



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 September 2017
EMA/641530/2017
Human Medicines Evaluation Division

List of nationally authorised medicinal products

Active substance: omega-3-acid-ethyl esters

Procedure no.: PSUSA/00010312/201701



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
Dualtis 1000 mg capsules, soft	FR/H/0261/001	PL 15905/0002	PRONOVA BIOPHARMA NORGE AS	UK
Dualtis 1000 mg meke kapsule	not available	UP/I-530-09/12-01/152	MYLAN HRVATSKA D.O.O.	HR
ESAPENT 1000 mg Capsule molli	not available	027617024	PFIZER ITALIA S.R.L.	IT
ESAPENT 500 mg Capsule molli	not available	027617012	PFIZER ITALIA S.R.L.	IT
ESKIM 1000 mg capsule molli	not available	027618040	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A.	IT
ESKIM 1000 mg capsule molli	not available	027618053	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A.	IT
ESKIM 500 mg capsule molli	not available	027618038	SIGMA-TAU INDUSTRIE FARMACEUTICHE RIUNITE S.P.A.	IT
Omacor 1000 mg cápsulas blandas	FR/H/0105/001	65.476	PRONOVA BIOPHARMA NORGE AS	ES
Omacor 1000 mg capsules molles	FR/H/0105/001	BE253066	PRONOVA BIOPHARMA NORGE AS	BE
Omacor 1000 mg capsules molles	FR/H/105/01	2011071232	PRONOVA BIOPHARMA NORGE AS	LU

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Omacor 1000 mg lágy kapzula	FR/H/105/01	OGYI-T-9691/01	PRONOVA BIOPHARMA NORGE AS	HU
Omacor 1000 mg lágy kapzula	FR/H/105/01	OGYI-T-9691/02	PRONOVA BIOPHARMA NORGE AS	HU
Omacor 1000 mg lágy kapzula	FR/H/105/01	OGYI-T-9691/03	PRONOVA BIOPHARMA NORGE AS	HU
Omacor 1000 mg mäkke kapsuly	FR/H/0105/001	31/0378/05-S	PRONOVA BIOPHARMA NORGE AS	SK
Omacor 1000 mg mehke kapsule	FR/H/105/01	H/05/01172/001	PRONOVA BIOPHARMA NORGE AS	SI
Omacor 1000 mg mehke kapsule	FR/H/0105/001	H/05/01172/002	PRONOVA BIOPHARMA NORGE AS	SI
Omacor 1000 mg mehke kapsule	FR/H/0105/001	H/05/01172/003	PRONOVA BIOPHARMA NORGE AS	SI
Omacor 1000 mg mehke kapsule	FR/H/0105/001	H/05/01172/004	PRONOVA BIOPHARMA NORGE AS	SI
Omacor 1000 mg mehke kapsule	FR/H/0105/001	H/05/01172/005	PRONOVA BIOPHARMA NORGE AS	SI

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Omacor 1000 mg mehke kapsule	FR/H/0105/001	H/05/01172/006	PRONOVA BIOPHARMA NORGE AS	SI
Omacor 1000 mg meke kapsule	not available	HR-H-239310133	MYLAN HRVATSKA D.O.O.	HR
Omacor 1000 mg mīkstās kapsulas	FR/H/0105/001	05-0465	PRONOVA BIOPHARMA NORGE AS	LV
Omacor 1000 mg minkštosios kapsules	FR/H/0105/001	LT/1/05/0319/003	PRONOVA BIOPHARMA NORGE AS	LT
Omacor 1000 mg minkštosios kapsules	FR/H/0105/001	LT/1/05/0319/001	PRONOVA BIOPHARMA NORGE AS	LT
Omacor 1000 mg minkštosios kapsules	FR/H/0105/001	LT/1/05/0319/004	PRONOVA BIOPHARMA NORGE AS	LT
Omacor 1000 mg minkštosios kapsules	FR/H/0105/001	LT/1/05/0319/002	PRONOVA BIOPHARMA NORGE AS	LT
Omacor 1000 mg minkštosios kapsules	FR/H/0105/001	LT/1/05/0319/005	PRONOVA BIOPHARMA NORGE AS	LT
Omacor 1000 mg Soft Capsules	FR/H/0105/001	1099/1/1	PRONOVA BIOPHARMA NORGE AS	IE

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Omacor 1000 mg Weichkapseln	FR/H/0105/001	1-21530	PRONOVA BIOPHARMA NORGE AS	AT
Omacor 1000 mg Weichkapseln	FR/H/0105/001	BE253066	PRONOVA BIOPHARMA NORGE AS	BE
Omacor 1000 mg Weichkapseln	FR/H/0105/001	2011071232	PRONOVA BIOPHARMA NORGE AS	LU
OMACOR 1000 mg zachte capsules	FR/H/0105/001	BE253066	PRONOVA BIOPHARMA NORGE AS	BE
Omacor 1000 mg, cápsulas moles	FR/H/0105/001	5336888	PRONOVA BIOPHARMA NORGE AS	PT
Omacor 1000 mg, cápsulas moles	FR/H/0105/001	4452884	PRONOVA BIOPHARMA NORGE AS	PT
Omacor 1000 mg, cápsulas moles	FR/H/0105/001	5336987	PRONOVA BIOPHARMA NORGE AS	PT
Omacor 1000 mg, cápsulas moles	FR/H/0105/001	4452983	PRONOVA BIOPHARMA NORGE AS	PT
Omacor 1000 mg, cápsulas moles	FR/H/0105/001	4453080	PRONOVA BIOPHARMA NORGE AS	PT

