

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 Lorviqua?

Lorviqua contains the active ingredient lorlatinib. Lorviqua is used to treat a rare type of lung cancer that is caused by defects in a gene called anaplastic lymphoma kinase (ALK).

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

2. What should I know before I use Lorviqua?

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

Talk to your doctor if you take any other medicines, or before starting any new medicines as Lorviqua can interact with some medicines. Talk to your doctor if you have any other medical conditions, or are pregnant or plan to become pregnant or are breastfeeding. Do not give this medicine to a child.

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

3. What if I am taking other medicines?

Some medicines may interfere with Lorviqua 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 use Lorviqua?

- Lorviqua is taken orally (by mouth) once a day. You are encouraged to swallow the tablet whole (do not chew, crush or split), and take it at approximately the same time each day
- Your doctor will advise how much Lorviqua to take prior to starting treatment

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

5. What should I know while using Lorviqua?

| | |
|------------------------------------|--|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, pharmacist or dentist you visit that you are using Lorviqua• Tell your doctor immediately if you become pregnant while using this medicine, or if you develop changes in your heartbeat, lightheadedness, fainting, dizziness or shortness of breath• Keep all of your doctors appointments so that your dose and progress can be monitored regularly |
| Things you should not do | <ul style="list-style-type: none">• Do not stop using this medicine or change the dosage without talking with your doctor• Do not give Lorviqua to anyone else, even if they have the same condition as you |
| Driving or using machines | <ul style="list-style-type: none">• Be careful driving or operating machinery until you know how Lorviqua affects you as you as you may experience neurological symptoms |
| Looking after your medicine | <ul style="list-style-type: none">• Keep your tablets in the pack/bottle until it is time to take them• Store them out of reach of children, in a cool dry place where the temperature stays below 30°C, heat and dampness (e.g., bathroom, window sill or car) may destroy them |

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

6. Are there any side effects?

Lorviqua may cause serious side effects, including: liver problems due to interactions with other medicines; neurological problems such as changes in mood, speech or sleep, seizures, hallucinations, or confusion; increases in the cholesterol, triglycerides, or sugar levels in your blood; heart problems, specifically irregular heartbeats; severe swelling (inflammation) of the lungs.

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.

Lorviqua®

Active ingredient(s): *lorlatinib*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Lorviqua. It does not contain all the available information. It does not take the place of you talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Lorviqua against the benefits they expect it will have for you.

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 Lorviqua.

Where to find information in this leaflet:

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

1. Why am I using Lorviqua?

Lorviqua contains the active ingredient lorlatinib.

Lorviqua blocks the action of an enzyme called 'ALK tyrosine kinase'. Abnormal forms of this enzyme (due to the fault in the ALK gene) help encourage cancer cell growth.

Lorviqua is used to treat a rare type of lung cancer that is caused by defects in a gene called anaplastic lymphoma kinase (ALK).

Lorviqua may slow down or stop the growth of your cancer. It may also help to shrink your cancer.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Lorviqua is available only with a doctor's prescription.

It is not addictive.

There is not enough information to recommend the use of this medicine for children.

2. What should I know before I use Lorviqua?

Warnings

Do not use Lorviqua if:

- You are allergic to lorlatinib, or any of the ingredients listed at the end of this leaflet.** Some of the symptoms of an allergic reaction may include:
 - shortness of breath
 - wheezing or difficulty breathing

- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

2. You are taking any of the following medicines:

- rifampicin, a medicine used to treat tuberculosis
- carbamazepine, phenytoin, medicines used to treat epilepsy
- enzalutamide, a medicine used to treat cancer of the adrenal glands
- mitotane, a medicine used to treat prostate cancer
- medicines containing St John's wort (hypericum perforatum, a herbal preparation)

Check with your doctor if:

- **you have been told that you cannot tolerate or digest some sugars.** Lorviqua contains lactose, a type of sugar found in milk or dairy products. Always check the ingredients to make sure you can use this medicine
- **you have allergies to any other medicines, food, preservatives or dyes**
- take any medicines for any other condition
- **you have or have had any of the following medical conditions:**
 - high levels of blood cholesterol or triglycerides
 - high blood pressure
 - high blood sugar levels (eg., diabetes)
 - heart problems, including reduced heart rate, or if the results of an electrocardiogram (ECG) have shown that you have an abnormality of the electrical activity of your heart known as "prolonged PR interval" or "AV block"
 - high levels of the enzymes known as amylase or lipase in the blood or a condition such as pancreatitis that can raise the levels of these enzymes
 - cough, chest pains, shortness of breath, or worsening of respiratory symptoms or ever had a lung condition called pneumonitis
 - liver problems
 - kidney problems
 - neurological problems

