

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 VITRAKVI?

VITRAKVI contains the active ingredient larotrectinib. Vitrakvi (larotrectinib) has provisional approval in Australia for the treatment of adult and paediatric patients from 1 month old, with locally advanced or metastatic solid tumours that:

- have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation,
- are metastatic or where surgical resection is likely to result in severe morbidity, and
- have either progressed following treatment or who have no satisfactory alternative therapy.

These cancers can appear in many different parts of the body.

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

2. What should I know before I use VITRAKVI?

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

Before starting the therapy, a test will be used to determine whether you have NTRK gene alteration.

Talk to your doctor if you 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 VITRAKVI?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with VITRAKVI and affect how it works. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including any that you get without a prescription from your pharmacy, supermarket, naturopath or health food shop such as vitamins, dietary supplements or herbal medicine.

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

4. How do I use VITRAKVI?

- The recommended dose for adults (from 18 years) is 100 mg, two times a day (= 200mg total per day)
- For babies and children from 1 month old up to 18 years, your child's doctor will work out the right dose for your child.

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

5. What should I know while using VITRAKVI?

Things you should do	<ul style="list-style-type: none"> • Remind any doctor, dentist or pharmacist you visit that you are using VITRAKVI.
Things you should not do	<ul style="list-style-type: none"> • Do not stop using this medicine suddenly or lower the dosage without checking with your doctor. • Do not breast-feed while taking this medicine and for 3 days after the last dose of VITRAKVI. • Do not give this medicine to infants under 1 month of age. • Do not eat grapefruit or drink grapefruit juice while taking VITRAKVI.
Driving or using machines	<ul style="list-style-type: none"> • This medicine may cause dizziness, tiredness and nausea in some people. Be careful driving or operating machinery until you know how VITRAKVI affects you.
Looking after your medicine	<ul style="list-style-type: none"> • Follow the instruction in the carton on how to take care of your medicine properly. • Store it in a cool dry place away from moisture, heat or sunlight

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

6. Are there any side effects?

Like all medicines, VITRAKVI can cause side effects, although not everybody gets them. Tell your doctor or pharmacist if you notice any of the following: feeling tired (fatigue), dizziness, nausea, vomiting, constipation, diarrhea, difficulty in walking, abnormal sense of touch, tingling, change in how things taste, weight increase. 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. [Include if applicable]

VITRAKVI®

Active ingredient(s): *larotrectinib*

Consumer Medicine Information (CMI)

This leaflet provides important information about using VITRAKVI. **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 VITRAKVI.**

Where to find information in this leaflet:

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

1. Why am I using VITRAKVI?

VITRAKVI contains the active ingredient larotrectinib. Larotrectinib is a highly selective, tropomyosin receptor kinase (TRK) inhibitor and is used to treat a type of cancer called “Tyrosine Receptor Kinase (TRK) fusion cancer”. It works by stopping the TRK fusion proteins working and may slow or stop the cancer growing. It may also help to shrink the cancer.

VITRAKVI has provisional approval in Australia for the treatment of adult and paediatric patients with locally advanced or metastatic solid tumours that:

- have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation,
- are metastatic or where surgical resection is likely to result in severe morbidity, and
- have either progressed following treatment or who have no satisfactory alternative therapy.

2. What should I know before I use VITRAKVI?

Warnings

Do not use VITRAKVI if:

- you are allergic to larotrectinib, 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:

- have any other medical conditions
- take any medicines for any other condition
- are pregnant or intend to become pregnant.
- breastfeeding or intend to breastfeed

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?](#)

Laboratory tests

VITRAKVI can increase the amount of some substances in the blood which are made by the liver. Your doctor will do blood tests before and during treatment to check the level of these substances and check how well your liver is working.

Pregnancy and breastfeeding

- You should not use VITRAKVI during pregnancy since the effect of VITRAKVI on the unborn is not known.
- Do not breast-feed while taking this medicine and for 3 days after the last dose. There are no data on the presence of larotrectinib in human milk, the effects of larotrectinib on the breastfed child, or the effects of larotrectinib on milk production.

