

ZYKADIA

ceritinib

Consumer Medicine Information

WARNING

The following information is needed to use ZYKADIA safely and effectively. If you have any concerns or questions about this medicine, please talk to your doctor. Familiarize yourself with the serious side effects described below and under the SIDE EFFECTS heading near the end of this document. Remember to report side effects to your doctor.

Your doctor will need to monitor your progress closely.

ZYKADIA must be taken on an empty stomach. No food should be eaten for at least two hours before and two hours after the dose of ZYKADIA is taken as taking ZYKADIA with food can lead to increased side effects.

ZYKADIA can cause serious side effects, including:

- Heart problems. ZYKADIA may cause very slow, very fast, or abnormal heartbeats. Your healthcare provider will carry out blood tests and 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.

- Lung problems (Interstitial Lung Disease/pneumonitis). ZYKADIA may cause severe or life-threatening inflammation of the lungs during treatment that can lead to death. Symptoms may be similar to those symptoms from lung cancer.

Tell your healthcare provider right away if you have any new or worsening symptoms, including: trouble breathing or shortness of breath, cough with or without mucous, chest pain, fever.

- Stomach and intestinal (gastrointestinal) problems. ZYKADIA causes stomach and intestinal problems in most people, including diarrhoea, nausea, vomiting, and stomach-area pain. These problems can sometimes be severe. Follow your healthcare provider's instructions about taking medicines to help these symptoms. Call your healthcare provider for advice if your symptoms are severe or do not go away.

- Liver problems. ZYKADIA may cause liver injury. Your healthcare provider should do blood tests at least every month to check your liver while you are taking ZYKADIA. Tell your healthcare provider right away if you get any of the following: you feel tired, your skin or the whites of your eyes turn yellow, you have a decreased appetite, your urine turns dark or brown (tea colour), you have itchy skin, you have nausea or vomiting, you have pain on the right side of your stomach-area, you bleed or bruise more easily than normal.

ZYKADIA should only be prescribed and supervised by a qualified physician experienced in the use of anticancer agents. ZYKADIA has not been studied in patients with moderate and severe hepatic impairment.

What is in this leaflet

This leaflet answers some common questions about ZYKADIA.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine. You can also download the most up to date leaflet from www.novartis.com.au.

Those updates may contain important information about the medicine and its use of which you should be aware.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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

If you have any concerns about this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What ZYKADIA is used for

ZYKADIA capsules contain an active substance called ceritinib. ZYKADIA is used to treat people with:

- non-small cell lung cancer (NSCLC) that is advanced or has

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- spread to other parts of the body (metastatic) and
- is caused by a defect in a gene called ALK (anaplastic lymphoma kinase) and
- have previously taken crizotinib but stopped because their cancer worsened or they could not tolerate the side effects.

ZYKADIA is approved as monotherapy (taken on its own) on the basis of overall response rates and duration of response in two early clinical trials and it is not yet known if it improves survival or quality of life. The approval required submission to the Therapeutic Goods Administration (TGA) of a phase III study (already underway) designed to provide further efficacy and safety data.

Some people may experience side effects not yet known or mentioned in this leaflet. If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

If you have any questions about how ZYKADIA works or why this medicine has been prescribed for you, ask your doctor or pharmacist.

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

This medicine is not addictive.

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

Before you take ZYKADIA

When you must not take it

Do not take ZYKADIA if you have an allergy to ceritinib, the active ingredient, or to any of the other ingredients listed at the end of this leaflet.

If you develop these symptoms tell your doctor straight away. They are some of the signs of an allergic reaction:

- difficulty in breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps

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

In that case, return it to your pharmacist.

Before you start to take it

Take special care with ZYKADIA. If any of these apply to you, tell your doctor or pharmacist before taking ZYKADIA:

- If you have problems with your liver.
- If you have problems with your lungs or problems breathing.
- If you have problems with your heart, including a condition called long QT syndrome.
- If you have diabetes (a high level of sugar in the blood).
- If you have/had problems with your pancreas.
- If you are currently taking steroids.
- If you are pregnant, think you may be pregnant, or plan to become pregnant (see section Pregnancy).
- If you are breast-feeding or plan to breast-feed (see section Breast-feeding).

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop such as vitamins or herbal supplements, because they might interact with ZYKADIA.

It is particularly important that you mention any of the following medicines:

- Medicines used to treat AIDS/HIV such as ritonavir or saquinavir
- Medicines used to treat infections. These include medicines which treat fungal infections, such as antifungals like ketoconazole, itraconazole, voriconazole or posaconazole, or medicines which treat certain types of bacterial infections, such as antibiotics like telithromycin
- Medicines used to treat depression such as nefazodone, or psychosis such as pimozide
- St. John's Wort - an herbal product used to treat depression and other conditions, also known as *Hypericum perforatum*
- Medicines which stop seizures or fits (anti-epileptics such as phenytoin, carbamazepine, or phenobarbitone).
- Medicines used to treat tuberculosis such as rifampin or rifabutin
- Medicines used to treat irregular heartbeat such as quinidine
- Medicines used for increasing motility in the upper gastrointestinal tract such as cisapride
- Midazolam, a medicine used to treat acute seizures, or as a sedative before or during surgery or medical procedures
- Warfarin, an anticoagulant medicine used to prevent blood clots
- Diclofenac, a medicine used to treat joint pain and inflammation
- Astemizole, an antihistamine medicine used to prevent allergies
- Cyclosporin, tacrolimus and sirolimus, medicines used in organ transplantation to prevent transplant organ rejection
- Ergotamine, a medicine used to treat migraine
- Alfentanil and fentanyl, medicines used to treat severe pain

- Gastric acid-reducing agents (e.g. proton pump inhibitors, H2-receptor antagonists, antacids)

Ask your doctor or pharmacist if you are not sure whether your medicine is one of the medicines listed above.

