My treatment with Lumykras™ ▼ (sotorasib)

LUMYKRAS (sotorasib) is used to treat adults with advanced stages of a type of lung cancer called non-small cell lung cancer (NSCLC) that has spread to other parts of the body.

LUMYKRAS (sotorasib) can only be prescribed if you have been previously treated for your lung cancer with other medicines, and if your cancer has an abnormal *KRAS G12C* gene.

Please read the patient information leaflet (PIL) that comes with this medicine before starting and during treatment. If you do not have a copy, your doctor or nurse will be able to provide you with one, or you can access it online.

If you live in Great Britain, please visit:
https://www.medicines.org.uk/emc/product/12871/pil

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this guide or the patient information leaflet that comes with your medicine. By reporting side effects you can help provide more information on the safety of this medicine (see details below).

Reporting side effects: You can also report side effects directly to the Yellow Card Scheme website *https://yellowcard.mhra.gov.uk*. You can also search for MHRA Yellow Card in the Google Play Store or Apple App store. Side effects should also be reported to Amgen Limited on +44 (0) 1223 436441

If you have any questions or concerns about any aspect of your treatment, please speak to your doctor, nurse or pharmacist who will be able to advise you.

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Contents

You have been prescribed a treatment called Lumykras. It is used to treat adults with advanced stages of a type of lung cancer called non-small cell lung cancer (NSCLC) that has spread to other parts of the body. Lumykras contains the active substance sotorasib and belongs to a group of medicines known as antineoplastic agents (anti-cancer medicines).

It is important to take the time to understand your treatment schedule and what you can expect. The information in this booklet may help you to do that.

If you have any questions after reading this booklet, please ask your doctor or nurse. Be open with them about any concerns you have about your treatment or your health. Communicating with your doctor or nurse can help you to better understand your treatment.

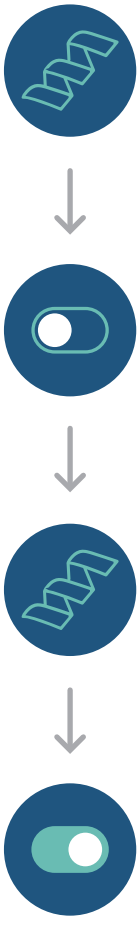
DAILY ORAL
LUMYKRAS™
(sotorasib)

Understanding *KRAS G12C*-mutated NSCLC

Non-small cell lung cancer (NSCLC) is a type of lung cancer. NSCLC happens when cells in the lungs grow rapidly and out of control, creating a mass of cancer cells called a tumour. Cancer cells may break off from the tumour and move to other parts of the body, forming new tumours. These are called metastases.

The rapid growth of cancer cells is caused by a range of factors, including mutations in genes that play key roles within our cells. Patients with *KRAS G12C*-positive NSCLC have an abnormal KRAS gene in their tumour.

What is *KRAS G12C*?



We all have a protein in our body called KRAS
Proteins are required for the structure, function and regulation of the body's cells, tissues and organs.

The KRAS protein works like an on/off switch
It relays messages that tell cells when to grow and when to stop growing.

Sometimes a protein can change and function abnormally
KRAS G12C is an altered form of the KRAS protein.

KRAS G12C causes the on/off switch to get stuck in the 'on' position
It causes continuous and uncontrollable cell growth, leading to cancer.

Facts about KRAS G12C

KRAS G12C is a type of biomarker
Biomarkers are molecules in your blood and other body fluids, and in the tissues of your body. Measuring biomarkers can help doctors to diagnose disease. There are different biomarkers in NSCLC, and looking at the biomarkers will show your doctor what type of NSCLC you have.

One of the most common NSCLC biomarkers is KRAS G12C
It relays messages that tell cells to grow.

13% of patients with NSCLC have the KRAS G12C biomarker

What is Lumykras (sotorasib)?

Lumykras is a prescription medicine for some adults with non-small cell lung cancer (NSCLC). You have been prescribed Lumykras by your doctor because:

Your tumour has a mutated (abnormal) form of the *KRAS G12C* gene and this has been verified via a biomarker test

Your NSCLC has been previously treated with other medicines (you may have already tried platinum-based chemotherapy and/or immunotherapy but cannot tolerate them or they have stopped working)

How does Lumykras work?

