

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using VAZKEPA®?

VAZKEPA® contains the active ingredient icosapent ethyl. VAZKEPA® is used with a statin medicine to prevent conditions that affect the heart and blood vessels.

For more information, see Section [1. Why am I using VAZKEPA®?](#) in the full CMI.

2. What should I know before I use VAZKEPA®?

Do not use if you have ever had an allergic reaction to VAZKEPA®, or to any of the ingredients listed at the end of the CMI.

Talk to your doctor if you are allergic to fish or to shellfish, have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use VAZKEPA®?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with VAZKEPA® and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take VAZKEPA®?

- 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.

More instructions can be found in Section [4. How do I use VAZKEPA®?](#) in the full CMI.

5. What should I know while using VAZKEPA®?

Things you should do	<ul style="list-style-type: none">• Attend your scheduled appointments so that your doctor can carry out blood tests to check for any problems and discuss appropriate precautions with you.• Remind any doctor, dentist or pharmacist you visit that you are using VAZKEPA®.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking this medicine until you have discussed with your doctor.
Looking after your medicine	<ul style="list-style-type: none">• Follow the instructions in the carton or product label on how to take care of your medicine properly.• Store below 30°C.

For more information, see Section [5. What should I know while using VAZKEPA®?](#) in the full CMI.

6. Are there any side effects?

The most common side effects of VAZKEPA® are bleeding, swelling of your hands, arms, legs and feet; heart palpitations or irregular heartbeat; constipation; pain in muscles, bones or joints; gout and rash.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



This medicine 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. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

VAZKEPA®

Active ingredient: *icosapent ethyl*

Consumer Medicine Information (CMI)

This leaflet provides important information about using VAZKEPA®. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using VAZKEPA®.**

Where to find information in this leaflet:

- [1. Why am I using VAZKEPA®?](#)
- [2. What should I know before I use VAZKEPA®?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take VAZKEPA®?](#)
- [5. What should I know while using VAZKEPA®?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using VAZKEPA®?

VAZKEPA® contains the active ingredient **icosapent ethyl, a highly purified omega-3 fatty acid obtained from the oil of fish**. VAZKEPA® is used with a statin medicine to prevent cardiovascular events, such as:

- Heart attack
- Stroke
- Death from heart or vascular disease

VAZKEPA® is a prescription medicine and 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 should I know before I use VAZKEPA®?

Warnings

Do not use VAZKEPA® if:

- you are **allergic to icosapent ethyl**, soya or peanut or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- are **allergic to fish or shellfish**. The active ingredient icosapent ethyl is derived from the oil of fish.
- have **problems with your liver**.
- have problems with **irregular heartbeat** (atrial fibrillation or flutter).

- take an anticoagulant medicine (which prevents blood from clotting), medicines that inhibit platelets in the blood or are at **risk of bleeding**.
- have an intolerance to some sugars or have been diagnosed with hereditary fructose intolerance (HFI). VAZKEPA contains maltitol and sorbitol.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. VAZKEPA® is not recommended for use during pregnancy unless your doctor advises you to take it.

Talk to your doctor if you are breastfeeding or intend to breastfeed. VAZKEPA® is not recommended for use while breast-feeding as the effect on your baby is not known.

Use in children and adolescents

VAZKEPA® should not be used in children and adolescents under the age of 18 years because it has not been studied in this age group.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect VAZKEPA®.

4. How do I take VAZKEPA®?

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.

If you forget to take VAZKEPA®

If you miss your dose at the usual time, take it as soon as you remember.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much VAZKEPA®

If you think that you have taken too much VAZKEPA®, you may need urgent medical attention.

You should immediately:

- Phone the Poisons Information Centre (in Australia telephone **13 11 26**. In New Zealand telephone **0800 POISON** or **0800 764 766**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using VAZKEPA®?

Things you should do

- Attend your scheduled appointments so that your doctor can check on your progress.
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.

Call your doctor straight away if you:

- get heart palpitations or irregular heartbeat. These could be symptoms of a serious condition known as atrial fibrillation.
- bruise easily or cannot stop bleeding. Your risk of bleeding may increase if you are also taking an anticoagulant medicine.

Remind any doctor, dentist or pharmacist you visit that you are using VAZKEPA®.

Things you should not do

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

Driving or using machines

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

Looking after your medicine

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.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Metabolism/ nutrition related: <ul style="list-style-type: none">• Gout (painful swelling in the joints because of a build-up of uric acid) Gastrointestinal related: <ul style="list-style-type: none">• Constipation• Burping Skin related: <ul style="list-style-type: none">• Rash Muscle and joints related: <ul style="list-style-type: none">• Pain in muscles, bones or joints. Other: <ul style="list-style-type: none">• Swelling of your hands, arms, legs and feet.	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Hypersensitivity/allergy related: <ul style="list-style-type: none">• shortness of breath, wheezing or difficulty in breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin. Bleeding related: <ul style="list-style-type: none">• Tendency to bruise easily or can't stop bleeding (especially if you are also taking an anticoagulant medicine). Heart related: <ul style="list-style-type: none">• Heart palpitations or irregular heart beats (atrial fibrillation)	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

Telephone: 1800 642 865
www.cslseqirus.com.au

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Vazkepa is a registered trademark of Amarin Pharmaceuticals Ireland Ltd.

7. Product details

This medicine is only available with a doctor's prescription.

What VAZKEPA® contains

Active ingredient (main ingredient)	Icosapent ethyl 998 mg
Other ingredients (inactive ingredients)	Capsule fill: dl-alpha-tocopherol Capsule shell: Gelatin, glycerol, maltitol solution, sorbitol solution (70 per cent) (non-crystallising), purified water, medium chain triglycerides, lecithin Printing ink: Titanium dioxide, propylene glycol, hypromellose
Allergens	Soya bean products and fish products.

Do not take this medicine if you are allergic to icosapent ethyl, soya or peanut or any of the ingredients listed above. Icosapent ethyl is obtained from the oil of fish. **Check with your doctor if you are allergic to fish or to shellfish** see 'Section 2. What should I know before I use VAZKEPA®?'

What VAZKEPA® looks like

VAZKEPA® is an oblong soft capsule, printed with "IPE" in white ink, with a light yellow to amber shell containing a colourless to pale yellow liquid.

VAZKEPA® is supplied in HDPE bottles with child-resistant polypropylene heat induction sealed closure containing 120 soft capsules and in PVC/PCTFE/Al perforated unit dose blisters containing 4x2 soft capsules.

Not all pack sizes may be available.

Who distributes VAZKEPA®

Seqirus Pty Ltd
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63 Poplar Road
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Australia