These medications should be used with care or may need to be avoided during your treatment with ZYKADIA.

If you are taking any of these, your doctor might prescribe an alternative medicine for you.

If you have not told your doctor about any of these things, tell him/her before you start taking this medicine.

How to take ZYKADIA

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

Always take ZYKADIA exactly as your doctor has told you. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Do not change the dose without talking to your doctor.

How much to take

The recommended dose of ZYKADIA is 750 mg once daily. Your doctor will tell you exactly how many capsules of ZYKADIA you need to take. Do not change the dose without talking to your doctor.

How to take it

Take ZYKADIA on an empty stomach.

No food should be eaten for at least two hours before and two hours after the dose of ZYKADIA is taken in order to avoid drug overexposure which can increase side effects.

Swallow ZYKADIA capsules whole with water. Do not chew or crush capsules.

You should not eat grapefruit or drink grapefruit juice during your treatment with ZYKADIA. It may make the amount of ZYKADIA in your blood increase to a harmful level.

When to take it

Take ZYKADIA once a day at about the same time each day.

If vomiting occurs after you swallow ZYKADIA capsules, do not take any more capsules until your next scheduled dose.

Do not stop taking ZYKADIA unless your doctor tells you to.

This is a long-term treatment, possibly lasting for months. Your doctor will monitor your condition to see that the treatment is having the desired effect.

If you have questions about how long to take ZYKADIA, talk to your doctor or pharmacist.

If you forget to take it

If you forget to take ZYKADIA, do not take the missed dose; just take your next dose at the regular time.

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

If you have any further questions on the use of this medicine, 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 (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital (take the pack with you) if you think that you or anyone else may have taken too much ZYKADIA. Do this even if there are no signs of discomfort or poisoning. Keep the telephone number handy.

While you are taking ZYKADIA

Things you must do

Tell your doctor or pharmacist immediately if you get any of these symptoms during treatment with ZYKADIA:

- If you experience 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.
- If you experience 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.
- If you experience 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.
- If you experience severe diarrhoea, nausea or vomiting because they may be signs of gastrointestinal problems.
- If you experience 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.

WOMEN OF CHILD BEARING AGE

- You must use a highly effective method of birth control during treatment with ZYKADIA and for 3 months after stopping ZYKADIA. Zykadia may decrease the effectiveness of the oral contraceptive.

Your doctor will discuss with you the optimal birth control (contraceptive) method for you to use during treatment with ZYKADIA.

PREGNANCY AND BREAST-FEEDING

- **ZYKADIA should not be used during pregnancy, unless the potential benefit to the patient outweighs the potential risk to the foetus.**
- If you are pregnant or think you might be pregnant or plan to become pregnant, ask your doctor for advice.
Your doctor will discuss with you the potential risks of taking ZYKADIA during pregnancy.
- **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.

Tell your doctor straight away if you become pregnant while taking this medicine.

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

Things you must 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.

Things to be careful of

Be careful driving, operating machinery or doing jobs that require you to be alert until you know how ZYKADIA affects you.

Side effects

Tell your doctor or pharmacist as soon as possible if you notice any side effects not listed in this leaflet.

As with all medicines, patients treated with ZYKADIA may experience side effects, although not everybody gets them.

STOP taking ZYKADIA and seek medical help immediately if you experience any of the following, which may be signs of an allergic reaction:

- difficulty in breathing or 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 IMMEDIATELY if you experience any of the following SERIOUS SIDE EFFECTS. You may need medical treatment.

- 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 resulting from inflammation of the pancreas

The following list includes OTHER SIDE EFFECTS of your medicine. If they BECOME SEVERE, please tell your doctor, pharmacist or healthcare provider.

VERY COMMON SIDE EFFECTS

- Diarrhoea
- Nausea
- Vomiting
- Abdominal pain
- Tiredness (fatigue)
- Decreased appetite
- Constipation
- Heartburn
- Rash

COMMON SIDE EFFECTS

- Vision problems
- Excessive thirst, high urine flow, increased appetite with weight loss
- Significantly decreased urine flow

Some people may have other side effects not yet known or mentioned in this leaflet. If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

Some side effects, for example, changes in kidney and liver function or abnormal blood test results (high levels of an pancreatic enzymes called lipase and amylase in the blood), can only be found when your doctor does tests from time to time to check your progress.

After using ZYKADIA

Storage

- Keep your medicine in the original package until it is time to take it.
- Store it in a cool, dry place, below 30°C
- Do not store this medicine or any other medicine in the bathroom or near a sink
- Do not leave it in the car or on window sills.

Keep the medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine you have left over.

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Product description

What it looks like

ZYKADIA hard capsules are opaque white and blue. The opaque blue cap is marked with black ink "LDK 150MG" and the opaque white 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.

Ingredients

ZYKADIA hard capsules contain 150 mg of the active ingredient ceritinib.

The inactive capsule contents are: microcrystalline cellulose, hypollose, sodium starch glycolate type A, magnesium stearate, colloidal anhydrous silica.

The hard capsule itself is made from gelatin and the capsule colouring agents are titanium dioxide, indigo carmine.

The printing ink used to mark the capsule is OPACODE monogramming ink S-1-277002 BLACK.

Sponsor

ZYKADIA® is supplied in Australia by:

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