PATIENT INFORMATION
LUMAKRAS® (loo-ma-krass)
(sotorasib)
tablets

What is LUMAKRAS?

LUMAKRAS 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 for their cancer.
- in combination with a prescription medicine called panitumumab to treat colon or rectal cancer (CRC):
  - that has spread to other parts of the body **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 LUMAKRAS is right for you.

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

What should I tell my healthcare provider before taking LUMAKRAS?

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

- have liver problems.
- have lung or breathing problems other than lung cancer.
- are pregnant or plan to become pregnant. It is not known if LUMAKRAS will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if LUMAKRAS passes into your breast milk. Do not breastfeed during treatment with LUMAKRAS and for 1 week after the last dose.

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

Especially tell your healthcare provider if you take antacid medicines, including Proton Pump Inhibitor (PPI) medicines or H_2 blockers during treatment with LUMAKRAS. Ask your healthcare provider if you are not sure.

How should I take LUMAKRAS?

- Take LUMAKRAS exactly as your healthcare provider tells you to take it. Do not change your dose or stop taking LUMAKRAS unless your healthcare provider tells you to.
- Take your prescribed dose of LUMAKRAS 1 time each day, at the same time each day.
- For colon or rectal cancer, you will also receive panitumumab through a vein in your arm (intravenously) given by your healthcare provider. You will first take LUMAKRAS before you receive your first dose of panitumumab. Your healthcare provider will temporarily or permanently stop your treatment with panitumumab if your treatment with LUMAKRAS is temporarily or permanently stopped.
- Take LUMAKRAS with or without food.
- Swallow LUMAKRAS tablets whole. Do not chew, crush, or split tablets.
- If you cannot swallow LUMAKRAS tablets whole:
  - Place your prescribed dose of LUMAKRAS in a glass of 4 ounces (120 mL) of non-carbonated, room temperature water without crushing the tablets. Do not use any other liquids.
  - Stir or swirl the cup for about 3 minutes until the tablets are in small pieces (the tablets will not completely dissolve). The color of the mixture may be pale yellow to bright yellow.
  - Drink the LUMAKRAS and water mixture right away or within 2 hours of preparing. Do not chew pieces of the tablet.
  - Rinse the glass with an additional 4 ounces (120 mL) of water and drink to make sure that you have taken the full dose of LUMAKRAS.
  - If you do not drink the mixture right away, stir or swirl the mixture again before drinking.
- If you take an antacid medicine, take LUMAKRAS either 4 hours before or 10 hours after the antacid.
- If you miss a dose of LUMAKRAS, take the dose as soon as you remember. If it has been more than 6 hours, do not take the dose. Take your next dose at your regularly scheduled time the next day. Do not take 2 doses at the same time to make up for a missed dose.

- If you vomit after taking a dose of LUMAKRAS, do not take an extra dose. Take your next dose at your regularly scheduled time the next day.

What are possible side effects of LUMAKRAS?

LUMAKRAS may cause serious side effects, including:

- **Liver problems.** Abnormal liver blood tests are common with LUMAKRAS and can sometimes be severe. Your healthcare provider should do blood tests before starting and during treatment with LUMAKRAS 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.** LUMAKRAS 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.

Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with LUMAKRAS if you develop side effects.

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

- diarrhea
- muscle or bone pain
- nausea
- tiredness
- cough
- changes in certain blood tests

The most common side effects of LUMAKRAS when used in combination with panitumumab for CRC include:

- skin rash
- dry skin
- diarrhea
- mouth sores
- tiredness
- muscle and bone pain
- changes in certain blood tests

These are not all the possible side effects of LUMAKRAS.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to Amgen at 1-800-772-6436 (1-800-77-AMGEN).

How should I store LUMAKRAS?

- Store LUMAKRAS at room temperature between 68°F to 77°F (20°C to 25°C).
- The bottle has a child-resistant closure.

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

General information about the safe and effective use of LUMAKRAS.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use LUMAKRAS for a condition for which it was not prescribed. Do not give LUMAKRAS 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 LUMAKRAS that is written for healthcare professionals.

What are the ingredients in LUMAKRAS?

Active Ingredient: sotorasib

Inactive Ingredients: microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, and magnesium stearate. Tablet film coating material contains polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, iron oxide yellow and iron oxide red (320 mg tablet only).

AMGEN

Manufactured by: Amgen Inc., One Amgen Center Drive, Thousand Oaks, CA 91320-1799 U.S.A.

For more information, go to www.LUMAKRAS.com or call 1-800-772-6436 (1-800-77-AMGEN).
This Patient Information has been approved by the U.S. Food and Drug Administration.
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