

REGULATORY TEXT – COMBINED LABEL-LEAFLET

MAXEPA CAPSULES, PL 01932/0002

Top of Label

SEVEN SEAS

Maxepa Capsules

200 capsules

Front of Label (design panel)

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Maxepa Capsules

Each 1 g capsule contains 170 mg Eicosapentaenoic Acid (EPA) and 115 mg Docosahexaenoic Acid (DHA) for adult use only.

200 capsules

Front of Label (text panel)

Ingredients

Each 1g capsule of Maxepa contains the following active ingredients: Eicosapentaenoic Acid (EPA) 170mg and Docosahexaenoic Acid (DHA) 115mg. Also contains Tocopheryl Acetate (Vitamin E), Gelatin and Glycerin.

What are Maxepa Capsules?

Maxepa Capsules belong to a group of fat lowering medicines. This medicine reduces the amount of fat (triglycerides) in the blood in those who have been told they may be at risk of heart disease and/or inflammation of the pancreas (pancreatitis).

DO NOT TAKE Maxepa Capsules if you:

- Are allergic (hypersensitive) to any of the ingredients of Maxepa Capsules
- Suffer from non-insulin dependent diabetes and have aspirin sensitive asthma

Before taking Maxepa Capsules tell your doctor or pharmacist if you:

- Suffer from non-insulin dependent diabetes
- Suffer with aspirin sensitive asthma (this is an allergy where taking aspirin or aspirin-like substances can bring on the symptoms of asthma)
- Suffer from haemophilia (a disorder that affects blood clotting)
- Suffer from liver problems
- Are taking any medicines, including those you have bought without a prescription
- Are taking any medicines that can thin your blood (e.g. warfarin, aspirin, cephalosporin)
- Are pregnant, trying to become pregnant or breast feeding

How to take Maxepa Capsules

For adult use only.

For oral use.

Adults and the elderly.

The usual dose is 5 capsules to be swallowed whole with water at meal times twice daily or as directed by your doctor. If you miss a dose do not worry. Take the next dose at your usual time. Do not take this medicine twice to make up for a forgotten dose. Consult your doctor or pharmacist before you stop your treatment with this medicine. If you are unsure about how to take this medicine or you have any other questions talk to your doctor or pharmacist.

Side effects

As with all medicines there may be some side effects with Maxepa Capsules, although not everyone will get them. Maxepa Capsules can sometimes cause nausea (feeling sick) vomiting (being sick), fishy after-taste, wind, skin reactions (e.g. acne, eczema) and a slight increase in liver enzymes if you have high levels of fat in your blood (hypertriglyceridaemia), diarrhoea or constipation. If any side effect becomes serious or you notice any side effects not listed on this label, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

What Maxepa Capsules look like:

Colourless, oblong shaped soft gelatin capsules containing 1g of clear golden oil contained in a plastic tub fitted with snap-on cap. Each tub contains 200 capsules. Check cap seal is not damaged before first use.

Storage instructions: Keep out of the reach and sight of children

Store below 25°C. Do not refrigerate. Keep Maxepa Capsules in the original container in order to protect from light and moisture. Do not use after the expiry date shown on the carton.

Further information:

Product Licence Holder and Manufacturer: Seven Seas Ltd., Hedon Road, Hull, HU9 5NJ, United Kingdom.

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This label was last revised: October 2013

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