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OMACOR 1000 mg, capsule molle	FR/H/0105/001	34009 339 435 3 0	PRONOVA BIOPHARMA NORGE AS	FR
OMACOR 1000 mg, capsule molle	FR/H/0105/001	34009 563 901 4 4	PRONOVA BIOPHARMA NORGE AS	FR
OMACOR 1000 mg, capsule molle	FR/H/105/001	34009 300 105 3 2	PRONOVA BIOPHARMA NORGE AS	FR
OMACOR 1000 mg, capsule molle	FR/H/105/001	34009 300 105 4 9	PRONOVA BIOPHARMA NORGE AS	FR
OMACOR 1000 mg, capsule molle	FR/H/105/001	34009 300 198 1 8	PRONOVA BIOPHARMA NORGE AS	FR
Omacor 1000 mg, capsule molle	FR/H/0105/001	34009 357 025 8 6	PRONOVA BIOPHARMA NORGE AS	FR
Omacor 1000 mg, capsules, soft	FR/H/0105/001	517/00101	PRONOVA BIOPHARMA NORGE AS	MT
Omacor 1000 mg, capsules, soft	FR/H/0105/001	PL 15905/0001	PRONOVA BIOPHARMA NORGE AS	UK
Omacor kapsel, myk	not available	8041	PRONOVA BIOPHARMA NORGE AS	NO

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Omacor, 1000 mg pehmekapslid	FR/H/0105/001	430203	PRONOVA BIOPHARMA NORGE AS	EE
Omacor, 1000 mg, capsule moi	not available	4325/2004/01	PRONOVA BIOPHARMA NORGE AS	RO
OMACOR, 1000 mg, capsule moi	not available	4325/2004/03	PRONOVA BIOPHARMA NORGE AS	RO
OMACOR, 1000 mg, capsule moi	not available	4325/2004/04	PRONOVA BIOPHARMA NORGE AS	RO
Omacor, 1000 mg, capsule moi,	not available	4325/2004/02	PRONOVA BIOPHARMA NORGE AS	RO
Omacor, 1000 mg, kapsułki miękkie	FR/H/0105/001	12303	PRONOVA BIOPHARMA NORGE AS	PL
Omacor, 1000 mg, měkké tobolky	FR/H/0105/001	31/366/05-C	PRONOVA BIOPHARMA NORGE AS	CZ
Omacor, zachte capsules, 460 mg/380 mg	FR/H/0105/001	RVG 28822	PRONOVA BIOPHARMA NORGE AS	NL
Omacor® 1000 mg Weichkapseln	FR/H/0105/001	37312.00.00	PRONOVA BIOPHARMA NORGE AS	DE

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OMACOR® 1000 mg, καψάκια, μαλακά	FR/H/0105/001	20055	PRONOVA BIOPHARMA NORGE AS	CY
OMACOR® καψάκιο, μαλακό	FR/H/0105/001	3196/13-1-2009	BGP PRODUCTS LTD (GREECE)	GR
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
Zidoril cápsula mole	not available	5550371	FERRER PORTUGAL, S.A.	PT
Zidoril cápsula mole	not available	5550405	FERRER PORTUGAL, S.A.	PT
Zodin 1000 mg - Weichkapseln	FR/H/261/01	1-26485	PRONOVA BIOPHARMA NORGE AS	AT
Zodin 1000 mg καψάκια, μαλακά	FR/H/0261/001	77126/30-10-2015	FERRER-GALENICA S.A.	GR

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ZODIN 1000 mg, capsule molle	FR/H/0261/001	34009 374 834 8 3	PRONOVA BIOPHARMA NORGE AS	FR
ZODIN 1000 mg, capsule molle	FR/H/0261/001	34009 361 971 1 4	PRONOVA BIOPHARMA NORGE AS	FR
ZODIN 1000 mg, capsule molle	FR/H/0261/001	34009 374 835 4 4	PRONOVA BIOPHARMA NORGE AS	FR
ZODIN 1000 mg, capsule molle	FR/H/0261/001	34009 564 880 0 1	PRONOVA BIOPHARMA NORGE AS	FR
ZODIN 1000 mg, capsule molle	FR/H/0261/001	34009 564 881 7 9	PRONOVA BIOPHARMA NORGE AS	FR
ZODIN, 1000 mg cápsula mole	FR/H/261/01	5015839	PRONOVA BIOPHARMA NORGE AS	PT
ZODIN, 1000 mg cápsula mole	FR/H/261/01	5409784	PRONOVA BIOPHARMA NORGE AS	PT
ZODIN, 1000 mg cápsula mole	FR/H/261/01	5015847	PRONOVA BIOPHARMA NORGE AS	PT
ZODIN, 1000 mg cápsula mole	FR/H/261/01	5409883	PRONOVA BIOPHARMA NORGE AS	PT

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Zodin, 1000 mg cápsula mole	FR/H/261/01	5409982	PRONOVA BIOPHARMA NORGE AS	PT
Zodin® Omega-3 1000 mg Weichkapseln	FR/H/0261/001	60885.00.00	PRONOVA BIOPHARMA NORGE AS	DE
Омакор 1000 мг меки капсули	not available	20040231	PRONOVA BIOPHARMA NORGE AS	BG