Your doctor should perform blood tests to check the level of cholesterol and triglycerides in your blood before you start treatment with Lorviqua and regularly during treatment

Your blood pressure and blood sugar levels should be controlled before starting treatment with Lorviqua. Your doctor should continue to monitor your levels regularly during treatment.

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

- **Do not take Lorviqua if you are pregnant,** it may affect your developing baby.

- **Do not breast-feed while taking Lorviqua or for 7 days after the last dose.** The active ingredient in Lorviqua may pass into breast milk and there is a possibility that your baby may be affected

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

You should avoid falling pregnant while using this medicine.

Use highly effective contraception (e.g. double-barrier contraception such as condom and diaphragm) during treatment and for at least 21 days after stopping treatment.

Lorviqua may reduce the effectiveness of hormonal contraceptive methods (e.g. birth control pill). If hormonal contraception is unavoidable it must be used with a form of barrier contraception such as a condom.

If your male partner is being treated with Lorviqua, he must use a condom during treatment and for at least 14 weeks after stopping treatment.

Talk to your doctor about the right methods of contraception for you and your partner.

Lorviqua may affect male fertility.

Talk to your doctor about fertility preservation before taking Lorviqua.

If you become pregnant when taking Lorviqua or during the 3 weeks after taking your last dose, tell your doctor straight away.

If you have not told your doctor about any of the above, tell him/her before you start taking Lorviqua.

Do not give this medicine to a child

Safety and effectiveness in children have not been established.

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 and Lorviqua may interfere with each other. These include:

- boceprevir, a medicine used to treat hepatitis C
- medicines used to treat AIDS/HIV such as efavirenz, cobicistat, ritonavir, paritaprevir in combination with ritonavir and ombitasvir and/or dasabuvir, and ritonavir in combination with either danoprevir, elvitegravir, indinavir, lopinavir, saquinavir or tipranavir
- medicines used to treat fungal infections such as itraconazole, ketoconazole, posaconazole, voriconazole, fluconazole
- troleandomycin, a medicine used to treat certain types of bacterial infections
- quinidine, a medicine used to treat irregular heartbeat and other heart problems
- medicines used to treat severe pain such as alfentanil and fentanyl
- medicines used to prevent organ transplant rejection such as ciclosporin, sirolimus and tacrolimus

Some medicines may interfere with Lorviqua or affect how it works.

You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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

4. How do I use Lorviqua?

How much to take

- The recommended dose is 100 mg taken orally once daily
- Your doctor may lower your dose, stop your treatment for a short time or stop your treatment completely if you feel unwell

Swallow the tablets whole and do not crush, chew or split the tablets

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the box/bottle, ask your doctor or pharmacist for help.

When to take Lorviqua

- **Take your medicine at about the same time each day** to have the best effect and to help you remember when to take it.
- It does not matter if you take this medicine before or after food. However, you should avoid eating grapefruit or drinking grapefruit juice while taking Lorviqua.

How long to take Lorviqua

Continue taking your medicine for as long as your doctor tells you.

If you forget to take Lorviqua

Lorviqua should be taken regularly at the same time each day.

If you miss your dose at the usual time, if it is less than 4 hours before your next dose, skip the dose you missed and take your next dose when you are meant to.

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 are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much Lorviqua

If you think that you have taken too much Lorviqua, 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 using Lorviqua?

Things you should do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Lorviqua
- Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine
- **If you become pregnant while taking this medicine, tell your doctor immediately**

Call your doctor straight away if you develop:

- changes in your heartbeat (fast or slow), light-headedness, fainting, dizziness or shortness of breath.

Your doctor may do some tests (electrocardiograms) to check that there are no problems with your heart during treatment with Lorviqua. If the results are abnormal he/she may decide to reduce your dose or stop your treatment.

