PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrLUMAKRAS™

sotorasib tablets

Read this carefully before you start taking **LUMAKRAS** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **LUMAKRAS**.

What is LUMAKRAS used for?

Please see the boxed text below.

"For the following indication LUMAKRAS has been approved with conditions (NOC/c). This means it has passed Health Canada's review and can be bought and sold in Canada, but the manufacturer has agreed to complete more studies to make sure the drug works the way it should. For more information, talk to your healthcare professional."

- LUMAKRAS is used to treat adults with non-small cell lung cancer (NSCLC) with an abnormal gene called "*KRAS G12C*". This cancer:
  - cannot be removed by surgery or other treatment, or has spread to other parts of the body, and
  - has been treated with at least one type of cancer treatment before.
- LUMAKRAS is not approved for use in children and adolescents under 18 years of age.

  Your healthcare professional will test your cancer for abnormal *KRAS G12C* and make sure that LUMAKRAS is right for you.

What is a Notice of Compliance with Conditions (NOC/c)?

A Notice of Compliance with Conditions (NOC/c) is a type of approval to sell a drug in Canada.

Health Canada only gives a NOC/c to a drug that treats, prevents, or helps identify a serious or life-threatening illness. The drug must show promising proof that it works well, is of high quality, and is reasonably safe. Also, the drug must either respond to a serious medical need in Canada or be much safer than existing treatments.

Drug makers must agree in writing to clearly state on the label that the drug was given an NOC/c, to complete more testing to make sure the drug works the way it should, to actively monitor the drug's performance after it has been sold, and to report their findings to Health Canada.

How does LUMAKRAS work?

LUMAKRAS helps block the abnormal KRAS G12C protein in your lung cancer. This may slow down or stop the growth and spread of the lung cancer.

If you have any questions about how LUMAKRAS works or why this medicine has been prescribed for you, ask your healthcare professional.

What are the ingredients in LUMAKRAS?

Medicinal ingredients: sotorasib

Non-medicinal ingredients:

croscarmellose sodium, iron oxide yellow, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide

LUMAKRAS comes in the following dosage forms:

Tablet,120 mg

Do not use LUMAKRAS if:

- You are allergic to sotorasib or any of the other ingredients in LUMAKRAS or the packaging.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take LUMAKRAS. Talk about any health conditions or problems you may have, including if you:

- Have or had liver problems.
- Have or had lung problems.
- Have an intolerance to lactose.

Other warnings you should know about:

LUMAKRAS can cause the following side effects, including:

- **Liver problems: Hepatotoxicity** (liver damage), including **liver injury** and **hepatitis** (liver inflammation) can happen in patients taking LUMAKRAS**.** Increased levels of liver enzyme levels can happen as well. You will have regular blood tests done before starting your treatment and then every 3 weeks during the first 3 months, then once a month after. You might need more tests depending on your health. These blood tests will tell your healthcare professional how your liver is working.
- **Lung problems: Interstitial lung disease (ILD) / pneumonitis** (inflamed or scarred lungs) can happen while taking LUMAKRAS. They might cause death.

See the “Serious side effects and what to do about them” table, below, for more information on these and other serious side effects.

Pregnancy, contraception and breastfeeding:

Female patients

- Tell your healthcare professional if you are pregnant, able to get pregnant or think you are pregnant. There are specific risks you should discuss with your healthcare professional.
- Tell your healthcare professional right away if you become pregnant or think you may be pregnant during your treatment with LUMAKRAS.
- Do not breastfeed while you are taking LUMAKRAS and for at least 1 week after your last dose.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following medicines may interact with LUMAKRAS:

- Medicines used to reduce stomach acid and to treat stomach ulcers, indigestion and heartburn such as:
  - dexlansoprazole, esomeprazole, lansoprazole, omeprazole, pantoprazole sodium, or rabeprazole (medicines known as 'proton pump inhibitors')
  - ranitidine, famotidine, cimetidine (medicines known as 'H_2 receptor antagonists')
- Medicines used to treat tuberculosis, such as rifampin
- Medicines used to treat epilepsy, such as carbamazepine, phenytoin, or phenobarbital
- St. John's Wort (a herbal medicine used to treat depression)
- Enzalutamide (used to treat prostate cancer)
- Medicines used to treat severe pain, such as alfentanil or fentanyl
- Medicines used to prevent organ rejection in transplants, such as cyclosporin, sirolimus, everolimus, or tacrolimus
- Medicines used to lower cholesterol levels, such as simvastatin, atorvastatin, or lovastatin
- Midazolam (used to treat acute seizures or as a sedative before or during surgery or medical procedures)
- Medicines used to treat heart rhythm problems, such as dronedarone or amiodarone
- Medicines to treat blood clots (anticoagulants), such as rivaroxaban or apixaban

