Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) 1986
This medicine is dispensed according to a doctor's prescription only

LUMYKRAS 120 mg film-coated tablets

Each film-coated tablet contains 120 mg of sotorasib.
For inactive ingredients and allergens in the product - see section 6 "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

Lumykras is indicated for the treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an approved test, who have received at least one prior systemic therapy.

Therapeutic group:

Lumykras belongs to a group of medicines known as antineoplastic agents (cancer medicines).

Lumykras is used to treat adults with a type of lung cancer called non-small cell lung cancer (NSCLC) when it is advanced and has spread to other parts of the body.

Lumykras is used when previous treatments were not effective in stopping the growth of the cancer, and when the cancer cells have a genetic change that allows them to produce an abnormal form of protein called KRAS G12C. The abnormal KRAS G12C protein, acts to help make cancer cells grow out of control. **Lumykras** attaches to the protein and stops it from working, which may slow down or stop the growth of the cancer.
Your doctor will test your cancer cells for this change beforehand to make sure that **Lumykras** is right for you.

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. Before using the medicine

X Do not use the medicine if:
you are sensitive (allergic) to sotorasib or any of the other ingredients of this medicine (listed in section 6).

Special warnings regarding use of the medicine

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

Before treatment with Lumykras, tell the doctor:

- if you have a history of liver problems. Your doctor may carry out blood tests to check your liver function, and may decide to either reduce the dose of **Lumykras** or stop your treatment.
- if you have ever had any other lung problems. Some lung problems may get worse during treatment with **Lumykras**, as **Lumykras** may cause inflammation of the lungs during treatment. Symptoms may be similar to those from lung cancer. Tell your doctor right away if you have any new or worsening symptoms including difficulty in breathing, shortness of breath, or cough with or without mucous, or fever.

Children and adolescents
This medicine is not intended to be used by children and adolescents under 18 years of age.
There is no information on safety and efficacy of this medicine in children and adolescents under 18 years of age.

Tests and follow-up
Your doctor may carry out blood tests to check how well your liver is working and may decide to either reduce the dose of **Lumykras** or stop your treatment (see section 4).

Other medicines and Lumykras
If you are taking or have recently taken other medicines, including non-prescription medications and nutritional supplements, tell your doctor or pharmacist.
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 phenytoin, phenobarbital or carbamazepine (also used to treat nerve pain);
- 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:
- Medicines used to treat certain cancers or inflammatory conditions, such as methotrexate, mitoxantrone, topotecan or lapatinib;
- Medicines used to treat heart failure, such as digoxin;
- Medicines used to lower cholesterol, such as rosuvastatin.

Contraception
If you take **Lumykras** whilst using oral contraceptives, the oral contraceptives may be ineffective. In addition, you should use another reliable method of birth control such as a barrier method (e.g. condom) so you do not become pregnant while you are taking this medicine. Talk to your doctor about the right methods of contraception for you and your partner.

Use of the medicine and food
Lumykras can be administered with or without food.

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

You should not become pregnant while taking this medicine because the effects of **Lumykras** in pregnant women are not known, it could harm the baby. If you are able to become pregnant, you must use highly effective contraception while on treatment and for at least 7 days after stopping treatment.

Breast-feeding
Do not breast-feed while taking this medicine and for 7 days after the last dose. This is because it is not known whether the ingredients in **Lumykras** pass into breast milk and could therefore harm your baby.

Driving and using machines
Lumykras has no marked influence on the ability to drive and use machines.

Important information regarding some of the ingredients of the medicine
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 medicine.
Lumykras contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How should you use the medicine?

Always use this medicine in accordance with doctor's instructions. Check with your doctor or pharmacist if you are uncertain about the medicine dosage and treatment regimen.

The dosage and treatment regimen will be determined by the doctor only.
Do not exceed the recommended dose.

Duration of treatment
Treatment with **Lumykras** is recommended until disease progression or unacceptable toxicity.

Do not change your dose or stop taking **Lumykras** unless your doctor tells you to. Your doctor may decrease the dose or stop your medicine depending on how well you tolerate it.

- The recommended dose is eight tablets (960 mg) once a day. Take your daily dose of **Lumykras** by mouth once a day, at the same time each day.

