PATIENT INFORMATION
KRAZATI® (krah zah tee)
(adagrasib)
Tablets

What is KRAZATI?

KRAZATI is a prescription medicine used in adults:

- alone to treat non-small cell lung cancer (NSCLC)
  - that has spread to other parts of the body or cannot be removed by surgery, **and**
  - whose tumor has an abnormal *KRAS* G12C gene, **and**
  - who have received at least one prior treatment.
- in combination with a medicine called cetuximab to treat colon or rectal cancer (CRC)
  - that has spread to other parts of the body or cannot be removed by surgery, **and**
  - whose tumor has an abnormal *KRAS* G12C gene, **and**
  - who have previously received certain chemotherapy medicines.

Your healthcare provider will perform a test to make sure that KRAZATI is right for you.
It is not known if KRAZATI is safe and effective in children.

Before taking KRAZATI, tell your healthcare provider about all of your medical conditions, including if you:

- have any heart problems, including heart failure and congenital long QT syndrome.
- have liver problems.
- are pregnant or plan to become pregnant. It is not known if KRAZATI can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if KRAZATI passes into your breastmilk. Do not breastfeed during treatment and for 1 week after your last dose of KRAZATI.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. KRAZATI can affect the way other medicines work, and other medicines can affect how KRAZATI works.

How should I take KRAZATI?

- Take KRAZATI exactly as your healthcare provider tells you to take it. Do not change your dose or stop taking KRAZATI unless your healthcare provider tells you to.
- Your healthcare provider may change your dose, or temporarily or permanently stop treatment with KRAZATI if you develop certain side effects.
- For colon or rectal cancer, you will also receive cetuximab through a vein in your arm (intravenously) given by your healthcare provider. Your healthcare provider will permanently or temporarily stop your treatment with cetuximab if your treatment with KRAZATI is permanently or temporarily stopped.
- Take your prescribed dose of KRAZATI 2 times each day, at about the same time each day.
- Take KRAZATI either with food or without food.
- Swallow KRAZATI tablets whole. Do not chew, crush or split tablets.
- If you vomit after taking a dose of KRAZATI, do not take an extra dose. Take your next dose at your next scheduled time.
- If you miss a dose of KRAZATI, take the dose as soon as you remember. If it has been more than 4 hours, do not take the dose. Take your next dose of KRAZATI at your next scheduled time. Do not take 2 doses at the same time to make up for a missed dose.

What are possible side effects of KRAZATI?

KRAZATI can cause serious side effects, including:

- **Stomach and intestinal (gastrointestinal) problems.** Stomach and intestinal side effects including nausea, diarrhea, or vomiting, are common with KRAZATI but can also sometimes be severe. KRAZATI can also cause serious stomach and intestinal side effects such as bleeding, obstruction, inflammation of the colon (colitis), and narrowing (stenosis).
  - **Call your healthcare provider if you develop any of the signs or symptoms of stomach or intestinal problems listed above during treatment with KRAZATI**.
  - Your healthcare provider may prescribe an antidiarrheal medicine or anti-nausea medicine, or other treatment, as needed.
- **Changes in the electrical activity of your heart called QTc prolongation.** Certain changes can occur in the electrical activity of your heart during treatment with KRAZATI and can be seen on a test called an electrocardiogram (ECG or EKG). QTc prolongation can increase your risk for irregular heartbeats that can be life-threatening, such as torsades de pointes, and can lead to sudden death.
  - You should not take KRAZATI if you have congenital long QT syndrome or if you currently have QTc prolongation. See **"Before taking KRAZATI, tell your healthcare provider about all of your medical conditions, including if you:"**
    - Your healthcare provider should monitor the electrical activity of your heart and the levels of body salts in your blood (electrolytes) especially potassium and magnesium before starting and during treatment with KRAZATI if you have heart failure, a slow heart rate, abnormal levels of electrolytes in your blood, or if you take a medicine that can prolong the QT interval of your heartbeat.
    - **Tell your healthcare provider if you feel dizzy, lightheaded, or faint, or if you get abnormal heartbeats during treatment with KRAZATI.**
- **Liver problems.** Abnormal liver blood test results are common with KRAZATI and can sometimes be severe. Your healthcare provider should do blood tests before starting and during treatment with KRAZATI to check your liver function. Tell your healthcare provider right away if you develop any signs or symptoms of liver problems, including:
  - your skin or the white part of your eyes turns yellow (jaundice)
  - dark or "tea-colored" urine
  - light-colored stools (bowel movements)
  - tiredness or weakness
  - nausea or vomiting
  - bleeding or bruising
  - loss of appetite
  - pain, aching or tenderness on the right side of your stomach area (abdomen)
- **Lung or breathing problems.** KRAZATI may cause inflammation of the lungs that can lead to death. Tell your healthcare provider or get emergency medical help right away if you have new or worsening shortness of breath, cough, or fever.

The most common side effects of KRAZATI when used alone for NSCLC include:

- nausea
- diarrhea
- vomiting
- tiredness
- kidney problems
- swelling
- decreased appetite
- trouble breathing

- muscle and bone pain

The most common side effects of KRAZATI when used in combination with cetuximab for CRC include:

- skin rash
- nausea
- diarrhea
- vomiting
- tiredness
- muscle and bone pain
- headache
- dry skin
- stomach pain
- decreased appetite
- swelling
- low red blood cell count
- cough
- dizziness
- constipation
- nerve damage in the arms and legs

Certain abnormal blood test results are common during treatment with KRAZATI, when used alone or in combination with cetuximab. Your healthcare provider will monitor you for abnormal blood tests and treat you if needed.

KRAZATI may cause fertility problems in males and females, which may affect your ability to have children. Talk to your healthcare provider if this is a concern for you.

These are not all of the possible side effects of KRAZATI.

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 KRAZATI?

- Store KRAZATI at room temperature between 68°F to 77°F (20°C to 25°C).
- KRAZATI comes in a child-resistant container.
- KRAZATI comes with a desiccant (drying agent) in the container to keep the medicine dry. Do not remove the desiccant from the container after opening. Do not eat or swallow the desiccant.

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

General information about the safe and effective use of KRAZATI.

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

What are the ingredients in KRAZATI?

Active ingredient: adagrasib

Inactive ingredients: colloidal silicon dioxide, crospovidone, magnesium stearate (vegetable sourced), mannitol, and microcrystalline cellulose. The tablet film coating contains hypromellose, maltodextrin, medium chain triglycerides (vegetable sourced), polydextrose, talc, and titanium dioxide.

Distributed by: Bristol-Myers Squibb Company, Princeton, NJ 08543 USA

For more information, go to www.KRAZATI.com or call 1-866-4-KRAZATI (1-866-457-2928)

This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: 07/2024