF AS	NO