Method of administration

- **Lumykras** can be taken with or without food.
- Swallow the tablets whole. You can disperse the tablets in water but do not chew, crush, or split the tablets.
- If you cannot swallow **Lumykras** tablets whole:
  - Place your daily dose of **Lumykras** in half a glass (not less than 120 mL) of plain, room temperature drinking water, without crushing the tablets. Do not use any other liquids, including acidic beverages (e.g. fruit juices).
  - Swirl gently until the tablets are in 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.
  - Fill the same 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 you need to take a medicine to reduce stomach acid, proton pump inhibitors and H2 receptor antagonists are not recommended (see section 2). You may use a local antacid and **Lumykras** should be taken either 4 hours before or 10 hours after the antacid (see section 2).

If you accidentally took a higher dose
Contact your doctor, pharmacist or nurse immediately if you take more tablets than recommended. If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or to a hospital emergency room and bring the package of the medicine with you.

If you vomit after taking the medicine
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 the medicine
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.

Persist with the treatment as recommended by the doctor.

If you stop treatment with the medicine
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting first with the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have any further questions regarding the use of this medicine, consult a doctor or a pharmacist.

4. Side effects

Like any medicine, using **Lumykras** may cause side effects in some of the users. Do not be alarmed by reading the list of side effects.You may not suffer from any one of them.

Very common and serious possible side effects of **Lumykras** are increased blood levels of certain liver enzymes (AST/ALT), which are a sign of liver problems. Your doctor may do blood tests to check how well your liver is working and may decide to either reduce the dose of **Lumykras** or stop your treatment (see section 2).

Other possible side effects of **Lumykras** may include:

Very common (may affect more than 1 in 10 patients)
- Diarrhoea;
- Feeling sick (nausea);
- Feeling tired;
- Vomiting;
- Constipation;
- Stomach pain;
- Fever;
- Joint pain;
- Back pain;
- Shortness of breath;
- Cough;
- Low red blood cell count (anaemia) which may cause tiredness and fatigue;
- Headache.

Common (may affect up to 1 in 10 patients)
- High levels of some enzymes including blood enzymes seen in tests (increased alkaline phosphatase, bilirubin and gamma-glutamyltransferase);
- Liver injury.

Uncommon (may affect up to 1 in 100 patients)
- Inflammation of the lungs called “interstitial lung disease”.

If a side effect occurs, if any of the side effects gets worse or if you suffer from a side effect not mentioned in the leaflet, you should consult with the doctor.

Reporting of side effects

You can report adverse reactions to the Ministry of Health by clicking on the link "report on adverse reactions following medication treatment" located on the homepage of the Ministry of Health website (www.health.gov.il) which directs you to the online form for reporting adverse reactions or by entering the link: https://sideeffects.health.gov.il/

5. How to store the medicine?

Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the sight and reach of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

Do not use this medicine after the expiry date (exp.date) which is stated on the blister and carton . 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. Additional Information

In addition to the active ingredient, this medicine also contains:
- Cellulose, microcrystalline (E460(i))
- Lactose monohydrate
- Croscarmellose sodium (E468)
- Magnesium stearate, Non-bovine (E470b)

The tablets are coated with:
- Polyvinyl alcohol (E1203), titanium dioxide (E171), macrogol 4000 (E1521), talc (E553b), iron oxide yellow (E172).

See **Lumykras** contains lactose and sodium in section 2.

What does the medicine look like and what are the contents of the pack?
Yellow, oblong-shaped, film-coated tablet, debossed with “AMG” on one side and “120” on the opposite side.

- The tablets are provided in blisters containing 8 film-coated tablets in packs of 240 tablets (one carton with 30 blisters) and bottles containing 120 film-coated tablets in packs of 240 tablets (one carton with 2 bottles).

Not all packs may be marketed.

Manufacturer: Amgen Europe B.V., Minervum 7061, 4817 ZK Breda, The Netherlands.

License Holder: Amgen Europe B.V., P.O. BOX 53313, Tel - Aviv, Israel.

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Registration number of the medicine in the National Drug Registry of the Ministry of Health:
169-95-37013