Package leaflet: Information for the patient

LUMYKRAS 120 mg film-coated tablets
LUMYKRAS 240 mg film-coated tablets

sotorasib

▼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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What LUMYKRAS is and what it is used for
2. What you need to know before you take LUMYKRAS
3. How to take LUMYKRAS
4. Possible side effects
5. How to store LUMYKRAS
6. Contents of the pack and other information

1. What LUMYKRAS is and what it is used for

LUMYKRAS contains the active substance sotorasib and belongs to a group of medicines known as antineoplastic agents (anti-cancer medicines).

LUMYKRAS 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 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. Your doctor will test your cancer and make sure that LUMYKRAS is right for you.

How does LUMYKRAS work?

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

If you have any questions about how LUMYKRAS works or why this medicine has been prescribed for you, ask your doctor, pharmacist, or nurse.

2. What 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 section 6).

Warnings and precautions

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 and may decide to temporarily or permanently 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.

Other medicines and 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.

The following medicines may reduce how well LUMYKRAS works:
- Medicines used to reduce stomach acid and to treat stomach ulcers, indigestion and heartburn (see section 3) 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 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

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)

Pregnancy and breast-feeding

The effects of LUMYKRAS in pregnant women are not known.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

The effects of LUMYKRAS in pregnant women are not known. Tell your doctor or pharmacist if you are pregnant, think you are pregnant, or if you intend to become pregnant. Your doctor 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 or pharmacist if you are breast-feeding or are planning to breast-feed.

Driving and using machines

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

LUMYKRAS contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take LUMYKRAS

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. Your doctor or pharmacist may decrease the dose or stop your medicine depending on how well you tolerate it.

- The recommended dose is 960 mg (eight 120 mg tablets or four 240 mg tablets) once a day. Take your daily dose of LUMYKRAS by mouth once a day at the same time each day.
- If your doctor or pharmacist decreases your dose depending on the tablet strength you are prescribed, you should take either four tablets, two tablets or one tablet once a day at the same time each day.
- LUMYKRAS can be taken with or without food.
- Swallow tablets whole, unless you have difficulty swallowing tablets.
- If you cannot swallow LUMYKRAS tablets whole:
  - Place your daily dose of LUMYKRAS in half a glass (not less than 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 appearance of the mixture may range from pale 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 two hours of preparation.
- If necessary, your doctor may recommend you receive LUMYKRAS through a feeding tube.

If you need to take a medicine to reduce stomach acid such as a proton pump inhibitor or an H_2 receptor antagonist, take LUMYKRAS with an acidic beverage (such as cola). Alternatively, you may

use a local antacid (such as magnesium hydroxide or calcium carbonate) and, in that case, LUMYKRAS should be taken either 4 hours before or 10 hours after that medicine (see section 2).

If you take more LUMYKRAS than you should

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

If you vomit after taking LUMYKRAS

If you vomit after taking a dose of LUMYKRAS, do not take an extra dose. Take your next dose at your regular scheduled time.

If you forget to take LUMYKRAS

If you forget to take a dose of LUMYKRAS at your regular scheduled time, and less than 6 hours have passed, take your dose as normal. If more than 6 hours have passed from your regular scheduled time, do not take the dose. Take your next dose at your regular scheduled time the next day.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

A serious possible side effect of LUMYKRAS is liver problems. Your healthcare provider should do blood tests before starting and during treatment with LUMYKRAS to check your liver function. **Tell your doctor, pharmacist or nurse immediately** if you experience any signs or symptoms of liver problems, including your skin or the white part of your eyes turns yellow (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).

Inflammation of the lungs occurred in some patients treated with LUMYKRAS. **Tell your doctor, pharmacist or nurse immediately** or get emergency medical help right away if you have new or worsening shortness of breath, cough, or fever.

Your doctor may decide to either reduce the dose of LUMYKRAS or stop your treatment if you develop side effects (see section 3).

Other possible side effects of LUMYKRAS may include:

Very common (may affect more than 1 in 10 people)
- Diarrhoea
- Joint, muscle or back pain
- Nausea
- Feeling tired
- Vomiting
- Cough
- Stomach pain
- Constipation
- Low red blood cell count (anaemia)
- Shortness of breath
- Decreased appetite
- Increased levels of liver enzymes in blood

Common (may affect more than 1 in 100 people)
- Swelling of your lower legs or hands
- 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
- Headache
- Inflammation of the lungs called “interstitial lung disease”
- Fever or high temperature

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store LUMYKRAS

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

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.

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.

6. Contents of the pack and other information

What LUMYKRAS contains

- The active substance is sotorasib. Each tablet contains 120 mg or 240 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 120 mg film-coated tablets

Each film-coated tablet 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).
- LUMYKRAS is provided in bottles of 120 tablets in a pack of 240 film-coated tablets (2 bottles) per carton.

LUMYKRAS 240 mg film-coated tablets

Each film-coated tablet is supplied as a yellow, oval-shaped, film-coated tablet, with “AMG” on one side and “240” on the other side.

- LUMYKRAS is provided in perforated unit dose blisters containing 8 film-coated tablets in a pack size of 120 film-coated tablets (1 carton with 15 blisters).

Not all pack sizes may be marketed.

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