

Package Leaflet: Information for the user

Trimega 1000mg Capsules

Omega-3-Acid Ethyl Esters 90

Read all of this leaflet carefully before you start taking this medicine, because it contains important information for you.

- Keep this leaflet. You may want to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Trimega is and what it is used for
2. What you need to know before you take Trimega
3. How to take Trimega
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1. What Trimega is and what it is used for

Trimega contains highly purified omega-3 polyunsaturated fatty acids. Trimega belongs to a group of so called reducers of cholesterol and triglycerides.

Trimega is used:

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- to treat certain forms of increased triglycerides (fats) in the blood after changes to the diet have not worked.

2. What you need to know before you take Trimega

Do not take Trimega:

■ If you are allergic to Omega-3-Acid Ethyl Esters 90 (the main ingredient) or any of the other ingredients of this medicine (listed in section 6)

If any of the above applies to you, do not take this medicine, and talk to your doctor.

Warnings and precautions:

Talk to your doctor or pharmacist before taking Trimega if:

- you are due to have or have had surgery recently
- you have had a trauma recently
- you have a kidney problem
- you have diabetes which is not controlled
- you have problems with your liver. Your doctor will monitor any effects Omega-3-Acid Ethyl Esters 90 may have on your liver with blood tests.
- you are allergic to fish.

If any of the above applies to you, talk to your doctor or pharmacist before taking this medicine.

Children

Children should not take this medicine.

Elderly

Use Trimega with care if you are over 70 years.

Other medicines and Trimega

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you are using a medicine to stop blood clotting in your arteries, such as warfarin, you may need extra blood tests and your usual dose of your blood thinning medicine may have to be changed.

Trimega with food and drink

You should take the capsules at meal times. This is to help lower the chances of side effects that affect the area in and around the stomach (the gastro-intestinal area).

Pregnancy, breast-feeding and fertility

You should not take this medicine if you are pregnant or breast-feeding, unless your doctor decides it is absolutely necessary.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

This medicine is not likely to affect you being able to drive or use any tools or machines.

Trimega contains soya bean oil.

Trimega may contain soya-bean oil. If you are allergic to peanut or soya, do not use this product.

3. How to take Trimega

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- Swallow the capsules with a drink of water.
- You may take the capsules at meal times to help reduce gastro-intestinal side effects.
- Your doctor will decide how long you should take this medicine.

Dose to treat high blood triglyceride levels (high levels of fat in the blood or hypertriglyceridaemia)

The usual dose is 2 capsules a day, as recommended by a doctor.

If the medicine is not working well enough at this dose, your doctor may increase this to 4 capsules a day.

If you take more of Trimega than you should

If you accidentally take more of this medicine than you should, do not worry, as this is unlikely to need special treatment. However, you should contact your doctor or pharmacist for further advice.

If you forget to take Trimega

If you miss a dose, take it when you remember unless it is almost time for your next dose, in which case take the next dose as usual. Do not take a double dose (twice the dose recommended by your doctor) to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following are side effects that may happen with this medicine:

Common side effects (occur in 1 to 10 users in 100):

- stomach problems like abdominal distension, pain, constipation, diarrhoea, indigestion (dyspepsia), gas, belching (eructation), acid reflux, feeling sick (nausea) and being sick (vomiting)

Uncommon side effects (occur in 1 to 10 users in 1,000):

- high blood sugar levels
- gout
- dizziness
- problems with taste
- headache
- low blood pressure
- nose bleed
- blood in your stools
- rash

Rare side effects (occur in 1 to 10 users in 10,000):

- allergic reactions
- itchy rash (hives or urticaria)
- liver disorders, with possible changes in the results of certain blood tests

Other side effects have occurred in a very small number of people but their exact frequency is unknown:

- Itching

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie, e-mail: medsafety@hpra.ie.

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

5. How to store Trimega

Keep this medicine out of the sight and reach of children.

Do not use Trimega after the expiry date which is stated on the carton and the label after EXP. The expiry date refers to the last day of the month.

Do not store Trimega above 25°C. Do not freeze.

Trimega soft gelatin capsules should be used within 100 days of opening the bottle.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Trimega contains

Each capsule contains 1000 mg omega-3-acid ethyl esters 90, comprising 840 mg eicosapentaenoic acid (EPA) ethyl ester (460 mg) and docosahexaenoic acid (DHA) ethyl ester (380 mg).

The capsule core is made of:

alpha-tocopherol (may contain vegetable oil e.g. soya oil)

The capsule shell is made up of: gelatin, glycerol, purified water, medium-chain triglycerides and lecithin (sunflower).

What Trimega looks like and contents of the pack

Omega-3-Acid Ethyl Esters 90 capsules are transparent soft gelatin capsules containing slightly yellow oil.

Trimega is available in the following pack sizes:

- 1 x 28 soft gelatin capsules
- 1 x 30 soft gelatin capsules
- 1 x 60 soft gelatin capsules
- 1 x 100 soft gelatin capsules
- 10 x 28 soft gelatin capsules

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer

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