

PACKAGE LEAFLET

Package leaflet: Information for the user

Omega-3-acid ethyl esters Lomegar 1000mg Capsules, Soft 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Omega-3-acid ethyl esters Lomegar 1000mg Capsules, Soft are and what it is used for
2. What you need to know before you take Omega-3-acid ethyl esters Lomegar 1000mg Capsules, Soft
3. How to take Omega-3-acid ethyl esters Lomegar 1000mg Capsules, Soft
4. Possible side effects
5. How to store Omega-3-acid ethyl esters Lomegar 1000mg Capsules, Soft
6. Contents of the pack and other information

1. What Omega-3-acid ethyl esters Lomegar 1000mg Capsules, Soft is and what it is used for

Omega-3-acid ethyl esters Lomegar 1000mg Capsules, Soft contains highly purified omega-3 polyunsaturated fatty acids.

Omega-3-acid ethyl esters Lomegar 1000mg Capsules, Soft belong to a group of medicines called reducers of cholesterol and triglycerides.

Omega-3-acid ethyl esters Lomegar 1000mg Capsules, Soft is used:

- together with other medicines for treatment after a heart attack.
- 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 Omega-3-acid ethyl esters Lomegar 1000mg Capsules, Soft

Do not take Omega-3-acid ethyl esters Lomegar 1000mg Capsules, Soft

- if you are allergic to omega-3 fatty acids, soya, peanut or any of the other ingredients of this medicine (listed in Section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Omega-3-acid ethyl esters Lomegar 1000mg Capsules, Soft

- if you are due to have or have had surgery recently
- if you have had a trauma recently
- if you have a kidney problem
- if you have diabetes which is not controlled

- if you have/have had problems with your liver. Your doctor will monitor any effects Omega-3-acid ethyl esters Lomegar 1000mg Capsules, Soft may have on your liver with blood tests.

Children and adolescents

In the absence of efficacy and safety data, Omega-3-acid ethyl esters Lomegar 1000mg Capsules, Soft are not indicated for use in children or adolescents.

The elderly

There is no data in the use of Omega-3-acid ethyl esters Lomegar 1000mg Capsules, Soft in elderly patients above 70 years of age. Use Omega-3-acid ethyl esters Lomegar 1000mg Capsules, Soft with care if you are over 70 years of age.

Other medicines and Omega-3-acid ethyl esters Lomegar 1000mg Capsules, Soft

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.

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

Omega-3-acid ethyl esters Lomegar 1000mg Capsules, Soft 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.

Omega-3-acid ethyl esters Lomegar 1000mg Capsules, Soft contains soya oil

The capsule shell may contain traces of soya oil. If you are allergic to peanut or soya, do not take this medicinal product.

3. How to take Omega-3-acid ethyl esters Lomegar 1000mg Capsules, Soft

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

The recommended dose after a heart attack is one capsule a day.

The recommended dose for high blood triglycerides 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.

Instructions for use

- 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.

If you take more Omega-3-acid ethyl esters Lomegar 1000mg Capsules, Soft 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.

If you forget to take Omega-3-acid ethyl esters Lomegar 1000mg Capsules, Soft

Do not take a double dose to make up for a forgotten dose. 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

If you stop using Omega-3-acid ethyl esters Lomegar 1000mg Capsules, Soft

Do not stop the treatment without consulting your doctor. Talk to your doctor if you are not satisfied with the effects of Omega-3-acid ethyl esters Lomegar 1000mg Capsules, Soft.

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

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: may affect up to 1 in 10 people:

- stomach problems and indigestion (dyspepsia)
- feeling sick (nausea)

Uncommon: may affect up to 1 in 100 people:

- abdominal and stomach pain
- allergic reactions
- dizziness
- problems with taste
- diarrhoea
- being sick (vomiting)

Rare: may affect up to 1 in 1,000 people:

- headache
- acne
- itchy rash (pruritus)
- high blood sugar levels
- liver problems

Very rare: may affect up to 1 in 10,000 people:

- blood in your stools
- low blood pressure
- dry nose
- raised red skin rash (hives or urticaria)
- changes in the results of certain blood tests

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 national reporting system listed below:

United Kingdom

Yellow Card Scheme

Tel: Freephone 0808 100 3352

Website: www.mhra.gov.uk/yellowcard

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

5. How to store Omega-3-acid ethyl esters Lomegar 1000mg Capsules, Soft

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

This product should be used within 100 days of opening the bottle.

Do not use this medicine after the expiry date which is stated on the outer carton. The expiry date refers to the last day of that month.

Keep the bottle in the outer carton in order to protect from the light.

Store below 25°C. Do not freeze.

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 protect the environment.

6. Contents of the pack and other information

What Omega-3-acid ethyl esters Lomegar 1000mg Capsules, Soft contain

The active substances are omega-3 fatty acids in a form of ethyl esters. Each capsule contains 840 mg of eicosapentaenoic acid ethyl ester (460 mg per capsule) and docosahexaenoic acid ethyl ester (380 mg per capsule).

The other ingredients are alpha tocopherol (in sunflower oil) and gelatin, glycerol and purified water which are the components of the soft capsule shell. The capsule shell can also contain traces of medium-chain triglycerides and soya (lecithin), see section 2.

What Omega-3-acid ethyl esters Lomegar 1000mg Capsules, Soft look like and contents of the pack

Omega-3-acid ethyl esters Lomegar 1000mg Capsules, Soft are transparent soft gelatin capsules filled with pale yellow oil.

Omega-3-acid ethyl esters Lomegar 1000mg Capsules, Soft come in plastic bottles with a snap-on cap and integrated seals, containing 28 and 100 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Trygg Pharma AS
Fjordalléen 16
PO Box 1423 Vika
0115 Oslo
Norway

Manufacturer:

EPAX Norway AS
PO Box 2047
6028 Ålesund
Norway

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria - *Omega-3-Säurenethylester Lomegar 1000 mg Weichkapseln*

Belgium - *Omega-3-acid ethyl esters Lomegar 1000 mg, capsules molles*

France - *Esters éthyliques d'acides oméga-3 Lomegar 1000 mg, capsules molles*

Germany - *Omega-3-Säurenethylester Lomegar 1000 mg Weichkapseln*

Greece - *OMEGA-3-ACID-ETHYL-ESTER/LOMEGAR 1000 mg καψάκια, μαλακά*

Ireland - *Omega-3-acid ethyl esters Lomegar 1000mg Capsules, Soft*

Spain - *Ácidos omega-3 Lomegar 1000 mg cápsulas blandas EFG*

United Kingdom - *Omega-3-acid-ethyl-esters 1000mg Capsules, Soft*

This leaflet was last revised in 04/2014