Lumykras is designed specifically for your type of lung cancer (NSCLC)

Lumykras targets KRAS G12C. It may slow down or stop the growth of your cancer

What do you need to know before you take Lumykras?

Do not take Lumykras if:
You are allergic to sotorasib or any of the other ingredients of this medicine listed in the patient information leaflet.

Warnings and precautions for Lumykras

Talk to your doctor, pharmacist, or nurse before taking Lumykras.

Tell your doctor, pharmacist or nurse if you have a history of liver problems. Your doctor should do blood tests to check your liver function before starting and during treatment with Lumykras, and may decide to either reduce the dose of Lumykras or stop your treatment.

Tell your doctor, pharmacist or nurse if you have lung or breathing problems other than lung cancer.

Children and adolescents

Lumykras has not been studied in children or adolescents. Treatment with Lumykras is not recommended in persons under 18 years of age.

Can I take other medications with Lumykras?

Before you begin taking Lumykras, tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, vitamins and herbal supplements. This is because Lumykras can affect the way some other medicines work, and some other medicines can affect the way Lumykras works.

Pregnancy and breastfeeding

The effects of Lumykras in pregnant women are not known. Tell your doctor, nurse or pharmacist if you are pregnant, think you are pregnant, or if you intend to become pregnant. Your doctor, nurse or pharmacist will help you weigh the benefit against the risk of taking Lumykras while you are pregnant.

It is not known whether the ingredients in Lumykras pass into breast milk. Tell your doctor, nurse or pharmacist if you are breast-feeding or are planning to breast-feed.

Lactose intolerance

If your doctor has told you that you have an intolerance to some sugars, you should not take Lumykras. Contact your doctor or nurse if you have any of these conditions.

Sodium

Lumykras contains less than 1 mmol sodium (23 mg) per tablet, so it is essentially 'sodium free'.

What do you need to know before you take Lumykras?

The following medicines may stop Lumykras from working as well:

- 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 'H2 receptor antagonists')
- Rifampicin (used to treat tuberculosis)
- Medicines used to treat epilepsy, called carbamazepine, phenytoin, or phenobarbital
- St. John's wort (herbal medicine used to treat depression)
- Enzalutamide (used to treat prostate cancer)

LUMYKRAS may increase the risk for side effects with the following medicines:

- Digoxin (used to treat heart problems including irregular heartbeat and heart failure)
- Rosuvastatin (used to lower cholesterol levels within your blood for those with complications such as heart disease)

Lumykras may reduce how well the following medicines work:

- Medicines used to treat severe pain, such as alfentanil or fentanyl
- Medicines used in organ transplantation to prevent organ rejection, such as cyclosporine, sirolimus, everolimus, or tacrolimus
- Medicines used to reduce 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 known as anticoagulants that stop your blood clotting, such as rivaroxaban or apixaban

How do I take Lumykras and when?

How do I take Lumykras and when?

Lumykras is a daily medicine
Take your daily dose of Lumykras by mouth once a day at the same time each day. Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Do not change your dose or stop taking Lumykras unless your doctor or pharmacist tells you to.

Lumykras recommended dose is 960 mg
Take eight 120 mg tablets once a day. This is your 960 mg dose. Your doctor, nurse or pharmacist could decrease your dose to either four tablets or two tablets once a day.

Swallow Lumykras tablets whole
Take Lumykras with or without food

Can Lumykras be given via a feeding tube?
Yes, If necessary, your doctor may recommend you receive LUMYKRAS through a feeding tube.

If you cannot swallow Lumykras tablets whole:

- Place your daily dose of Lumykras in half a glass (120 ml) of non-carbonated room-temperature water without crushing the tablets. Do not use any other liquids.
- Swirl gently until the tablets are in small pieces (the tablets will not completely dissolve). The colour of the mixture may be pale yellow to bright yellow.
- Drink the Lumykras and water mixture right away.
- Rinse the glass with an additional half a glass of water and drink right away to make sure that you have taken the full dose of Lumykras.
- If you do not drink all of the mixture immediately, stir the mixture again before you finish drinking it. Drink all of the mixture within 2 hours of preparation.

