Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) – 1986

The medicine is dispensed with a doctor's prescription only

Vazkepa

Soft capsules

Active ingredient:

Each capsule of Vazkepa contains 998 mg icosapent ethyl

Inactive ingredients and allergens: see section 6 – "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine.

If you have any further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

Vazkepa contains the active ingredient icosapent ethyl, a highly purified omega-3 fatty acid from fish oil.

Vazkepa is indicated to reduce the risk of cardiovascular events in adults treated with statins (a group of medicines that lowers blood cholesterol) who are at high risk of cardiovascular events with elevated triglyceride levels in the blood (≥ 150 mg/dL [≥ 1.7 mmol/L]) and in addition:

- suffer from a cardiovascular disease, or:
- suffer from diabetes, and have at least one other risk factor for cardiovascular disease

Therapeutic group: lipid modifying agents.

2. Before using Vazkepa

Do not use Vazkepa if:

- You are sensitive (allergic) to icosapent ethyl, soya or any of the other ingredients that the medicine contains (listed in section 6).

Special warnings regarding the use of the medicine

Consult your doctor or pharmacist before taking Vazkepa:

- If you are allergic to fish or to shellfish.
- If you suffer from liver problems.

- If you have problems with irregular heartbeat (atrial fibrillation or flutter).
- If you are taking an anticoagulant medicine (which prevents blood from clotting), medicines that inhibit platelets or are at risk of bleeding.

Blood tests

During the treatment your doctor may carry out blood tests to check for any problems with your liver and to check how your blood is clotting.

Children and adolescents

This medicine is not intended for children and adolescents under 18 years of age.
There is no information regarding the safety and effectiveness of the use of this medicine in children and adolescents under the age of 18.

If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell the doctor or pharmacist.

If you are taking other medicines concomitantly with Vazkepa that affect how your blood clots, such as an anticoagulant medicine, you will have blood tests during treatment.

Use of the medicine and food

Vazkepa should be taken with or after a meal

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult your doctor or pharmacist before taking this medicine.

Pregnancy

Vazkepa is not recommended for use during pregnancy unless your doctor advises you to take this medicine.

Breastfeeding

Vazkepa is not recommended for use while breastfeeding as the effect on your baby is not known. Your doctor will help you to weigh up the benefit of treatment against any risk to your breastfeeding baby.

Fertility

Talk with your doctor about fertility during treatment.

Driving and using machines

Vazkepa is expected to have no or negligible influence on the ability to drive and use machines.

Important information about some of the medicine's ingredients

Vazkepa contains maltitol, sorbitol and soya lecithin.

Maltitol (E965 ii)

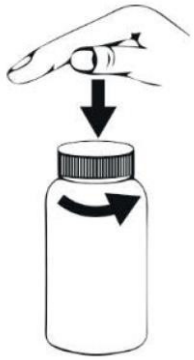
If you have been told by your doctor that you have an intolerance to certain sugars, refer to the doctor before taking the medicine.

Sorbitol (E420 ii)

This medicine contains 83 mg sorbitol in each capsule.
Sorbitol is a source of fructose. If your doctor has told you that you have an intolerance to certain sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you take this medicine.
Soya lecithin
This medicine contains soya lecithin. If you are allergic to soya or peanuts, do not use this medicine.

3. How should you use Vazkepa?

Always use according to the doctor's instructions. Check with your doctor or pharmacist if you are not sure. The dosage and treatment regimen will be determined only by the doctor.
How to open the bottle
Push down the screw cap and turn it counterclockwise.



How much to take
The recommended dosage is two capsules orally, twice a day, with or after a meal.
Swallow the capsules whole. Do not break, crush, dissolve or chew the capsules.
Do not exceed the recommended dose.
Use in the elderly
There is no need to change the dosage in elderly patients. They can take the usual recommended dosage.
In case you take an overdose of Vazkepa
If you have accidentally taken more capsules than your doctor has prescribed, refer to the doctor or pharmacist for advice.
If a child has accidentally swallowed the medicine, refer to the doctor immediately or go immediately to a hospital emergency room and bring the medicine package with you.

If you have forgotten to take Vazkepa

If you have forgotten to take a dose, take it as soon as you remember. If you have missed taking the medicine for a whole day, take your next scheduled dose at the regular time. Do not take a double dose to compensate for a forgotten dose.

If you stop the treatment with Vazkepa

Even if your health condition has improved, do not stop taking this medicine until you consult your doctor.

Continue the treatment as recommended by your doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have any further questions regarding use of the medicine, consult the doctor or pharmacist.

4. Side effects

As with any medicine, use of Vazkepa may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Contact your doctor

- If you feel heart palpitations at rest or irregular heartbeat. These could be symptoms of a serious condition known as atrial fibrillation. This is a **common** side effect (may affect up to 1 in 10 people).
- If you bruise easily or cannot stop bleeding. This is a **very common** side effect (may affect more than 1 in 10 people). Your risk of bleeding may increase if you are also taking an anticoagulant medicine.

Seek medical assistance if you experience any of the following side effects. These symptoms could be due to a serious condition known as **hypersensitivity** which can happen at any time during treatment. This is an **uncommon** side effect (may affect up to 1 in 100 people):

- Breathing difficulties
- Tight or itching throat
- Swelling of the lips
- Hives (raised bumps on the skin)
- Rash and itchy skin
- Abdominal pain or cramps
- Diarrhea
- Nausea and vomiting

Other side effects that may occur

Common side effects – may affect up to 1 in 10 people:

- Swelling of the hands, arms, legs and feet
- Pain in the muscles, bones or joints
- Gout (painful swelling of the joints due to a buildup of uric acid)
- Rash
- Constipation
- Burping

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

- Bad taste in the mouth

If a side effect occurs, if one of the side effects gets worse, or if you suffer from any side effects not listed in the leaflet, consult the doctor.

Reporting of side effects

Side effects may be reported to the Ministry of Health by clicking on the link "report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il/ and by sending an email to the Patient Safety Unit of the marketing authorization holder at: drugsafety@neopharmgroup.com

5. How to store Vazkepa?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use this medicine after the expiry date (exp. date) which is stated on the blister or on the package. The expiry date refers to the last day of that month.
- Store below 30°C.
- Bottle: keep the bottle tightly closed in order to protect from moisture. After first opening, the bottle can be stored for up to 3 months below 25°C.
- Blister pack: store in the original package in order to protect from moisture.
- Do not throw away the medicine 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. Additional information

In addition to the active ingredient the medicine also contains:

Gelatin, liquid sorbitol (non-crystallising), glycerol, purified water, liquid maltitol, all-rac-alpha-tocopherol.

Printing ink: Opacode WB White, NS-78-18011

What does the medicine look like and what are the contents of the package?

In this pack you will find oblong soft capsules, 10x25 mm, printed with “IPE” in white ink, with a yellow to amber shell containing a colorless to pale yellow liquid.

The bottles containing 120 capsules are made of 300-cc white polyethylene (HDPE) with a sealed, child-resistant polypropylene closure.

Pack size – one bottle per carton.

The blister pack contains 8 capsules in PVC/PCTFE/Al blisters with detachable perforations.

Manufacturer:

Amarin Pharmaceuticals Ireland Limited, 88 Harcourt Street, Dublin 2, D02DK18, Ireland

Marketing authorization holder:

Neopharm Israel 1996 Ltd., 6 HaShiloach, Petach Tikva, Israel.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 172-61-37268-99

Revised in October 2023 in accordance with the Ministry of Health guidelines.