

**Summary of European Union decisions on marketing authorisations in respect of medicinal products from
1 June 2019 to 30 June 2019**

(Decisions taken pursuant to Article 34 of Directive 2001/83/EC ⁽¹⁾ or Article 38 of Directive 2001/82/EC ⁽²⁾)

(2019/C 252/02)

— Issuing, maintenance or modification of a national marketing authorisation

Date of the decision	Name(s) of the medicinal product	INN (International Non-Proprietary Name)	Holder(s) of the marketing authorisation	Member State concerned	Date of notification
6.6.2019	Omega-3 acid ethyl esters	omega-3 acid ethyl esters	See Annex	See Annex	7.6.2019

⁽¹⁾ OJ L 311, 28.11.2001, p. 67.

⁽²⁾ OJ L 311, 28.11.2001, p. 1.

List of medicinal products and presentations

Member State in EEA	Marketing authorisation holder	Product name	INN + Strength	Pharmaceutical form	Route of administration
Austria	Pronova Biopharma Norge As	Omacor	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Austria	Pronova Biopharma Norge As	Zodin	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Belgium	Pronova Biopharma Norge As	Omacor	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Belgium	Ibsa Farmaceutici Italia	Trimacor	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Bulgaria	Pronova Biopharma Norge As	Омакоп	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Croatia	Pliva Hrvatska D.O.O.	Corprotect	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Croatia	Mylan Hrvatska D.O.O.	Dualtis	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Croatia	Mylan Hrvatska D.O.O.	Omacor	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Cyprus	Pronova Biopharma Norge As	Omacor	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Denmark	Strides Arcolab International Limited	Megazza Strides	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Estonia	Pronova Biopharma Norge As	Omacor	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use

Member State in EEA	Marketing authorisation holder	Product name	INN + Strength	Pharmaceutical form	Route of administration
France	Eg Labo Laboratoires Eurogenerics	Esters Ethyliques D'acides Omega 3 Eg Labo Conseil	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
France	Laboratoires Genevrier	Esters Ethyliques D'acides Omega-3 Genevrier	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
France	Pronova Biopharma Norge As	Omacor	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
France	Pronova Biopharma Norge As	Zodin	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Germany	Pronova Biopharma Norge As	Omacor	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Germany	Glenmark Pharmaceuticals Europe Limited	Omega 3	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Germany	Biomom Pharma GmbH	Omega-3	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Germany	Ntc Srl	Omega-3 Ntc	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Germany	Ratiopharm GmbH	Omega-3 Ratiopharm	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Germany	Heumann Pharma GmbH & Co. Generica Kg	Omega-3-Säureethylester 90 Heumann	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Germany	Ibsa Farmaceutici Italia	Omegoil	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Germany	Pronova Biopharma Norge As	Zodin Omega-3	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Greece	Bennett Pharmaceuticals Sa	Becolip	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use

Member State in EEA	Marketing authorisation holder	Product name	INN + Strength	Pharmaceutical form	Route of administration
Greece	Zwitter Pharmaceuticals ΕπΕ	Dynapen-3	Fish Oil 1000 mg Capsule	Capsule, Soft	Oral Use
Greece	Pharmanel Commercial Pharmaceutical S.A.	Eicodol	Eicosapentaenoic Acid Ethyl Ester 460 mg Capsule, Docosahexaenoic Acid Ethyl Ester 380 mg Capsule	Capsule, Soft	Oral Use
Greece	Heremco	Emfrastop	Docosahexaenoic Acid 527 mg/5 ml, Eicosapentaenoic Acid 791 mg/5 ml	Oral Solution	Oral Use
Greece	Alapis Abee	Epadoc	Docosahexaenoic Acid 527 mg/5 ml, Vitamin D 10 I.U.G, Eicosapentaenoic Acid 791 mg/5 ml, Vitamin A 100 I.U.G	Oral Solution	Oral Use
Greece	Mediapharm Ltd	Farlipid	Docosahexaenoic Acid 115 mg Capsule, Vitamin D 1 I.U.G, Eicosapentaenoic Acid 170 mg Capsule, Vitamin A 1 I.U.G	Capsule, Soft	Oral Use
Greece	Mediapharm Ltd	Farlipid	Docosahexaenoic Acid 265 mg/5 ml, Eicosapentaenoic Acid 390 mg/5 ml	Oral Emulsion	Oral Use
Greece	Mediapharm Ltd	Farlipid	Docosahexaenoic Acid 527 mg/5 ml, Eicosapentaenoic Acid 791 mg/5 ml	Oral Solution	Oral Use
Greece	Naturalia S.A.	Hemido	Eicosapentaenoic Acid Ethyl Ester 460 mg Capsule, Docosahexaenoic Acid Ethyl Ester 380 mg Capsule	Capsule, Soft	Oral Use
Greece	Verisfield (Uk) Ltd	Lipemia	Docosahexaenoic Acid 115 mg Capsule, Eicosapentaenoic Acid 170 mg Capsule	Capsule, Soft	Oral Use
Greece	Verisfield (Uk) Ltd	Lipemia	Fish Oil 0,5 ml/ml	Oral Emulsion	Oral Use
Greece	Verisfield (Uk) Ltd	Lipemia Forte	Omega-3-Acid Ethyl Esters 1000 mg Capsule	Capsule, Soft	Oral Use
Greece	Rafarm Sa.	Loitrol	Docosahexaenoic Acid 115 mgg, Eicosapentaenoic Acid 170 µgg	Oral Solution	Oral Use

Member State in EEA	Marketing authorisation holder	Product name	INN + Strength	Pharmaceutical form	Route of administration
Greece	Trygg Pharma As	Lypiad	Eicosapentaenoic Acid Ethyl Ester 460 mg Capsule, Docosahexaenoic Acid Ethyl Ester 380 mg Capsule	Capsule, Soft	Oral Use
Greece	Pharmanel Commercial Pharmaceutical S.A.	Macoil	Omega-3-Acid Ethyl Esters 1000 mg Capsule	Capsule, Soft	Oral Use
Greece	Cana S.A. Farmakeftika Ergastiria	Maxepa	Docosahexaenoic Acid 115 mg Capsule, Vitamin D 10 I.U.G, Eicosapentaenoic Acid 170 mg Capsule, Vitamin A 100 I.U.G	Capsule, Soft	Oral Use
Greece	Cana S.A. Farmakeftika Ergastiria	Maxepa	Docosahexaenoic Acid 527 mg/5 ml, Vitamin D 10 I.U.G, Eicosapentaenoic Acid 791 mg/5 ml, Vitamin A 100 I.U.G	Oral Solution	Oral Use
Greece	Bgp Products Ltd (Greece)	Omacor	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Greece	Trygg Pharma As	Omega-3-Acid-Ethyl-Ester/Lomegar	Eicosapentaenoic Acid Ethyl Ester 460 mg Capsule, Docosahexaenoic Acid Ethyl Ester 380 mg Capsule	Capsule, Soft	Oral Use
Greece	Novendia Pharmaceuticals Ltd	Pazeril	Docosahexaenoic Acid 115 mg Capsule, Eicosapentaenoic Acid /Docosahexaenoic Acid 170 mg Capsule	Capsule, Soft	Oral Use
Greece	Novendia Pharmaceuticals Ltd	Pazeril	Docosahexaenoic Acid 527 mg/5 ml, Eicosapentaenoic Acid/Docosahexaenoic Acid 791 mg/5 ml	Oral Solution	Oral Use
Greece	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Prolipid	Docosahexaenoic Acid 120 mg Capsule, Eicosapentaenoic Acid 180 mg Capsule	Capsule, Soft	Oral Use
Greece	Uni-Pharma Kleon Tsetis Pharmaceutical Laboratories S.A.	Prolipid	Docosahexaenoic Acid 60 mg Capsule, Eicosapentaenoic Acid 90 mg Capsule	Capsule, Soft	Oral Use

