

LUMAKRAS[®] FILM-COATED TABLET

Sotorasib (120 mg, 240 mg)

What is in this Leaflet?

1. What LUMAKRAS is Used for
2. How LUMAKRAS Works
3. Before You Use LUMAKRAS
4. How to Use LUMAKRAS
5. While You are Using LUMAKRAS
6. Side Effects
7. Storage and Disposal of LUMAKRAS
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What LUMAKRAS is Used for

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.

This indication is approved under conditional registration which is based on overall response rate (ORR) and duration of response (DOR).

Continued approval for this indication may be based on the outcome of clinical benefit in a confirmatory trial.

- 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.

How LUMAKRAS Works

LUMAKRAS is a medicine that inhibits the abnormal *KRAS* G12C, which is involved in the growth of cells. LUMAKRAS binds to *KRAS* G12C and blocks its function, which may slow down or stop the growth of your cancer.

Before You Use LUMAKRAS

- *When you must not use it*

Use LUMAKRAS exactly as your doctor tells you to use it.

- *Before you start to use it*

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.

- *Taking other medicines*

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 H₂ blockers during treatment with LUMAKRAS. Ask your healthcare provider if you are not sure.

How to Use LUMAKRAS

- *How much to use*

- 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 necessary, your doctor may recommend you receive LUMAKRAS through a feeding tube.

- *When to use it*

Use LUMAKRAS exactly as your doctor tells you to use it.

- How long to use it

Use LUMAKRAS exactly as your doctor tells you to use it.

- If you forget to use it

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.

- If you use too much (overdose)

If you use more LUMAKRAS than you should, talk to your doctor or pharmacist.

While You are Using LUMAKRAS

- Things you must do

Use LUMAKRAS exactly as your doctor tells you to use it. Tell your healthcare provider if you become pregnant while taking LUMAKRAS.

- Things you must not do

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.

- Things to be careful of

Use LUMAKRAS exactly as your doctor tells you to use it.

Side Effects

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

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine. You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side

Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of LUMAKRAS

- Storage

Store LUMAKRAS below 30°C.

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

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

LUMAKRAS (sotorasib) 120 mg tablets are yellow, oblong shaped, film coated, debossed with “AMG” on one side and “120” on the opposite side.

LUMAKRAS (sotorasib) 240 mg tablets are yellow, oval-shaped, film-coated, debossed with “AMG” on one side and “240” on the opposite side.

- Ingredients

- 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, and iron oxide yellow.

- MAL numbers:

LUMAKRAS FILM-COATED TABLET 120 MG
MAL23096003ACRZ

LUMAKRAS FILM-COATED TABLET 240 MG
MAL25126009ACRZ

Manufactured by

Patheon Inc.,
2100 Syntex Court Mississauga, Ontario
L5N 7K9 Canada

Product Registration Holder

Amgen Biopharmaceuticals Malaysia
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12/11/2025

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