LUMAKRAS®

This medicine has **provisional approval** in Australia for some patients with non small cell lung cancer. The decision to approve this medicine has been made on the basis of promising results from preliminary studies. More evidence is required to be submitted when available to fully confirm the benefit and safety of the medicine for this use.

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new. Please report side effects. See the full CMI for further details.

1. Why am I using LUMAKRAS?

LUMAKRAS contains the active ingredient sotorasib. LUMAKRAS is used to treat a type of lung cancer. For more information, see Section 1. Why am I using LUMAKRAS? in the full CMI.

2. What should I know before I use LUMAKRAS?

Your doctor has tested your tumour (cancer) to make sure that this medicine is right for you. Your doctor may ask you to do some other tests from time to time to check your progress. Do not use if you have ever had an allergic reaction to sotorasib or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use LUMAKRAS? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with LUMAKRAS and affect how it works. LUMAKRAS may interfere with how some medicines work. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use LUMAKRAS?

The recommended dose is 8 tablets taken by mouth once daily with or without food. Your doctor may have prescribed a lower dose. More instructions can be found in Section 4. How do I use LUMAKRAS? in the full CMI.

5. What should I know while using LUMAKRAS?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking LUMAKRAS. • Keep all your doctor's appointments so that your progress can be checked. • Tell your doctor if you become pregnant while taking LUMAKRAS.
Things you should not do	• Do not change your dose or stop taking LUMAKRAS unless your healthcare provider tells you to. • Do not give this medicine to anyone else, even if they have the same condition as you.
Driving or using machines	• LUMAKRAS should not affect your ability to drive and use machines.
Drinking alcohol	• There is no information on the effects of drinking

	alcohol while taking this medicine.
Looking after your medicine	• Store LUMAKRAS below 30°C. • Keep away from children.

For more information, see Section 5. What should I know while using LUMAKRAS? in the full CMI.

6. Are there any side effects?

Very common side effects include diarrhoea, nausea, vomiting, stomach pain, fatigue, and some abnormal blood test results. Serious side effects can include liver problems or new/ worsening shortness of breath, cough, or fever. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

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LUMAKRAS® (loo-ma-krass)

Active ingredient(s): *sotorasib* (so-tor-a-sib)

Consumer Medicine Information (CMI)

This leaflet provides important information about using LUMAKRAS. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using LUMAKRAS.**

Where to find information in this leaflet:

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1. Why am I using LUMAKRAS?

LUMAKRAS contains the active ingredient sotorasib.

It is used to treat a type of lung cancer called non-small cell lung cancer (NSCLC). The cancer is caused by an abnormal protein, called *KRAS G12C* that is involved in the growth of cells.

LUMAKRAS binds to the *KRAS G12C* protein and blocks the function of the protein in tumour cells. This may slow down or stop the growth of your lung cancer.

LUMAKRAS can only be prescribed if you have been previously treated for your lung cancer with other medicines, and your cancer is advanced or has spread to other parts of your body.

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

2. What should I know before I use LUMAKRAS?

Your healthcare provider will test your tumour (cancer) to make sure that LUMAKRAS is right for you.

Your healthcare provider may do further assessments including blood tests to check your liver function. If you have abnormal liver test results, your healthcare provider may decide to reduce the dose of LUMAKRAS or stop your treatment.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Before taking LUMAKRAS

Talk to your healthcare provider before taking this medicine. Tell them if you have:

- liver problems.
- lung or breathing problems.
- an intolerance to some sugars, such as lactose, or a rare genetic disorder (such as galactosaemia, or glucose-galactose intolerance or congenital lactase deficiency).

Warnings

Do not use LUMAKRAS if:

- You are allergic to sotorasib, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. The effects of LUMAKRAS in pregnant women are not known. Your healthcare provider will help you weigh the benefit against the risk of taking LUMAKRAS while you are pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known if the ingredients in LUMAKRAS pass into breast milk. Do not breastfeed during treatment with LUMAKRAS and for 1 week after the final dose.

Use in children or adolescents

- LUMAKRAS has not been studied in patients younger than 18 years of age.

3. What if I am taking other medicines?

Tell your healthcare provider if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect LUMAKRAS.

Medicines that may <u>reduce</u> the effect of LUMAKRAS include:

- Rifampin, an antibiotic, used to treat tuberculosis

- Medicines used to treat epilepsy called phenytoin, carbamazepine, or phenobarbital
- St. John's wort, which is herbal medicine used to treat depression
- Enzalutamide, a medicine that is used for prostate cancer
- Medicines used to reduce stomach acid and to treat stomach ulcers, indigestion, and heartburn such as: esomeprazole, lansoprazole, omeprazole, pantoprazole sodium, or rabeprazole (medicines known as 'proton pump inhibitors'); famotidine, nizatidine (medicines known as 'H2 receptor antagonists'). See special instructions in When to take LUMAKRAS.

LUMAKRAS may increase the effectiveness of some medicines including:

- Digoxin, a medicine used to treat heart failure.

