Package leaflet: Information for the patient

Alunbrig 30 mg film-coated tablets
Alunbrig 90 mg film-coated tablets
Alunbrig 180 mg film-coated tablets
brigatinib

▼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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Alunbrig is and what it is used for

Alunbrig contains the active substance brigatinib, a type of cancer medicine called a kinase inhibitor. Alunbrig is used to treat adults with advanced stages of a **lung cancer** called non-small cell lung cancer. It is given to patients whose lung cancer is related to an abnormal form of a gene called anaplastic lymphoma kinase (*ALK*).

How Alunbrig works

The abnormal gene produces a protein known as a kinase that stimulates the growth of the cancer cells. Alunbrig blocks the action of this protein and thus slows down the growth and spread of the cancer.

2. What you need to know before you take Alunbrig

Do not take Alunbrig:

- if you are **allergic** to brigatinib or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor before taking Alunbrig or during treatment if you have:

- **lung or breathing problems**
  Lung problems, some severe, are more frequent within the first 7 days of treatment. Symptoms may be similar to symptoms from lung cancer. Tell your doctor of any new or worsening symptoms including breathing discomfort, shortness of breath, chest pain, cough and fever.
- **high blood pressure**
- **a slow heartbeat (bradycardia)**
- **vision disturbance**
  Inform your doctor of any visual disturbance that occurs during treatment, such as seeing flashes of light, blurry vision or light hurting your eyes.
- **muscle problems**
  Report any unexplained muscle pain, tenderness or weakness to your doctor.
- **pancreas problems**
- **liver problems**
- **high blood sugar**

Tell your doctor if you have kidney problems or you are on dialysis.

Your doctor may need to adjust your treatment or stop Alunbrig temporarily or permanently. See also the beginning of section 4.

Children and adolescents

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

Other medicines and Alunbrig

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The following medicines can affect or be affected by Alunbrig:
- **ketoconazole, itraconazole, voriconazole:** medicines to treat fungal infections
- **indinavir, nelfinavir, ritonavir, saquinavir:** medicines to treat HIV infection
- **clarithromycin, telithromycin, troleandomycin:** medicines to treat bacterial infections
- **mibefradil:** a medicine to treat irregular heart rhythm and high blood pressure
- **nefazodone:** a medicine to treat depression
- **St. John's wort:** a herbal product used to treat depression
- **carbamazepine:** a medicine to treat epilepsy, euphoric/depressive episodes and certain pain conditions
- **phenobarbital, phenytoin:** medicines to treat epilepsy
- **rifabutin, rifampicin:** medicines to treat tuberculosis or certain other infections
- **digoxin:** a medicine to treat heart problems
- **dabigatran:** a medicine to inhibit blood clotting
- **colchicine:** a medicine to treat gout attacks
- **pravastatin, rosuvastatin:** medicines to lower elevated cholesterol levels
- **methotrexate:** a medicine to treat severe joint inflammation, cancer and the skin disease psoriasis
- **sulfasalazine:** a medicine to treat severe bowel and rheumatic joint inflammation
- **efavirenz**, **etravirine:** medicines to treat HIV infection
- **modafinil:** a medicine to treat narcolepsy
- **bosentan:** a medicine to treat pulmonary hypertension

- **nafcillin:** a medicine to treat bacterial infections
- **alfentanil, fentanyl:** medicines to treat pain
- **quinidine:** a medicine to treat irregular heart rhythm
- **cyclosporine, sirolimus, tacrolimus:** medicines to suppress the immune system

Alunbrig with food and drink

Avoid any grapefruit products during treatment as they may change the amount of brigatinib in your body.

Pregnancy

Alunbrig is **not recommended** during pregnancy unless the benefit outweighs the risk to the baby. If you are pregnant or think you may be pregnant or are planning to have a baby, talk to your doctor to discuss the risks of taking Alunbrig during pregnancy.

Women of childbearing age being treated with Alunbrig should avoid becoming pregnant. Effective non-hormonal contraception must be used during treatment and for 4 months after stopping Alunbrig. Ask your doctor about the birth control methods that may be right for you.

Breast-feeding

Do not breast-feed during treatment with Alunbrig. It is unknown if brigatinib passes into breast milk and could potentially harm the baby.

Fertility

Men receiving treatment with Alunbrig are advised not to father a child during treatment and to use effective contraception during treatment and for 3 months after stopping.

Driving and using machines

Alunbrig may cause visual disturbances, dizziness or tiredness. Do not drive or use machines during treatment if such signs occur.

Alunbrig 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.

3. How to take Alunbrig

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is

One 90 mg tablet once daily for the first 7 treatment days; thereafter, one 180 mg tablet once daily. Do not change the dose without talking to your doctor. Your doctor may adjust your dose according to your needs and this may require use of a 30 mg tablet to achieve the new recommended dose.

Treatment initiation pack

At the beginning of your treatment with Alunbrig your doctor may prescribe a treatment initiation pack.

