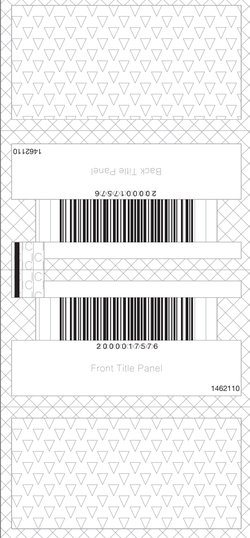

Package leaflet: Information for the patient
KRAZATI 200 mg film-coated tablets
adagrasib

▼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 KRAZATI is and what it is used for

KRAZATI contains the active substance adagrasib and belongs to a group of medicines known as antineoplastic agents (cancer medicines).

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

KRAZATI is used when previous treatments were not effective in stopping the growth of the cancer, and when the cancer cells have been altered, they produce a rare protein called KRAS G12C. Your doctor will test for this alteration in your cancer cells to make sure that KRAZATI is right for you.

How does KRAZATI work?
The rare KRAS G12C protein makes the cancer cells grow out of control. KRAZATI attaches to the protein and stops it from working, which may slow down or stop the growth of the cancer.

If you have any questions about how this medicine 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 KRAZATI

Do not take KRAZATI
- If you are allergic to adagrasib 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 KRAZATI.

KRAZATI may affect your liver. Your doctor may carry out some tests before you begin taking KRAZATI and once a month for the first 3 months of your treatment. Your dose may then be either reduced, interrupted, or stopped accordingly.

Talk to your doctor **before** you take KRAZATI if you have heart or circulation problems, if you experience fast or irregular heartbeats or take any heart medication. Your doctor will decide if this medicine is suitable for you and may monitor your heart with an ECG (electrocardiogram) and adjust your dose of KRAZATI accordingly.

Talk to your doctor **during** your treatment if you:
- feel dizzy or develop any heart problems such as a fast or irregular heartbeat.
- feel nauseous, vomit and/or experience diarrhoea. Your doctor may give you medicine and fluids to help with these symptoms, or he may temporarily reduce or stop your treatment where these symptoms persist.
- develop increased breathlessness, cough or a fever.

Tell your healthcare provider or get medical help right away if you notice any progressive symptoms related to serious skin reactions, such as inflammation of the skin (which may include rash, itching, skin blistering, peeling or sores), and/or ulcers in mouth or in lining of nose, throat, or genital area, accompanied by fever or flu-like symptoms.

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

Other medicines and KRAZATI
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes herbal supplements and medicines obtained without prescription. This is because KRAZATI can affect how some other medicines work. Also, some other medicines can affect how KRAZATI works.

The following medicines may reduce how well KRAZATI works:
- carbamazepine, phenytoin, phenobarbital (used to treat epilepsy)
- rifampicin (used to treat tuberculosis)
- St John's Wort (Hypericum perforatum; available as either a medicine or a herbal supplement and is used to treat depression)

The following medicines may increase the risk for side effects with KRAZATI by increasing the levels of KRAZATI in the blood. These medicines can only be used once you have taken KRAZATI for 8 days:
- itraconazole, ketoconazole (used to treat fungal infections)
- ritonavir (used with other medications to treat HIV infection)

The following medicines may increase the risk for side effects with KRAZATI by increasing the levels of KRAZATI in the blood:
- gemfibrozil (used to lower high cholesterol)

KRAZATI may increase the side effects of some medicines by increasing the amount of these medicines in the blood. Examples of these medicines include:
- alfuzosin (used to treat benign prostatic hyperplasia)
- amiodarone (used to treat heart problems)
- cisapride (used to treat symptoms of nighttime heartburn and other gastrointestinal disorders)
- colchicine (used to treat gout)
- dabigatran (used to treat and prevent blood clots)
- digoxin, propafenone (used to treat heart problems)
- ergotamine, dihydroergotamine (used to treat migraines)
- lovastatin, simvastatin (used to lower cholesterol levels)
- sildenafil (for the treatment of pulmonary arterial hypertension)
- pimozide, quetiapine, thioridazine (antipsychotic medicines)
- quinidine (used to treat malaria and heart problems)
- triazolam (used to treat insomnia)
- sirolimus, tacrolimus (used to prevent rejection of transplanted organs)
- ticagrelor (used to prevent heart attack and stroke)
- warfarin (used to treat blood clots). Your doctor may need to monitor the time your blood takes to clot (INR test).