LUMAKRAS may reduce the effectiveness of some medicines including:

- Alfentanil or fentanyl (used to treat severe pain)
- Medicines used to prevent organ rejection, such as cyclosporin, sirolimus, everolimus, or tacrolimus
- Medicines used to reduce cholesterol levels, such as simvastatin, or atorvastatin
- Midazolam, a medicine 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 amiodarone

- Some medicines known as anticoagulants that stop your blood clotting, such as rivaroxaban and apixaban.

4. How do I take LUMAKRAS?

How much to take

Take LUMAKRAS tablets exactly as your healthcare provider tells you to take it.

The recommended starting dose for LUMAKRAS dose is 8 tablets taken together once every day. Your healthcare provider may decrease your dose or ask you to stop your medicine, depending on how well you tolerate it.

How to take LUMAKRAS

LUMAKRAS can be taken with or without food.

Swallow your daily dose of LUMAKRAS tablets whole. Do not break, crush or chew tablets.

If you cannot swallow whole tablets

Place your daily dose of LUMAKRAS tablets in a drinking glass or cup with 120 mL of room temperature tap water.

- Do not use or any other liquids to disperse the tablets.
- Do not crush the tablets.

Gently swirl the glass or cup until the tablets disperse into small pieces. The tablets will not dissolve completely.

The appearance of the mixture may range from pale to bright yellow. Drink the mixture right away.

Rinse the glass or cup with an additional half a glass of tap water and drink it straight away to make sure that you have taken the full dose of LUMAKRAS.

If you do not drink the mixture immediately, stir the mixture again, and drink it within 2 hours of preparation.

When to take LUMAKRAS

- Take LUMAKRAS at about the same time each day.
- If you need to take an antacid medicine, take LUMAKRAS tablets either 4 hours before or 10 hours after the antacid.

If you throw up (vomit) after taking LUMAKRAS

If you vomit after taking a dose of LUMAKRAS, do not take an extra dose.

Take your next dose at your regular scheduled time.

If you forget to take LUMAKRAS

LUMAKRAS should be taken at the same time each day.

If you forget to take your dose at the usual time and it is:

- more than 6 hours until your next dose, **take** the missed dose as soon as you remember and then take your next dose at the usual time.

- less than 6 hours until your next dose, **skip** the missed dose and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much LUMAKRAS

If you think that you have used too much LUMAKRAS, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your healthcare provider, or
- go to the Emergency Department at your nearest hospital and take the LUMAKRAS pack with you.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using LUMAKRAS?

Things you should do

- Keep all your doctor's appointments so that your progress can be checked. Your doctor may ask you to have some tests from time to time to make sure the medicine is working.
- Contact your doctor without delay if you become pregnant while taking LUMAKRAS.

- Remind any doctor, dentist or pharmacist you visit that you are taking LUMAKRAS.

Call your doctor straight away if you:

- Show signs of a serious allergic reaction.

Things you should not do

- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not change your dose or stop taking LUMAKRAS unless your healthcare provider tells you to.
- Do not use this medicine after the expiry date (EXP) that is given on the blister and carton.

Driving or using machines

LUMAKRAS has no marked influence on the ability to drive and use machines.

Be careful before you drive or use any machines or tools until you know how LUMAKRAS affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

There is no information on the effects of taking LUMAKRAS and drinking alcohol.

Looking after your medicine

Store LUMAKRAS tablets below 30°C in the original carton.

Store the pack in a cool dry place away from moisture, heat or sunlight. For example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects are very common.

Less serious side effects	What to do
Gastrointestinal effects • Diarrhoea • Nausea • Vomiting • Stomach pain or discomfort **General effects** • Fatigue (feeling tired) **Blood test related** • Abnormal levels of some liver enzyme(s)	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects	What to do
Signs of liver problems • pain, aching, or tenderness on the right side of your stomach area (abdomen) • your skin or the white part of your eyes turn yellow (jaundice) • dark or “tea coloured” urine • light coloured stools (bowel movements)	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious liver side effects.**

Serious side effects	What to do
• tiredness or weakness • nausea or vomiting • bleeding or bruising • loss of appetite **Signs of lung inflammation** • new or worsening shortness of breath, cough, or fever.	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What LUMAKRAS tablets contain

Active ingredient **(main ingredient)**	sotorasib
Other ingredients **(inactive ingredients)**	microcrystalline cellulose (E460), lactose monohydrate, croscarmellose sodium (E468), magnesium stearate (vegetable-source, E470b), polyvinyl alcohol (E1203), titanium dioxide (E171), polyethylene glycol (E1521), purified talc (E553b), iron oxide yellow (E172).
Potential allergens	lactose 108 mg/tablet (as monohydrate)

LUMAKRAS is gluten-free.

Seek medical advice if you are allergic to any of the ingredients.

What LUMAKRAS looks like

LUMAKRAS is a yellow, oblong-shaped, film coated tablet, marked “AMG” on one side and “120” on the reverse (AUST R 353210).

LUMAKRAS is packed in blister cartons of 56* and 240 tablets. Some pack sizes* may not be marketed.

Who distributes LUMAKRAS

Amgen Australia Pty Ltd

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Sydney NSW 2000

Ph: 1800 803 638

www.amgenmedinfo.com.au

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