Contraception – for men and women

- You should avoid getting pregnant while taking this medicine.
- If you are able to become pregnant, your doctor should do a pregnancy test before you start treatment.
- You should also use effective methods of contraception while taking VITRAKVI and for at least one month after the last dose of VITRAKVI. Ask your doctor about the best method of contraception for you.

Children and adolescents

- There is not enough information to recommend the use of this medicine for children under the age of 1 month.

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.

Some medicines may interfere with VITRAKVI and affect how it works.

Medicines that may increase the amount of larotrectinib in your blood and increase the risk of side effect include:

- itraconazole, ketoconazole, posaconazole, fluconazole and voriconazole, clarithromycin, telithromycin - used to treat fungal and bacterial infections
- atazanavir, indinavir, nelfinavir, ritonavir, saquinavir - used to treat HIV infection
- nefazodone - used to treat depression
- diltiazem – used to treat heart conditions and high blood pressure

Medicines that may reduce the amount of larotrectinib in your blood and make VITRAKVI less effective include:

- phenytoin, carbamazepine and phenobarbital - medicines used to treat seizures
- St. John's wort - herbal medicine used to treat depression
- Rifampicin - used to treat bacterial infections
- Efavirenz – used to treat HIV infection

VITRAKVI may affect how some medicines work.

Medicines that larotrectinib may decrease the amount of how much of them is found in the blood and make them less effective includes:

- alfentanil - used as a narcotic pain medication
- cyclosporine, sirolimus, tacrolimus - used to prevent organ rejection in patients after transplantation
- Quinidine - used to treat abnormal heart rhythms
- dihydroergotamine, ergotamine - used in migraine or cluster headache attack
- fentanyl - used to treat chronic pain
- pimozide - antipsychotic drug used to control motor or verbal tics

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

4. How do I take VITRAKVI?

How much to take

Adults (from 18 years):

- The recommended dose of VITRAKVI in adults is 100 mg, two times a day (=200 mg total per day).
- You will either take 1 capsule of 100 mg or 4 capsules of 25 mg to make a total dose of 100 mg, two times a day.
- Your doctor will review your dose and change it as needed.
- Follow the instructions provided and use VITRAKVI until your doctor tells you to stop.

Babies and children (from 1 month old up to 18 years):

- Your child's doctor will work out the right dose for your child.
- The maximum recommended dose is 100 mg (maximum of 1 capsule of 100 mg per dose, or 4 capsules of 25 mg per dose, or 5mL of the 20mg/mL solution), two times a day (=200 mg total per day).
- Your child's doctor will review your dose and change it as needed.
- Follow the instructions provided and use VITRAKVI until your child's doctor tells you to stop.

How to take VITRAKVI

- Swallow VITRAKVI capsules whole with a full glass of water.
- Do not open, chew or crush the capsule.
- VITRAKVI can be taken with or without food.
- Do not eat grapefruit or drink grapefruit juice while taking VITRAKVI. This may increase the amount of VITRAKVI in your body.

If you forget to take VITRAKVI

VITRAKVI should be taken regularly at the same time each day. If you miss your dose at the usual time, take your missed dose as soon as you remember prior to the next scheduled dose.

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 take too much VITRAKVI

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

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), 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 taking VITRAKVI?

Things you should do

Call your doctor straight away if you:

- get any of these symptoms during treatment: feeling dizzy, difficulty walking normally, tingling, feeling numb, or a burning feeling in your hands and feet
- become pregnant during treatment with VITRAKVI or in the first month after your last dose.

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

Things you should not do

- Do not give this medicine to infants under 1 month of age
- Do not stop using this medicine suddenly or lower the dosage without checking with your doctor.

VITRAKVI with food and drink

Do not eat grapefruit or drink grapefruit juice while taking VITRAKVI. This may increase the amount of VITRAKVI in your body.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how VITRAKVI affects you.

VITRAKVI may cause dizziness, tiredness and nausea in some people. If you have any of these symptoms, do not drive, cycle, use any tools or machines or do anything else that could be dangerous. Children should be careful when riding bicycles or climbing trees.