Some medicines may cause a change in the electrical conduction in your heart, particularly when taken with KRAZATI.
Examples include:
- some medicines for heart rhythm disorders (e.g. amiodarone, disopyramide, dofetilide, ibutilide, quinidine, sotalol)
- some medicines to treat bacterial infections (e.g. azithromycin, ciprofloxacin, moxifloxacin)
- some medicines used to treat schizophrenia and mood disorders (e.g. haloperidol)
- others (e.g. methadone for pain and opioid addiction)

Pregnancy
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.

Do not take KRAZATI if you are pregnant, or suspect you are pregnant, unless advised by your doctor. The effects of KRAZATI in pregnant women are not known.

Contraception
Women must use an effective method of contraception to avoid becoming pregnant during treatment with KRAZATI.

Breast-feeding
Do not breast-feed your baby whilst you are being treated with KRAZATI, and for at least 7 days after your final dose. It is not known if this medicine passes to the baby via breast milk.

Driving and using machines
KRAZATI has a minor influence on the ability to drive and use machines. If you feel dizzy or a spinning sensation, do not drive, use machinery, or take part in activities where this puts yourself or others at risk.

3. How to take KRAZATI

You will be prescribed this medicine by a doctor experienced in the use of anti-cancer medicines. Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much to take
The recommended dose is **three 200 mg tablets twice daily**.

Do not change your dose or stop taking KRAZATI unless your doctor or pharmacist tells you to.

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

How to take
Take the medicine at the same time each day. You can take the medicine with or without food.
Swallow the tablets whole with water.

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

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

If you forget to take KRAZATI
If you miss a dose, take it as soon as possible. If you miss your dose by more than 4 hours, skip that dose and take your usual dose at the next scheduled time. Do not take a double dose to make up for a forgotten dose.

If you stop taking KRAZATI
Do not stop taking this medicine. Talk to your doctor first. It is important to take this medicine every day, for as long as your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
Very common and serious possible side effects of KRAZATI are abnormalities with the electrical system of the heart called QT prolongation.

Tell your doctor immediately if you develop
- chest pain,
- shortness of breath,
- a fast heart rate or pounding heartbeat.

Your doctor may monitor your heart with an ECG (electrocardiogram) and may decide to either reduce the dose of KRAZATI or stop your treatment (see section 2).

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

Other possible side effects of KRAZATI may include:

Very common
(may affect more than 1 in 10 people)
- low red blood cell counts which can cause tiredness and pale skin
- low blood sodium levels which can cause headache, tiredness, fits and coma
- loss of appetite
- feeling dizzy, a spinning sensation
- feeling sick (nausea)
- diarrhoea
- vomiting
- blood test results indicating a sign of kidney problems
- tiredness, weakness
- swelling especially of the ankles and feet due to fluid retention
- abnormal blood test results indicate high levels of lipase and/or amylase in your blood stream

Common
(may affect up to 1 in 10 people)
- inflammation of the lungs
- decreased level of white blood cells in the blood
- decreased number of platelets, components that help blood to clot
- low blood potassium levels which can cause weakness, muscle cramps, tingling and heart rhythm disturbance
- low blood magnesium levels
- low levels of albumin, a blood protein

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 via the Yellow Card Scheme. Website www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store KRAZATI

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

This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from moisture. Keep the bottle tightly closed.

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

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 KRAZATI contains
- The active substance is adagrasib. Each film-coated tablet contains 200 mg adagrasib.
- The other ingredients are:
  Tablet core
  Microcrystalline cellulose (E 460), Mannitol (E 421), Crospovidone, Colloidal silicon dioxide (E 551), Magnesium stearate (vegetable).
  Film-coating
  Hypromellose, Titanium dioxide (E 171), Polydextrose (E 1200), Talc (E 553b), Maltodextrin, Medium chain triglycerides (vegetable).

What KRAZATI looks like and contents of the pack
KRAZATI film-coated tablets are white to off-white and oval shaped, with a stylised 'M' on one side and '200' marked on the other side.

The medicine comes in white opaque plastic bottles with white, child resistant lid and a heat-induction seal. Each bottle contains two silica gel desiccant packets which must be kept in the bottle to help protect your tablets from moisture. They must not be swallowed.

The pack sizes are bottles with either 120 or 180 film-coated tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder
Bristol-Myers Squibb Pharma EEIG
Plaza 254
Blanchardstown Corporate Park 2
Dublin 15, D15 T867
Ireland

Manufacturer
Swords Laboratories Unlimited Company
T/A Bristol-Myers Squibb Pharmaceutical Operations
External Manufacturing
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