

VASCEPA® 1 gram capsules

Icosapent ethyl

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet

1. What Vascepa is and what it is used for
2. Before you take Vascepa
3. How to take Vascepa
4. Possible side effects
5. How to store Vascepa
6. Further information

1. WHAT VASCEPA IS AND WHAT IT IS USED FOR

Vascepa contains a single highly purified omega-3 fatty acid and belongs to a group of triglyceride and lipid reducers.

Vascepa is used along with a low-fat and low-cholesterol diet to lower high levels of triglycerides (fats) in adult patients over 18 years of age.

2. BEFORE YOU TAKE VASCEPA

Do not take Vascepa:

- if you are allergic to icosapent ethyl or any of the other ingredients of this medicine (listed in section 6).

Take special care with Vascepa if you:

- have diabetes.
- have a low thyroid problem.
- have a liver problem.
- have a pancreas problem.
- are allergic to fish or shellfish. It is not known if people who are allergic to fish or shellfish are also allergic to Vascepa.

Safety and effectiveness in children under the age of 18 have not been established.

Taking other medicines, herbal or dietary supplements

Vascepa can interact with certain other medicines that you are taking.

Especially tell your doctor if you take medicines that affect your blood clotting (anticoagulants or blood thinners).

Tell your doctor or pharmacist about all the medicines you take, including prescription and non-prescription medicines, vitamins, and dietary or herbal supplements.

Taking Vascepa with food and drink

Vascepa capsules should be taken with food. Attempts should be made to control alcohol intake that may contribute to lipid abnormalities.

Pregnancy and breast-feeding

If you are pregnant, or planning to become pregnant, ask your doctor for advice before taking this medicine. It is not known if Vascepa will harm you unborn baby. If you are breastfeeding or plan to breastfeed, ask your doctor for advice before taking this medicine. Vascepa can pass into your milk, and may harm your baby. Talk to your doctor about the best way to feed your baby if you take Vascepa.

Driving and using machines

Vascepa is not expected to interfere with your ability to drive or to use machinery. However, caution should always be taken when taking a new medication.

3. HOW TO TAKE VASCEPA

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 is 4 grams per day taken as two (2) 1-gram capsules twice daily with food.

Take Vascepa capsules whole. Do not break, crush, dissolve, or chew Vascepa capsules before swallowing.

Your doctor may start you on a diet that is low in saturated fat, cholesterol, carbohydrates, and low in added sugars before giving you Vascepa. Stay on this diet while taking Vascepa.

Your doctor may do blood tests to check your triglyceride and other lipid levels while you take Vascepa.

If you take more Vascepa than you should

You should not take more than four (4) 1-gram capsules of Vascepa each day. Do not take more capsules than what is prescribed by your doctor. 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 for further advice.

If you forget to take Vascepa

If you miss a dose of Vascepa, take it as soon as you remember. However, if you miss one day of Vascepa, do not double your dose when you take it.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Vascepa can cause side effects, although not everybody gets them.

Common side effects (>1/100 and ≤ 1/10):

- sore throat

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE VASCEPA

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

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

Do not store above 30°C.

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. FURTHER INFORMATION

What Vascepa contains

- The active substance is icosapent ethyl. Each capsule contains 1 gram of icosapent ethyl.
- The other excipients are tocopherol, gelatin, glycerin, maltitol, sorbitol, and purified water.

What Vascepa looks like and contents of the pack

Supplied as 1-gram, amber-colored, soft-gelatin capsules imprinted with Vascepa.

One bottle containing 120 capsules.

Marketing Authorisation Holder

Amarin Pharmaceuticals Ireland Ltd.
2 Pembroke House
Upper Pembroke Street 28-32
Dublin 2 Ireland

Applicant name

Amarin Pharma Inc.
1430 Route 206
Bedminster, NJ 07921
United States of America

Bulk manufacturer and Final Batch Releaser:

Patheon Softgels BV
De Posthoornstraat 7
5048 AS Tilburg
The Netherlands

This leaflet was last revised in July 2017 - version 1.

To report any side effect(s):

- **Saudi Arabia:**

The National Pharmacovigilance and Drug Safety Centre (NPC)

- Fax: +966-11-205-7662
- Call NPC at +966-11-2038222, Ext: 2317-2356-2340.
- Toll free phone: 8002490000
- E-mail: npc.drug@sFDA.gov.sa
- Website: www.sFDA.gov.sa/npc

- **United Arab Emirates:**

Pharmacovigilance
Drug Department
Ministry of Health and Prevention
P.O. Box: 1853 Dubai
United Arab Emirates

- Hotline: 80011111
- Email: pv@moh.gov.ae

- **Other GCC States:**

- Please contact the relevant competent authority.

Council of Arab Health Ministers:

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists