Zykadia®

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.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before taking this medicine.

1. Why am I taking Zykadia?

Zykadia contains the active ingredient ceritinib. Zykadia is used to treat advanced non-small cell lung cancer (NSCLC) that may have spread to other parts of the body and is caused by a defect in a gene called ALK (anaplastic lymphoma kinase). For more information, see Section 1. Why am I taking Zykadia? in the full CMI.

2. What should I know before I take Zykadia?

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

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 take Zykadia? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Zykadia 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 Zykadia?

- The usual dose is three (3) capsules once a day with food. Take your capsules at the about the same time each day. Do not take Zykadia with grapefruit juice. More instructions can be found in Section 4. How do I take Zykadia? in the full CMI.

5. What should I know while taking Zykadia?

Things you should do	• **Remind any doctor, dentist or pharmacist you visit that you are taking Zykadia.** • **Call your doctor straight away if you experience any of the serious side effects listed.** • **Keep all of your doctor's appointments and do the blood tests so your progress can be checked.** • **Tell your doctor if you become pregnant.**
Things you should not do	• Do not stop taking this medicine unless advised by your doctor. • Do not take Zykadia for any other complaints unless your doctor tells you to.
Driving or using machines	• Be careful before you drive or use any machines or tools until

Things you should do	• **Remind any doctor, dentist or pharmacist you visit that you are taking Zykadia.** • **Call your doctor straight away if you experience any of the serious side effects listed.** • **Keep all of your doctor's appointments and do the blood tests so your progress can be checked.** • **Tell your doctor if you become pregnant.**
	you know how Zykadia affects you.
Looking after your medicine	• Store Zykadia in a cool dry place where the temperature stays below 30°C. Store it away from moisture, heat or sunlight.

For more information, see Section 5. What should I know while taking Zykadia? in the full CMI.

6. Are there any side effects?

- Common side effects include diarrhoea, tiredness, nausea, vomiting, abdominal pain, heartburn, rash, vision problems, excessive thirst, high urine flow, increased appetite with weight loss, significantly decreased urine flow.
- Other serious side effects are irregular or slow heartbeat, pain in the chest, cough, difficult or painful breathing, wheezing, pain in chest when breathing in, fever, yellow skin and eyes, nausea, loss of appetite, dark urine, severe upper stomach pain.

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.

WARNING: Zykadia may cause QT prolongation, a heart rhythm condition. Your healthcare provider will do an electrocardiogram (ECG) test periodically during treatment with Zykadia. REPORT: new chest pain or discomfort, changes in heartbeat, palpitations, dizziness, light-headedness, discomfort, fainting, and changes in or new use of heart or blood pressure medications.

Zykadia®

Active ingredient(s): *Ceritinib*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

1. Why am I taking Zykadia?
2. What should I know before I take Zykadia?
3. What if I am taking other medicines?
4. How do I take Zykadia?
5. What should I know while taking Zykadia?
6. Are there any side effects?
7. Product details

---

1. Why am I taking Zykadia?

Zykadia contains the active ingredient ceritinib.

Zykadia is used to treat a type of a cancer called non-small cell lung cancer (NSCLC) that is either advanced or has spread to other parts of the body. This type of cancer is caused by a defect in a gene called ALK (anaplastic lymphoma kinase). This medicine belongs to a type of medicine called an ALK inhibitor.

2. What should I know before I take Zykadia?

Warnings

Do not take Zykadia if:

- You are allergic to ceritinib, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can take Zykadia.

Check with your doctor if you have/have had:

- Problems with your liver.
- Problems with your lungs or problems breathing.
- Problems with your heart including a condition called long QT syndrome.
- Diabetes.
- Problems with your pancreas.

Tell your doctor or pharmacist if you are currently taking steroids.

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 before taking Zykadia. This medicine should not be used during pregnancy unless the potential benefit outweighs the potential risk to the baby. Your doctor will discuss with you the potential risks of taking Zykadia during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed because Zykadia should not be used during breast-feeding. You and your doctor will decide together whether you should breast-feed or take Zykadia. **You should not do both**.

Use in Children

Zykadia is not to be used in children or adolescents under 18 years of age.

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 Zykadia and affect how it works.

Medicines, foods & drink that may <u>increase</u> the effect of Zykadia include:

- Antifungals such ketoconazole, itraconazole, voriconazole and posaconazole.
- Medicines used to treat AIDS or HIV such as ritonavir, saquinavir.
- Antibiotics such as telithromycin.
- Antidepressants such as nefazodone.
- Grapefruit & grapefruit juice.

Medicines that may <u>reduce</u> the effect of Zykadia include:

- Medicines which stop seizures or fits (anti-epileptics such as carbamazepine, phenobarbitone and phenytoin.
- Medicines that are used to treat tuberculosis (TB) such as rifabutin, rifampicin.
- St John's Wort *(Hypericum perforatum),* available in health food stores to treat depression, anxiety and insomnia.

- Medicines used to treat heartburn (gastric reflux). These include proton pump inhibitors such as esomeprazole, H2 antagonists or antacids.

Other medicines to be careful of:

- Midazolam, a medicine used to treat acute seizures, or as a sedative before or during surgery or medical procedures.
- Fentanyl and alfentanil which is used to treat severe pain.
- Migraine medications such dihydroergotamine, ergotamine.
- Diclofenac, a medicine used to treat joint pain and inflammation.
- Cyclosporin, tacrolimus and sirolimus, used to prevent organ rejection in transplant patients.
- Warfarin, a blood thinner.
- Birth control pills (oral contraceptives.)
- Medicines used to treat irregular heartbeat such as quinidine.
- Medicines used for increasing motility in the upper gastrointestinal tract such as cisapride.
- Medicine used to treat psychosis such as pimozide.