Member State in EEA	Marketing authorisation holder	Product name	INN + Strength	Pharmaceutical form	Route of administration
Greece	Pharmanel Commercial Pharmaceutical S.A.	Sea-Oil	Eicosapentaenoic Acid Ethyl Ester 460 mg Capsule, Docosahexaenoic Acid Ethyl Ester 380 mg Capsule	Capsule, Soft	Oral Use
Greece	Ioulia And Irene Tseti Pharmaceutical Laboratories S.A.	Tropolipid	Eicosapentaenoic Acid Ethyl Ester 430 mg Capsule, Docosahexaenoic Acid Ethyl Ester 437 mg Capsule	Capsule, Soft	Oral Use
Greece	Ferrer-Galenica S.A.	Zodin	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Hungary	Pronova Biopharma Norge As	Omacor	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Hungary	Ibsa Pharma Kft	Panoil	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Ireland	Pronova Biopharma Norge As	Omacor	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Ireland	Clonmel Healthcare Ltd	Trimega	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Italy	I.B.N. Savio S.R.L.	Agemo	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Italy	Pfizer Italia S.R.L.	Esapent	Esters Of Unsaturated Fatty Acids 1000 mg Capsule	Capsule, Soft	Oral Use
Italy	Pfizer Italia S.R.L.	Esapent	Esters Of Unsaturated Fatty Acids 500 mg Capsule	Capsule, Soft	Oral Use
Italy	Alfasigma S.P.A.	Eskim	Omega-3-Acid Ethyl Esters 90 With A Specific Composition For Epa And Dha Not Lower Than 85 %. 1000 mg Capsule	Capsule, Soft	Oral Use
Italy	Alfasigma S.P.A.	Eskim	Omega-3-Acid Ethyl Esters 90 With A Specific Composition For Epa And Dha Not Lower Than 85 %. 500 mg Capsule	Capsule, Soft	Oral Use

Member State in EEA	Marketing authorisation holder	Product name	INN + Strength	Pharmaceutical form	Route of administration
Italy	Ibsa Farmaceutici Italia	Olevia	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Italy	Alfasigma S.P.A.	Omega 3 Alfasigma	Omega-3-Acid Ethyl Esters 90 With A Specific Composition For Epa And Dha Not Lower Than 85 %. 1000 mg Capsule	Capsule, Soft	Oral Use
Italy	S.P.A. Italiana Laboratori Bouty	Omega 3 Bouty	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Italy	Doc Generici S.R.L.	Omega 3 Doc	Esters Of Unsaturated Fatty Acids 1000 mg Capsule	Capsule, Soft	Oral Use
Italy	Doc Generici S.R.L.	Omega 3 Doc Generici	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Italy	Eg S.P.A.	Omega 3 Eg	Esters Of Unsaturated Fatty Acids 1000 mg Capsule	Capsule, Soft	Oral Use
Italy	Strides Arcolab International Limited	Omega 3 Strides Arcolab International	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Italy	Teva Italia S.R.L.	Omega 3 Teva	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Italy	Altergon Italia S.R.L.	Omegoil	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Italy	Spa – Società Prodotti Antibiotici S.P.A.	Seacor	Omega-3-Acid Ethyl Esters 90 With A Specific Composition For Epa And Dha Not Lower Than 85 %. 1000 mg Capsule	Capsule, Soft	Oral Use
Italy	Spa – Società Prodotti Antibiotici S.P.A.	Seacor	Omega-3-Acid Ethyl Esters 90 With A Specific Composition For Epa And Dha Not Lower Than 85 %. 500 mg Capsule	Capsule, Soft	Oral Use