- difficulty speaking, including slurred or slow speech
- change in your mood (including depression, euphoria and mood swings), feelings of irritability, aggression, agitation, anxiety or a change in your personality, memory loss or impairment, episodes of confusion

Tell your doctor if you notice any of the following:

- you feel more tired than usual
- your skin and whites of your eyes turn yellow
- your urine turns dark brown (tea colour)
- you have nausea, vomiting or decreased appetite
- you have pain in the upper area of and/or on the right side of your stomach
- you have itching
- you bruise more easily than usual
- you develop a fever
- you develop a cough, chest pains, shortness of breath, or worsening of respiratory symptoms.

Your doctor may do some tests (blood tests, scans) to check your liver function and pancreas. If the results are abnormal he/she may decide to reduce your dose or stop your treatment.

Your doctor should continue to monitor your blood pressure and blood sugar levels regularly during treatment.

Keep all of your doctor's appointments so that your progress can be checked.

Remind any doctor or dentist you visit that you are using Lorviqua.

Things you should not do

- **Do not stop using this medicine suddenly** or lower the dosage without checking with your doctor
- **Do not take Lorviqua to treat any other complaints** unless your doctor tells you to.
- **Do not give your medicine to anyone else**, even if they have the same condition as you.

If you are not able to take the medicine as your doctor has prescribed, contact your doctor right away.

Driving or using machines

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Follow the instructions in the carton on how to take care of your medicine properly
- **Keep your tablets in the pack/bottle until it is time to take them**

Store it in a cool dry place away from moisture, heat or sunlight; below 30°C. For example, do not store it:

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

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Keep it where young children cannot reach it.

Keep Lorviqua in a locked cupboard at least one-and-a-half metres above the ground.

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.

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.

Serious side effects

| Serious side effects | What to do |
|--|---|
| <p>Allergic type reactions</p> <ul style="list-style-type: none"> • swelling of the skin or limbs <p>Nervous system</p> <ul style="list-style-type: none"> • feeling of pain, numbness, burning, or pins and needles in your arms or legs • problems with your eyes such as difficulty seeing out of one or both eyes, double vision or perceived flashes of light • seizures • difficulty walking or performing usual activities such as writing • changes in speech, including difficulty speaking, such as slurred or slow speech • effects on memory, including confusion, memory loss and disturbance of attention | <p>Call your doctor straight away if you notice any of these serious side effects.</p> |

| Serious side effects | What to do |
|---|------------|
| <p>Psychiatric disorders</p> <ul style="list-style-type: none"> changes in mood, including mood swings seeing or hearing things that are not real (hallucinations) <p>Vascular disorders</p> <ul style="list-style-type: none"> high blood pressure* <p>Muscle related issues</p> <ul style="list-style-type: none"> pain in your joints <p>Stomach related issues</p> <ul style="list-style-type: none"> Diarrhea Constipation <p>Metabolism</p> <ul style="list-style-type: none"> weight gain changes in cholesterol and/or triglyceride levels* high blood sugar levels* <p>General disorders</p> <ul style="list-style-type: none"> tiredness <p>*These side effects may show up when you have a blood test.</p> | |

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 Lorviqua contains

| | |
|---|--|
| Active ingredient (main ingredient) | lorlatinib |
| Other ingredients (inactive ingredients) | microcrystalline cellulose calcium hydrogen phosphate sodium starch glycollate magnesium stearate hypromellose (E464) lactose monohydrate macrogol 3350 triacetin titanium dioxide (E171) iron oxide black (E172) |

| |
|-----------------------|
| iron oxide red (E172) |
|-----------------------|

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

What Lorviqua looks like

Lorviqua 25 mg tablets are round tan coloured film-coated tablets debossed with "Pfizer" on one side and "25" and "LLN" on the other side.

Lorviqua 25 mg tablets are available as blister packs containing 90 or 120 tablets and in bottles containing 30 tablets.

(AUST R 310778 (blister pack))

(AUST R 310781 (bottle))

Lorviqua 100 mg tablets are oval lavender coloured film-coated tablets debossed with "Pfizer" on one side and "LLN 100" on the other side.

Lorviqua 100 mg tablets are available as blister packs and in bottles containing 30 tablets.

(AUST R 310780 (blister pack))

(AUST R 310779 (bottle))

Who distributes Lorviqua

Lorviqua is supplied in Australia by:

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

www.pfizer.com.au

This leaflet was prepared in December 2021.