

ZYKADIA
PATIENT
INFORMATION

TO HELP YOU GET STARTED

ZYKADIA™
ceritinib 150 mg capsules

Read this patient information before you start taking ZYKADIA and each time you get a refill.

This information does not take the place of talking to your doctor about your condition or treatment.



WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT ZYKADIA™ (ceritinib)?

ZYKADIA MAY CAUSE SERIOUS SIDE EFFECTS, INCLUDING:

STOMACH AND INTESTINAL (GASTROINTESTINAL) PROBLEMS

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

LIVER PROBLEMS

ZYKADIA may cause liver injury. Your health care provider should do blood tests at least every month to check your liver while you are taking ZYKADIA. Tell your health care provider right away if you experience any of the following:

- › You feel tired
- › You have itchy skin
- › Your skin or the whites of your eyes turn yellow
- › You have nausea or vomiting
- › You have a decreased appetite
- › You have pain on the right side of your stomach-area
- › Your urine turns dark or brown (tea color)
- › You bleed or bruise more easily than normal

LUNG PROBLEMS (PNEUMONITIS)

ZYKADIA may cause severe or life-threatening swelling (inflammation) of the lungs during treatment that can lead to death. Symptoms may be similar to those symptoms from lung cancer. Tell your health care provider right away if you have any new or worsening symptoms, including:

- › Trouble breathing or shortness of breath
- › Cough with or without mucous
- › Fever
- › Chest pain

HEART PROBLEMS

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

See "What are 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, and
- › Who have taken the medicine crizotinib, but their NSCLC worsened or they cannot tolerate taking crizotinib

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



WHAT SHOULD I TELL MY HEALTH CARE PROVIDER BEFORE TAKING ZYKADIA™ (ceritinib)?

BEFORE YOU TAKE ZYKADIA, TELL YOUR HEALTH CARE 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, think you may be pregnant, or plan to become pregnant. ZYKADIA may harm your unborn baby. Women who are able to become pregnant should use an effective method of birth control during treatment with ZYKADIA and for at least 2 weeks after stopping ZYKADIA. Talk to your health care provider about birth control methods that may be right for you
- › Are breastfeeding or plan to breastfeed. It is not known if ZYKADIA passes into your breast milk. You should not breastfeed if you take ZYKADIA

TELL YOUR HEALTH CARE 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 health care provider tells you. Do not change your dose or stop taking unless your health care provider tells you to
- › Take ZYKADIA 1 time each day
- › Take ZYKADIA on an empty stomach, do not eat for 2 hours before, and do not eat for 2 hours after taking ZYKADIA
- › If you vomit after taking ZYKADIA, do not take an additional dose, but 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



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 health care provider will check your blood sugar level before starting ZYKADIA and as needed during treatment with ZYKADIA. Call your health care 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 health care 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 constipation

These are not all of the possible side effects of ZYKADIA. For more information, ask your health care provider or pharmacist.



CALL YOUR DOCTOR FOR MEDICAL ADVICE ABOUT SIDE EFFECTS.
YOU MAY REPORT SIDE EFFECTS TO FDA AT **1-800-FDA-1088**.



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