

Package Leaflet: Information for the user
Teromeg® 1000 mg 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 need 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 Teromeg capsules are and what they are used for
2. What you need to know before you take Teromeg capsules
3. How to take Teromeg capsules
4. Possible side effects
5. How to store Teromeg capsules
6. Contents of the pack and other information

1. What Teromeg capsules are and what they are used for

Teromeg capsules contain highly purified omega-3 polyunsaturated fatty acids and belong to a group of so called reducers of cholesterol and triglycerides. They are used:

- 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 Teromeg capsules

Do not take Teromeg capsules and tell your doctor if:

- you are **allergic** (hypersensitive) to **omega-3-acid ethyl esters 90** 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 Teromeg capsules 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 this medicine may have on your liver with blood tests.
- you are allergic to fish.
- you have, or have had, heart problems
- you develop light-headedness, asthenia (feeling of weakness), palpitations or shortness of breath as these may be symptoms of an irregular and often very rapid heart rhythm (atrial fibrillation).

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 Teromeg capsules with care if you are over 70 years.

Other medicines and Teromeg capsules

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.

Teromeg capsules 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

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.

Teromeg contains soya bean oil.

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

3. How to take Teromeg capsules

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 Teromeg capsules 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 Teromeg capsules

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 (may affect up to 1 in 10 people):

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

Uncommon side effects (may affect up to 1 in 100 people):

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

Rare side effects (may affect up to 1 in 1000 people):

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

Not known (frequency cannot be estimated from the available data):

- 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Teromeg capsules

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

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

Do not use this medicine 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.

Teromeg capsules should be used within 100 days of opening the bottle.

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

6. Contents of the pack and other information

What Teromeg capsules contain:

The active substance is omega-3-acid ethyl esters 90, comprising principally 840 mg ethylesters of eicosapentaenoic acid (EPA) 460 mg and docosahexaenoic acid (DHA) 380 mg.

The capsule core is made of alpha-tocopherol (which 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 Teromeg capsules look like and the contents of the pack

Teromeg capsules are transparent soft gelatin capsules containing slightly yellow oil.

Teromeg capsules are available in the following pack sizes:

- 1 x 20 soft gel capsules
- 1 x 28 soft gel capsules
- 1 x 30 soft gel capsules
- 1 x 60 soft gel capsules
- 1 x 100 soft gel capsules
- 10 x 28 soft gel capsules

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

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