How do I take Lumykras and when?

What if I need to take a medicine to reduce stomach acid?

If you need to take a medicine to reduce stomach acid, Lumykras should be taken either 4 hours before or 10 hours after the stomach acid medicine.

What if I take more Lumykras than I should?

Contact your doctor, pharmacist or nurse immediately if you take more tablets than recommended.

What if I vomit after taking Lumykras?

If you vomit after taking Lumykras, do not take an additional dose on the same day. Take the next dose as prescribed the next day.

What if I miss a dose of Lumykras?

- If less than 6 hours have passed since the scheduled time of dosing, take the dose as normal.
- If more than 6 hours have passed since the scheduled time of dosing, do not take the dose.Take your next dose at your regular scheduled time the next day.

Important Lumykras safety information

Some possible side effects of Lumykras can be serious in nature. Most of these are not very common, but it's important to be aware of them because some people respond to medicines differently compared with others.

Contact your doctor, nurse or pharmacist immediately if you experience any of the following:

- **Liver problems:** A serious possible side effect of Lumykras is liver problems. Your doctor will have conducted blood tests to check your liver function before starting and during treatment with Lumykras. **Tell your doctor, nurse or pharmacist immediately if you get any signs or symptoms of liver problems,** including:
  - yellowing of the skin or the white part of your eyes (jaundice)
  - dark or "tea-coloured" urine
  - light-coloured 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:** Inflammation of the lungs occurred in some patients treated with Lumykras. This inflammation can damage your lungs and lead to breathing problems. **Tell your doctor, nurse or pharmacist immediately or get emergency medical help right away if you have new or worsening shortness of breath, cough or fever.**

Important Lumykras safety information

Other possible side effects of Lumykras may include:

Very common (may affect more than 1 in 10 people)	
Diarrhoea	Stomach pain
Joint, muscle or back pain	Constipation
Nausea	Low red blood cell count (anaemia)
Feeling tired	Shortness of breath
Vomiting	Headache
Cough	Fever or high temperature

Common (may affect more than 1 in 100 people)	
Swelling of your lower legs or hands	Decreased appetite
Increased enzyme levels in your blood (increased alkaline phosphatase)	Pneumonia
Increased blood pressure	Urinary tract infection
Decreased potassium in your blood	Rash
Decreased sodium in your blood	Decreased calcium in your blood

While these are the most common side effects of Lumykras, you may experience others too.

- It may help to write down any side effects you are having and how you feel. You can use these notes to remind yourself when you speak to your doctor, nurse or pharmacist

For more information on side effects, please see the Patient Information Leaflet (PIL) provided in your box of tablets.

This can also be accessed via the QR code or by visiting www.medicines.org.uk/emc/product/12871/pil#gref

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Storage and contents of Lumykras

How to store Lumykras?

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment

BLISTER PACK:
Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Contents of the pack and other information

Lumykras contains the active substance sotorasib. Each tablet contains 120 mg of sotorasib.

The other ingredients are:

- Microcrystalline cellulose
- Lactose monohydrate
- Croscarmellose sodium
- Magnesium stearate

The tablets are coated with:

- Polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, and iron oxide yellow

What Lumykras looks like and contents of the pack:

- Lumykras is supplied as a yellow, oblong-shaped, film-coated tablet, with 'AMG' on one side and '120' on the other side.
- Lumykras is provided in blisters containing 8 film-coated tablets in a pack size of 240 tablets (30 blisters)

Definitions

Chemotherapy
A treatment that uses drugs to stop the growth and division of cancer cells, either by killing the cells or by stopping them from dividing. It is often called 'chemo.'

Immunotherapy
A type of medicine that uses your body's own immune system to help fight cancer.

Intolerant
Inability to tolerate the adverse effects of a medication at the prescribed doses.

Mutation
A change in the DNA sequence of a gene.

Progressed
Worsening of disease. With cancer, progressive disease means that the tumour size has increased or the cancer has spread since the beginning of treatment.

For information please visit the following website.

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