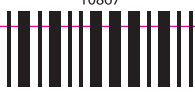


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Package Leaflet: Information for the user

Omega 3-acid-ethyl esters 1000mg Soft 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 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
5. How to store Omega 3-acid-ethyl esters
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 to omega-3-acid ethyl esters or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Omega 3-acid-ethyl esters if:

- you are due to have or have recently had surgery;
- you have recently had a trauma;
- 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 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 and adolescents

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

Older people

There is limited data on the use of Omega-3-acid ethyl esters in older people above 70 years of age.

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

Other medicines and Omega 3-acid-ethyl esters

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.

Omega 3-acid-ethyl esters with food

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

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.

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

Driving and using machines

This medicine is not likely to affect you being able 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 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 recommended dose is 2 capsules a day.

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 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 that you will need special treatment.

However, you should contact your doctor or pharmacist for further advice.

Dimension - 135 x 295 mm

Front Side

ARTWORK DETAIL LABEL

NON PRINTING COLOUR

Product	Omega-3-acid ethyl esters 1000 mg soft capsules			
Buyer/Country	SPUK	Component	PACK INSERT	
Dimension	135 x 295 mm	Pack	----	
New Item Code	1049841	Old Item Code	1049297	
Colour Shades	BLACK	No. of Colours	1	
Change Control No.	PC-ODF/2023/788 - Record Number: 406546 & PC-ODF/2023/836 - Record Number: 408433		Artwork Version	9.0
Design/Style	Front & Back side printing. To be supplied in the Un-folded size.			
Substrate	60 GSM Paper.			
Special Instructions	PRINTING CLARITY TO BE CLEAR AND SHARP.			
Autocartanator Requirements	Pack insert supply should be as per auto-cartanator. Refer auto-cartanator drawing for instructions.			
<p>Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.</p>				

RD/PD/003/F-08/R0

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 using 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, 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, 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 1,000 people):

- allergic reactions
- raised red skin 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
- Itchy rash (hives or urticaria)

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.

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.
Store Omega 3-acid-ethyl esters capsules below 30°C. Shelf life after first opening of HDPE container is 120 days.
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 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 ethylesters of eicosapentaenoic acid (EPA) (465 mg) and docosahexaenoic acid (DHA) (375 mg).
- The other ingredients are alpha-tocopherol, gelatin, glycerol, medium-chain triglycerides and ink (composition of ink is dewaxed bleach shellac resin, isopropyl alcohol, propylene glycol, titanium dioxide, sodium lauryl sulphate, twin 80).

What Omega 3-acid-ethyl esters looks like and contents of the pack
Omega 3-acid-ethyl esters is a soft, oblong, transparent gelatin capsule containing pale yellow colored oily liquid, imprinted with '740'.
Omega 3-acid-ethyl esters is available in the following pack sizes:
– White opaque HDPE container with white opaque HDPE screw closure with induction sealing. Each bottle contains 20, 28, 100 or 120 capsules.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Strides Pharma UK Ltd.
Unit 4, The Metro Centre
Dwight Road, Watford,
WD 189 SS
United Kingdom

The leaflet was last revised on 01/2024.

Dimension - 135 x 295 mm



Back Side

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NON PRINTING COLOUR

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