Member State in EEA	Marketing authorisation holder	Product name	INN + Strength	Pharmaceutical form	Route of administration
Italy	Alfasigma S.P.A.	Trioreg	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Italy	Piam Farmaceutici S.P.A.	Triscudil	Eicosapentaenoic Acid Ethyl Ester 460 mg Capsule, Docosahexaenoic Acid Ethyl Ester 380 mg Capsule	Capsule, Soft	Oral Use
Latvia	Pronova Biopharma Norge As	Omacor	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Lithuania	Pronova Biopharma Norge As	Omacor	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Luxembourg	Pronova Biopharma Norge As	Omacor	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Luxembourg	Ibsa Farmaceutici Italia	Omegoil	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Malta	Pronova Biopharma Norge As	Omacor	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Netherlands	Pronova Biopharma Norge As	Omacor	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Netherlands	Teva Nederland B.V.	Omega-3 Vetzuren Ethylesters 90 Teva	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Netherlands	Ibsa Farmaceutici Italia	Omegoil	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Norway	Pronova Biopharma Norge As	Omacor	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Poland	Pronova Biopharma Norge As	Omacor	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Portugal	Ntc Srl	Ésteres Etílicos 90 Do Ácido Omega-3 Ntc	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use

Member State in EEA	Marketing authorisation holder	Product name	INN + Strength	Pharmaceutical form	Route of administration
Portugal	Pharmanel Commercial Pharmaceutical S.A.	Ésteres Etílicos 90 Dos Ácidos Omega-3 Pharmanel	Omega-3-Acid Ethyl Esters 1000 mg Capsule	Capsule, Soft	Oral Use
Portugal	Pronova Biopharma Norge As	Omacor	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Portugal	Ibsa Farmaceutici Italia	Panoil	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Portugal	Pronova Biopharma Norge As	Zodin	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Romania	Pronova Biopharma Norge As	Omacor	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Romania	Pronova Biopharma Norge As	Omacor	Triglycerides Medium Chain 1qs Capsule, Lecithin Soya 1qs Capsule, Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Romania	Teva Pharmaceuticals S.R.L	Tevocor	Omega-3 Fatty Acids 1000 mg Capsule	Capsule, Soft	Oral Use
Romania	Ntc Srl	Vasoteran	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Slovenia	Pronova Biopharma Norge As	Omacor	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Slovenia	Pronova Biopharma Norge As	Omacor	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Spain	Aristo Pharma Iberia, S.L.	Ácidos Omega 3 Aristo	Omega-3-Acid Ethyl Esters 1000 mg Capsule	Capsule, Soft	Oral Use
Spain	Kern Pharma, S.L.	Ácidos Omega 3 Kern Pharma	Eicosapentaenoic Acid Ethyl Ester 460 mg Capsule, Docosahexaenoic Acid Ethyl Ester 380 mg Capsule	Capsule, Soft	Oral Use

Member State in EEA	Marketing authorisation holder	Product name	INN + Strength	Pharmaceutical form	Route of administration
Spain	Laboratorio Stada, S.L.	Acidos Omega 3 Stada	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Spain	Strides Arcolab International Limited	Ácidos Omega 3 Strides	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Spain	Tarbis Farma, S.L.	Ácidos Omega 3 Tarbis	Docosahexaenoic Acid 380 mg Capsule, Eicosapentaenoic Acid 460 mg Capsule, Omega-3-Acid Ethyl Esters 90 1000 mg Tablet	Capsule, Soft	Oral Use
Spain	Pronova Biopharma Norge As	Omacor	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Spain	Ibsa Farmaceutici Italia	Omegoil	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
Sweden	Strides Arcolab International Limited	Megazza Strides	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
United Kingdom	Pronova Biopharma Norge As	Omacor	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
United Kingdom	Teva Uk Limited	Omega 3-Acid-Ethyl Esters Teva Uk	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
United Kingdom	Strides Arcolab International Limited	Omega-3-Acid Ethyl Esters Strides Arcolab International Limited	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
United Kingdom	Teva Uk Limited	Prestylon	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use
United Kingdom	Mercury Pharmaceuticals Ltd	Teromeg	Omega-3-Acid Ethyl Esters 90 1000 mg Capsule	Capsule, Soft	Oral Use