

PATIENT INFORMATION
ZYKADIA® (zye kaye' dee ah)
(ceritinib) capsules
(ceritinib) tablets

Read this Patient Information leaflet that comes with ZYKADIA before you start taking it and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

What is the most important information I should know about ZYKADIA?

ZYKADIA may cause serious side effects, including:

Stomach and intestinal (gastrointestinal) problems. ZYKADIA may cause stomach and intestinal problems, including diarrhea, nausea, vomiting, and stomach-area pain. Follow your healthcare provider's instructions about taking medicines to help with these symptoms. Call your healthcare provider for advice if your symptoms are severe or cannot be tolerated.

Liver problems. ZYKADIA may cause liver injury. Your healthcare provider should do blood tests at least every month to check your liver during treatment with 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 color)
- 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

Lung problems (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
- fever
- cough with or without mucus
- chest pain

Heart problems. ZYKADIA may cause very slow, very fast, or abnormal heartbeats. Your healthcare provider may check your heart during treatment with ZYKADIA. Tell your healthcare provider right away if you feel new chest pain or discomfort, dizziness or lightheadedness, if you faint, or have abnormal heartbeats. Tell your healthcare provider if you start to take or have any changes in heart or blood pressure medicines.

See "What are the possible side effects of ZYKADIA?" for more information about side effects.

What is ZYKADIA?

ZYKADIA is a prescription medicine that is used to treat people with non-small cell lung cancer (NSCLC) that:

- is caused by a defect in a gene called anaplastic lymphoma kinase (ALK), and
- has spread to other parts of the body

It is not known if ZYKADIA is safe and effective in children.

Before you take ZYKADIA, tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems
- have diabetes or high blood sugar
- have heart problems, including a condition called long QT syndrome
- have or have had pancreatitis
- are pregnant or plan to become pregnant. ZYKADIA can harm your unborn baby. Females who are able to become pregnant should use an effective method of birth control during treatment with ZYKADIA and for 6 months after stopping ZYKADIA. Talk to your healthcare provider about birth control methods that may be right for you. Tell your healthcare provider right away if you become pregnant or think that you may be pregnant.
 - Males with female partners who are able to become pregnant should use condoms during treatment with ZYKADIA and for 3 months after stopping ZYKADIA.
- are breastfeeding or plan to breastfeed. It is not known if ZYKADIA passes into your breast milk. Do not breastfeed during treatment with ZYKADIA and for 2 weeks after stopping ZYKADIA.

Tell your healthcare provider about all the medicines you take, including prescription medicines, over-the-counter medicines, vitamins, and herbal supplements.

How should I take ZYKADIA?

- Take ZYKADIA exactly as your healthcare provider tells you. Do not change your dose or stop taking ZYKADIA unless your healthcare provider tells you to.
- Take ZYKADIA one time a day.
- Take ZYKADIA with food.
- If you vomit after taking ZYKADIA, do not take an additional dose. Continue with the next scheduled dose.
- If you miss a dose of ZYKADIA, take it as soon as you remember. If your next dose is due within 12 hours, then skip the missed dose. Just take the next dose at your regular time.

What should I avoid while taking ZYKADIA?

- You should not drink grapefruit juice or eat grapefruit during treatment with ZYKADIA. It may make the amount of ZYKADIA in your blood increase to a harmful level.
- Avoid spending time in sunlight during treatment with ZYKADIA. Your skin may become more sensitive to the sun and you may burn more easily. Use sunscreen and wear protective clothing that covers your skin to help protect against sunburn.

What are the possible side effects of ZYKADIA?

ZYKADIA may cause serious side effects, including:

- **See "What is the most important information I should know about ZYKADIA?"**
- **High blood sugar (hyperglycemia).** People who have diabetes or glucose intolerance or who take a corticosteroid medicine have an increased risk of high blood sugar with ZYKADIA. Your healthcare provider will check your blood sugar level before starting ZYKADIA and as needed during treatment with ZYKADIA. Call your healthcare provider right away if you have any symptoms of high blood sugar, including:
 - increased thirst
 - increased hunger
 - headaches
 - trouble thinking or concentrating
 - urinating often
 - blurred vision
 - tiredness
 - your breath smells like fruit
- **Inflammation of the pancreas (pancreatitis).** ZYKADIA can cause pancreatitis that has led to death. You may develop increased pancreatic enzyme blood levels, which may be a sign of pancreatitis. Signs and symptoms of pancreatitis include upper abdominal pain that may spread to the back and get worse with eating. Your healthcare provider should do blood tests to check your pancreatic enzyme blood levels before you start ZYKADIA and as needed during your treatment.

The most common side effects of ZYKADIA include:

- stomach and intestinal (gastrointestinal) problems. **See "What is the most important information I should know about ZYKADIA?"**
- tiredness, decreased appetite, and weight loss

These are not all of the possible side effects of ZYKADIA. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ZYKADIA?

- Store ZYKADIA at room temperature between 68°F to 77°F (20°C to 25°C).

Keep ZYKADIA and all medicines out of the reach of children.

General information about the safe and effective use of ZYKADIA

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use ZYKADIA for a condition for which it was not prescribed. Do not give it to other people, even if they have the same symptoms you have. It may harm them. You can ask your healthcare provider or pharmacist for more information about ZYKADIA that is written for health professionals.

What are the ingredients in ZYKADIA?

Active ingredient: ceritinib

Inactive ingredients capsules: colloidal silicon dioxide, hard gelatin capsule shells, low-substituted hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, and sodium starch glycolate. Capsule shell contains FD&C Blue # 2, gelatin, and titanium dioxide.

Inactive ingredients tablets: Tablet core: colloidal silicon dioxide, croscarmellose sodium, low-substituted hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose and povidone. Tablet coating: FD&C Blue # 2 aluminum lake, hypromellose, polyethylene glycol 4000, talc, and titanium dioxide.

Distributed by: Novartis Pharmaceuticals Corporation, East Hanover, New Jersey 07936. For more information, go to www.US.ZYKADIA.com or call 1-888-669-6682.