How to take LUMAKRAS:

- Take LUMAKRAS exactly as your healthcare professional tells you to take it. Do not change your dose or stop taking LUMAKRAS unless your healthcare professional tells you to.
- LUMAKRAS can be taken with or without food.
- If you need to take an antacid medicine (to reduce stomach acid), take LUMAKRAS either 4 hours before or 10 hours after the antacid.
- Swallow tablets whole. Do not chew, crush, or split tablets.

If you cannot swallow LUMAKRAS tablets whole:

- Place your daily dose of LUMAKRAS in a glass of 120 mL (4 ounces) non-carbonated, room temperature water without crushing the tablets. Do not use any other liquids.
- Stir until the tablets are in small pieces (the tablets will not completely dissolve). The water mixture may have a pale to bright yellow look.
- Drink the LUMAKRAS and water mixture right away.
- Add another 120 mL (4 ounces) of water and drink right away to make sure that you have taken the full dose of LUMAKRAS.
- If you do not drink the mixture right away, stir the mixture again. Drink within two hours of making the mixture.

Usual dose:

Recommended dose: 960 mg (eight 120 mg tablets) once per day. Take by mouth at the same time each day.

Your healthcare professional may lower your dose, stop your treatment for a period of time or recommend that you stop treatment completely. This may happen if you:

- experience serious side effects, or
- your disease gets worse.

Overdose:

Contact your healthcare professional right away if you take more tablets than recommended.

If you think you, or a person you are caring for, have taken too much LUMAKRAS, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose of LUMAKRAS, do not take the dose if 6 hours have passed from your regular scheduled time. Take your next dose at your regular scheduled time.

If you vomit at any time after taking LUMAKRAS, do not take another dose. Take the next dose at your usual time.

What are possible side effects from using LUMAKRAS?

These are not all the possible side effects you may have when taking LUMAKRAS. If you experience any side effects not listed here, tell your healthcare professional.

- Diarrhea
- Nausea, vomiting
- Feeling tired (fatigue)
- Cough
- Stomach pain
- Constipation
- Decreased appetite
- Joint pain (arthralgia)
- Rash

LUMAKRAS can cause abnormal blood test results. Your healthcare professional will do blood tests during your treatment. These will tell your healthcare professional how LUMAKRAS is affecting your blood and liver.

Serious side effects and what to do about them			
Symptom / effect	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
COMMON			
Diarrhea	X		
Edema: unusual swelling of the arms, hands, legs, feet and ankles, face or airway passages	X		
Hepatotoxicity (swelling of your liver), **Hepatitis** (liver inflammation), **Liver Injury:** jaundice (yellowing of the skin or whites of eyes), urine turns dark, light-coloured stool, loss of appetite for several days or longer, nausea, lower stomach pain, fever, fatigue, weakness, vomiting		X	
Lung problems (pneumonia, pneumonitis, interstitial lung disease): new or worsening lung problems, trouble breathing, shortness of breath, chest pain, cough, or fever		X	
Pulmonary embolism (blood clot in the lung): chest pain that may increase with deep breathing, cough, coughing up bloody sputum, shortness of breath		X	
Nausea	X		
Musculoskeletal pain (pain that affects the muscles and tendons along with bones): muscle pain, limb pain, joint pain and bone pain	X		
Vomiting	X		

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

This medicine does not require any special storage conditions.

Store at 15°C to 30°C.

Keep LUMAKRAS out of the sight and reach of children.

Ask your pharmacist how to throw away drugs you no longer use.

If you want more information about LUMAKRAS:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; the manufacturer's website www.amgen.ca, or by calling 1-866-50-AMGEN (1-866-502-6436).

This leaflet was prepared by Amgen Canada Inc.

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