Check with your doctor or pharmacist about what medicines, vitamins or supplements you are taking and if these affect Zykadia.

4. How do I take Zykadia?

How much to take

Follow the instructions provided and use Zykadia until your doctor tells you to stop.

The usual dose is three (3) capsules once a day with food.

The capsules should be swallowed whole with water. Do not chew or crush the capsules.

When to take Zykadia

Take your capsules at about the same time every day.

If you forget to take Zykadia

If you miss a dose of Zykadia do not take the missed dose. Take your next dose when you are meant to.

Do <u>not</u> take a double dose to make up for the dose you missed.

If you take too much Zykadia

If you think that you have taken too much Zykadia, or anyone else has taken your medicine you / they must seek 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 Zykadia?

Things you should do

Call your doctor straight away if you:

- Experience any side effects. Your doctor may need to adjust the amount of Zykadia you are taking or stop the medication altogether. Some of the symptoms include:
  - tiredness, itchy skin, yellow skin or the whites of your eyes turn yellow, nausea or vomiting, decreased appetite, pain on the right side of your stomach, dark or brown urine, or you bleed or bruise more easily than normal because these may be signs of liver problems.
  - new or worsening symptoms such as cough with or without mucous, fever, chest pain, trouble breathing or shortness of breath because these may be signs of lung problems.
  - chest pain or discomfort, changes in your heartbeat (fast or slow), light-headedness, fainting, dizziness, blue discoloration of your lips, shortness of breath,

or swelling of your lower limbs (oedema) or skin because these may be signs of heart problems.

- diarrhoea, nausea or vomiting because they may be signs of gastrointestinal problems.
- excessive thirst or increased frequency of urination because they may be signs of a high level of sugar in the blood.

Your doctor may need to adjust, temporarily stop or completely discontinue your treatment with Zykadia.

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

- Your doctor should do blood tests before you start treatment with Zykadia to check your liver and pancreas and to check the level of sugar in your blood.
- Your doctor should do blood tests every month thereafter to check your liver while you are taking Zykadia.
- Your doctor should also do blood tests to check your pancreas and the level of sugar in your blood regularly while you are taking Zykadia.
- If you are a women who can still have children you need to be on an effective method of birth control. You must continue using birth control measures for 3 months after you stop taking Zykadia. Remember that Zykadia may affect the oral contraceptive so you should discuss effective birth control with your doctor.
- If you are pregnant or think you might be pregnant or plan to become pregnant, your doctor will discuss the risk of Zykadia on your pregnancy and your developing baby.

Remind any doctor, dentist or pharmacist that you visit that you are taking Zykadia.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Things you should not do

- This medicine has been prescribed for you only. Do not use it for any other complaints unless your doctor tells you to.
- Do not give this medicine to anyone else, even if their condition seems similar to yours. It may harm them.
- Do not stop taking this medicine suddenly unless advised by your doctor.

Driving or using machines

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

There is no specific information on Zykadia and driving or operating machines.

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. Store it in a cool dry place, where the temperature stays below 30°C. Store it away

from moisture, heat or sunlight. Keep your Zykadia in the original blister container until it is time to take it.

Do not store it:

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

Keep this medicine 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 take 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
• Diarrhoea. • Nausea. • Vomiting.	**Speak to your doctor, pharmacist or healthcare provider if these side**

Less serious side effects	What to do
• Abdominal pain. • Tiredness (fatigue). • Decreased appetite. • Weight decreased. • Constipation. • Heartburn. • Rash. • Vision problems. • Excessive thirst, high urine flow. • Weight loss whilst eating more. • Significantly decreased urine flow.	**effects become severe or they worry you.**

Serious side effects

Serious side effects	What to do
<u>Heart:</u> • Irregular or slow heartbeat. • Pain in the chest. **<u>Lung:</u>** • Cough, difficult or painful breathing, wheezing,	**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.**

Serious side effects	What to do
pain in chest when breathing in, fever. **Liver:** • Yellow skin and eyes, nausea, loss of appetite, dark urine. **Pancreas:** • Severe upper stomach pain. **Allergic reactions:** • Difficulty breathing, swallowing, swelling of the face, lips, tongue or throat, severe itching of the skin with a red rash or raised bumps.	

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.

Some side effects, for example, changes in kidney and liver function or abnormal blood test results, can only be found when your doctor does tests from time to time to check your progress.

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 Zykadia contains

Active ingredient **(main ingredient)**	**Ceritinib**
Other ingredients **(inactive ingredients)**	Capsule contents: Microcrystalline cellulose Hyprolose Sodium starch glycolate type A Magnesium stearate

Active ingredient **(main ingredient)**	**Ceritinib**
	Colloidal anhydrous silica Capsule shell: Gelatin Indigo carmine Titanium dioxide The printing ink used to mark the capsule is: OPACODE monogramming ink S-1-277002 BLACK
Potential allergens	Sulfites

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

What Zykadia looks like

Zykadia is supplied as hard capsules. Each capsule has an opaque white body and opaque blue cap. The cap is marked with black ink “LDK 150MG” and the body is marked with black ink “NVR”. The capsule contains a white to almost white powder. One blister strip contains 10 hard capsules. Multipacks contain 150 (3 packs of 50) hard capsules.

Australian Registration Number AUST R 235737.

Who distributes Zykadia

ZYKADIA is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

Level 25, Victoria Cross Tower

155 Miller Street

North Sydney NSW 2060

Telephone 1 800 671 203

Website: www.novartis.com.au

This leaflet was prepared in July 2026.

®Registered trademark.

© Copyright 2026.

(zyk280726c) based on PI (zyk280726i)