Package leaflet: Information for the user

Omega-3-Acid Ethyl Esters 90, 1000 mg 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 or your 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 your pharmacist. 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 is and what it is used for
2. What you need to know before you take Omega-3-acid ethyl esters
3. How to take Omega-3-acid ethyl esters
4. Possible side effects
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6. Contents of the pack and other information

1. WHAT OMEGA-3-ACID ETHYL ESTERS IS AND WHAT IT IS USED FOR

Omega-3-acid ethyl esters contains highly purified omega-3 polyunsaturated fatty acids.
Omega-3-acid ethyl esters belongs to a group of so-called reducers of cholesterol and triglycerides.
Omega-3-acid ethyl esters is 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 OMEGA-3-ACID ETHYL ESTERS

Do not take Omega-3-acid ethyl esters
- if you are allergic (hypersensitive) to the active substances or any of the other ingredients of Omega-3-acid ethyl esters (listed in Section 6: Contents of the pack and other information).

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 Omega-3-acid ethyl esters:
- 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 problems with your liver. Your doctor will monitor any effects Omega-3-acid ethyl esters may have on your liver with blood tests.
- if you are allergic to fish
- if you have, or have had, heart problems
- if 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).

Children and adolescents

In the absence of efficacy and safety data, children and adolescents should not take this medicine.

Older people

Use Omega-3-acid ethyl esters with care if you are over 70 years.

Other medicines and Omega-3-acid ethyl esters

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.
Please tell your doctor or pharmacist if you are using, have recently used or might use any other medicines including medicines obtained without prescription.

Omega-3-acid ethyl esters 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 and breast-feeding

You should not take this medicine if you are pregnant or breast-feeding, unless your doctor decides it is absolutely necessary.
Ask your doctor or pharmacist for advice before using any medicine.

Driving and using machines

This medicine is not likely to affect your ability to drive or use any tools or machines.

3. HOW TO TAKE OMEGA-3-ACID ETHYL ESTERS

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- Swallow the capsules with a drink of water.
- 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 Omega-3-acid ethyl esters 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 Omega-3-acid ethyl esters

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 stop taking Omega-3-acid ethyl esters

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Omega-3-acid ethyl esters 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):
- Irregular, rapid rhythm of the heart
- 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 (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 1,000 people):
- allergic reactions
- itchy rash (hives or urticaria)
- liver disorders, with possible changes in the results of certain blood tests

Frequency not known:
Other side effects have occurred in a very small number of people but their exact frequency is unknown
- itching

If any of these side effects get serious, or if you notice any side effects not listed in this leaflet, 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/yellow card 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.

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5. HOW TO STORE OMEGA-3-ACID ETHYL ESTERS

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

Do not use Omega 3-acid-ethyl esters after the expiry date which is printed on the carton and the label after EXP. The expiry date refers to the last day of that month.

Do not refrigerate or freeze. Keep the container tightly closed in order to protect from moisture.

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.

Shelf life after first opening of HDPE container is 28 days.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Omega-3-acid ethyl esters contains

The active substance is Omega-3-acid ethyl esters 90.

Each capsule contains 1000 mg of Omega-3-acid ethyl esters 90 comprising principally 840 mg ethyl esters of eicosapentaenoic acid (EPA) (460 mg) and docosahexaenoic acid (DHA) (380 mg) and including also 4 mg of alpha-tocopherol.

The other ingredients are alpha-tocopherol, gelatin, glycerol, medium chain triglycerides and purified water.

What Omega-3-acid ethyl esters looks like and contents of the pack

Omega 3-acid-ethyl esters is a transparent, soft-gelatin capsule, 24.01 mm x 9.31 mm, filled with light to pale yellow oil.

Omega-3-Acid Ethyl Esters 90, 1000 mg Capsules, soft is available in the following pack size:
28 capsules in a white opaque high-density polyethylene (HDPE) bottle, with Polypropylene CR Closure with white opaque outer cap, translucent inner cap and liner.

Marketing Authorisation Holder and manufacturer

Farmak Pharmaceuticals UK Ltd,
First Floor, 47 Queen Street, Hull, HU1 1UU United Kingdom

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For information in large print, audio CD or Braille, please telephone +44 (0)1482 738200 or email medinfo@farmak.uk

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