Drinking alcohol

Tell your doctor if you drink alcohol.

There is no information on the use of VITRAKVI with alcohol.

Looking after your medicine

- For capsules, store below 25°C (77°F).
- For solution, keep refrigerated at 2°C to 8°C (36°F to 46°F). Do not freeze. Use within 30 days of opening.

Follow the instructions in the carton on how to take care of your medicine properly.

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.

Side effects

Very common side effects	What to do
<ul style="list-style-type: none">• Dizziness• Feeling tired (fatigue)• Stomach upset, including feeling sick (nausea), being sick (vomiting), diarrhea or constipation• Abnormal weight gain or weight increase	Speak to your doctor if you have any of these side effects and they worry you.

Common side effects	What to do
<ul style="list-style-type: none">• Difficulty walking normally (gait disturbance)• Abnormal sense of touch, tingling, feeling numb, or burning feeling in your hands and feet (paraesthesia)• Change in how things taste (dysgeusia)• Muscle pain (myalgia)• Muscle weakness	Speak to your doctor if you have any of these side effects and they worry you.

Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

These test results include:	What to do
<ul style="list-style-type: none">• Reduction in the number of red blood cells which makes you feeling tired, looking pale and you may feel your heart pumping (anaemia)• Reduction in the number of white blood cells which can result in flu-like symptoms including fever (neutropenia, leukopenia)• Reduction in the number of platelets (cells that help your blood clot)• Increased liver enzymes shown in blood tests (called “alanine aminotransferase” and “aspartate aminotransferase”)• Abnormal results of tests to check for liver disease or bone disorders (high levels of “alkaline phosphatase”)	Your doctor will tell you if there are any changes in your blood test that might need treatment.

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.

7. Product details

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

What VITRAKVI contains

For Capsules:

Active ingredient	larotrectinib
Other ingredients	<ul style="list-style-type: none">• Gelatin• Titanium dioxide• Printing ink – blue: Shellac, FD&C Blue #2 aluminium lake, titanium dioxide, propylene glycol, ammonia solution and dimethicone

For Solution (AUST R 320239):

Active ingredient	larotrectinib
Other ingredients	<ul style="list-style-type: none">• Purified water• Hydroxypropyl betadex• Sodium citrate• Ora-Sweet®: purified water, sucrose, glycerol, sorbitol, citric acid, sodium dihydrogen phosphate, flavouring and preservative agents - methylparahydroxybenzoate and potassium sorbate• Natural Masking Type Flavor: glycerol, natural flavour ingredients• Natural Bitterness Masking Type Flavor: glycerol, natural flavour ingredients• Bitterness Masking Flavor: propylene glycol, natural flavour• FONATECH® Taste Modifier Flavor: propylene glycol, glycerol, natural flavour

For Solution – New formulation (AUST R 388084):

Active ingredient	larotrectinib
Other ingredients	<ul style="list-style-type: none">• Purified water• Hydroxypropyl betadex• Sucralose• Sodium citrate• Sodium benzoate• Strawberry flavour• Citric acid

Do not take this medicine if you are allergic to any of these ingredients.

What VITRAKVI looks like

- **VITRAKVI 25 mg hard capsules** are white opaque hard gelatin capsule, size 2, with blue printing of “BAYER” cross and “25 mg” on body of capsule (AUST R 320237)
- **VITRAKVI 100 mg hard capsules** are white opaque hard gelatin capsule, size 0, with blue printing of “BAYER” cross and “100 mg” on body of capsule (AUST R 320238)
- **VITRAKVI 20 mg/mL oral solution** are 100 mL clear yellow to orange liquid solution (AUST R 320239)
- **VITRAKVI 20 mg/mL oral solution - new formulation** is a colourless to yellow or orange or red or brownish liquid solution contained in 2 child-resistant glass bottles containing 50 mL oral solution each (AUST R 388084)

Who distributes VITRAKVI

Bayer Australia Limited
ABN 22 000 138 714
875 Pacific Highway Pymble NSW 2073
www.bayer.com.au

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