Package leaflet: Information for the patient

Vazkepa 998 mg soft capsules

icosapent ethyl

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Vazkepa is and what it is used for
2. What you need to know before you take Vazkepa
3. How to take Vazkepa
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1. What Vazkepa is and what it is used for

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

Vazkepa lowers levels of triglycerides (types of fat) in the blood and it is used with a statin medicine (that lowers blood cholesterol) to prevent cardiovascular events, such as:
- heart attack
- stroke
- death from heart or vascular disease

Vazkepa is used in adults with high blood triglycerides who already have heart disease or have diabetes and other conditions that put them at a higher risk of cardiovascular events.

2. What you need to know before you take Vazkepa

Do not take Vazkepa
- If you are **allergic to icosapent ethyl**, soya or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before taking Vazkepa:
- If you are **allergic to fish or to shellfish**.
- If you have **problems with your liver**.
- If you have **problems with irregular heartbeat** (atrial fibrillation or flutter).
- If you take an anticoagulant medicine (which prevents blood from clotting), medicines that inhibit platelets in the blood or are at **risk of bleeding**.

If any of the above applies to you, talk to your doctor.

Blood tests
During your 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
Do not give this medicine to children and young people below 18 years of age because it has not been studied in these people.

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

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

Pregnancy, breast-feeding and fertility
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.

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

Breast-feeding
Vazkepa is not recommended for use while breast-feeding 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 breast-feeding baby.

Fertility
Talk with your doctor about fertility during treatment.

Driving and using machines
This medicine is unlikely to affect your ability to drive or use tools or machines.

Vazkepa contains maltitol, sorbitol and soya lecithin

Maltitol (E965 ii)
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this 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 some 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 peanut, do not use this medicine.

3. How to take Vazkepa

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Do not change your dose without talking to your doctor.

How to open bottle
Push down the screw cap and turn it anticlockwise.



How much to take
The recommended dose is two capsules by mouth, twice a day, with or after a meal.

Swallow the capsules whole; **Do not** break, crush, dissolve or chew the capsules.

Use in elderly
There is no need to change the dose in elderly patients. They can take the usual recommended dose.

If you take more Vazkepa than you should
If you accidentally take more capsules than your doctor has prescribed, contact your doctor or pharmacist for advice.

If you forget to take Vazkepa
If you miss a dose, take it as soon as you remember. However if you missed taking the medicine for a whole day, just take your next scheduled dose. **Do not take a double dose** to make up for a forgotten dose. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

If you stop taking Vazkepa
Do not stop taking this medicine until you have spoken with your doctor.
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.

Contact your doctor
- if you get heart palpitations 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.

Get medical help if you get 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)
- difficulty breathing
- tightening or scratching of the throat
- swelling of the lips
- hives (raised bumps on the skin)
- rash and an itchy skin
- stomach pain or cramps
- diarrhoea
- nausea and vomiting

Other side effects that may occur

Common side effects (may affect up to 1 in 10 people):
- swelling of your hands, arms, legs and feet
- pain in muscles, bones or joints
- gout (painful swelling in the joints because of a build up of uric acid)
- rash
- constipation
- burping

Uncommon side effect (may affect up to 1 in 100 people)
- bad taste in the mouth

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme - Website: www.mhra.gov.uk/yellowcard 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.

5. How to store Vazkepa

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 bottle label or blister carton after EXP. 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.
Blister pack: store in the original package 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.

6. Contents of the pack and other information

What Vazkepa contains
- The **active substance** is icosapent ethyl. Each Vazkepa capsule contains 998 mg of icosapent ethyl.
- The other ingredients are
  - all-rac-alpha-tocopherol, gelatin, glycerol, liquid maltitol (E965 ii), liquid sorbitol (non-crystallising) (E420 ii), purified water and soya lecithin (see section 2 “Vazkepa contains maltitol, sorbitol and soya lecithin”).
  - printing ink: titanium dioxide, propylene glycol, hypromellose.

What Vazkepa looks like and contents of the pack

In this pack you will find oblong soft capsules, 25 x 10 mm, printed with “IPE” in white ink, with a light yellow to amber shell containing a colourless to pale yellow liquid.
The bottles containing 120 capsules are white 300-cc, high density polyethylene (HDPE) with a child-resistant polypropylene heat induction sealed closure.
Pack size of one bottle or three bottles per carton.

The blister packs contain 4x2 capsules in PVC/PCTFE/Al perforated unit dose blisters.

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