**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS:** **S4**

**Vazkepa 998 mg soft capsules**

icosapent ethyl

Each capsule **contains sweetener:** 30 mg maltitol (E965 ii), 83 mg sorbitol (E420 ii)

**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.
- Vazkepa 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.

**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
4. Possible side effects
5. How to store Vazkepa
6. Contents of the pack and other information


## 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**
Vazkepa 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 Vazkepa.

Sorbitol (E420 ii)
Vazkepa 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 Vazkepa.

Soya lecithin
Vazkepa contains soya lecithin. If you are allergic to soya or peanut, do not use Vazkepa.

## 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 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

Vazkepa can cause side effects.

Not all side effects reported for Vazkepa are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Vazkepa, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking / using Vazkepa and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- Rash or itching
- Fainting
- if you get heart palpitations or irregular heartbeat. These could be symptoms of a serious condition known as atrial fibrillation, and could be experianced as dizziness, diffficulty in breathing or an irregular heartbeat. This is a **common** side effect.
- if you bruise easily or cannot stop bleeding. This is a **very common** side effect Your risk of bleeding may increase if you are also taking an anticoagulant medicine.

These are all very serious side effects. If you have them, you may have had a serious reaction to Vazkepa. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- difficulty breathing
- tightening or scratching of the throat
- chest pain
- changes in the way your heart beats, for example, if you notice it beating faster
- signs of recurrent infections such as fever or sore throat,
- less urine than is normal for you,

- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Common/Frequent side effects:

- 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/Less frequent side effects:

- bad taste in the mouth
- swelling of the lips
- hives (raised bumps on the skin)
- rash and an itchy skin
- stomach pain or cramps
- diarrhoea
- nausea and vomiting

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects**
If you get any side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of Vazkepa.

Additionally, suspected adverse reactions can be reported to the Holder of Certificate of Registration via pv@mcpharma.co.za

## 5. How to store Vazkepa

Store all medicines out of 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.

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

**Holder of Certificate of Registration**

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**Access to the corresponding Professional Information**

The Professional Information is available on the company website, https://www.mcpharma.co.za, or may be requested telephonically: (0)12 668 3019.