Method of use

- Take Alunbrig once daily at the same time each day.
- Swallow the tablets whole, with a glass of water. Do not crush or dissolve the tablets.
- The tablets can be taken with or without food.
- If you vomit after taking Alunbrig, do not take any more tablets until your next scheduled dose.

Do not swallow the desiccant canister contained in the bottle.

If you take more Alunbrig than you should

Tell your doctor or pharmacist right away if you have taken more tablets than recommended.

If you forget to take Alunbrig

Do not take a double dose to make up for a forgotten dose. Take your next dose at your regular time.

If you stop taking Alunbrig

Do not stop taking Alunbrig before talking to your doctor.

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

4. Possible side effects

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

Tell your doctor or pharmacist immediately if you have any of the following serious side effects:

Very common (may affect more than 1 in 10 people):

- **high blood pressure**
  Tell your doctor if you get headaches, dizziness, blurred vision, chest pain or shortness of breath.
- **vision problems**
  Tell your doctor if you experience any visual disturbances, such as seeing flashes of light, blurry vision or light hurting eyes. Your doctor may stop Alunbrig treatment and refer you to an ophthalmologist.
- **increased blood level of creatine phosphokinase in tests** – may indicate muscle damage, such as of the heart. Tell your doctor if you have any unexplained muscle pain, tenderness or weakness.
- **increased blood levels of amylase or lipase in tests** – may indicate inflammation of the pancreas
  Tell your doctor if you have upper abdominal pain, including abdominal pain that gets worse with eating and may spread to the back, weight loss or nausea.
- **increased blood levels of liver enzymes (aspartate aminotransferase, alanine aminotransferase) in tests** -may indicate liver cell damage. Tell your doctor if you have pain on the right side of your stomach area, yellowing of your skin or the whites of your eyes, or dark urine.
- **increased blood sugar**
  Tell your doctor if you are feeling very thirsty, need to urinate more than usual, feeling very hungry, sick to your stomach, weak or tired, or confused.

Common (may affect up to 1 in 10 people):

- **lung inflammation**
  Tell your doctor if you have any new or worsening lung or breathing problems, including chest pain, cough, and fever, especially within the first week of taking Alunbrig, as they may be a sign of serious lung problems.
- **slow heartbeat**
  Tell your doctor if you have chest pain or discomfort, changes in heartbeat, dizziness, light-headedness or fainting.
  See also section 2, "Warnings and precautions".

Other possible side effects are:
Tell your doctor or pharmacist if you notice any of the following side effects

Very common (may affect more than 1 in 10 people):

- lung infection (pneumonia)
- cold-like symptoms (upper respiratory tract infection)
- reduced number of red blood cells (anaemia)
- reduced number of white blood cells, called neutrophils and lymphocytes, in blood tests
- increased blood clotting time shown by test of activated partial thromboplastin time
- low platelet counts in blood tests, which may increase the risk of bleeding and bruising
- increased blood level of insulin
- reduced blood level of phosphorus
- decreased appetite
- reduced blood level of potassium
- reduced blood level of magnesium
- reduced blood level of sodium
- increased blood level of calcium
- difficulty sleeping (insomnia)
- headache
- symptoms such as numbness, tingling, prickling sensation, weakness or pain in hands or feet (peripheral neuropathy)
- dizziness
- cough
- shortness of breath
- nausea
- diarrhoea
- vomiting
- constipation
- abdominal (belly) pain
- dry mouth
- inflammation of the mouth and lips (stomatitis)
- increased blood level of the enzyme alkaline phosphatase – may indicate organ malfunction or injury
- rash
- skin itching
- joint or muscle pain
- musculoskeletal chest pain
- increased blood level of creatinine – may indicate reduced kidney function
- fatigue
- tissue swelling caused by excess fluid
- fever

Common (may affect up to 1 in 10 people):

- memory impairment
- change in sense of taste

- rapid heartbeat (tachycardia)
- abnormal electrical activity of the heart (prolonged electrocardiogram QT interval)
- palpitations
- indigestion
- flatulence
- increased blood level of lactate dehydrogenase – may indicate tissue breakdown
- increased blood level of bilirubin
- dry skin
- sensitivity to sunlight
- pain in arms and legs
- muscle and joint stiffness
- pain
- chest pain and discomfort
- weight loss

Uncommon (may affect up to 1 in 100 people)
- inflammation of pancreas which may cause severe and persistent stomach pain, with or without nausea and vomiting (pancreatitis)

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. 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 Alunbrig

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

Do not use this medicine after the expiry date which is stated on either the bottle label or blister and carton 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 waste water 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 Alunbrig contains
- The active substance is brigatinib.
  Each 30 mg film-coated tablet contains 30 mg brigatinib.
  Each 90 mg film-coated tablet contains 90 mg brigatinib.
  Each 180 mg film-coated tablet contains 180 mg brigatinib.

- The other excipients are lactose monohydrate, microcrystalline cellulose, sodium starch glycolate (type A), silica colloidal hydrophobic, magnesium stearate, talc, macrogol, polyvinyl alcohol, and titanium dioxide.

What Alunbrig looks like and contents of the pack

Alunbrig film-coated tablets are white to off-white, oval (90 mg and 180 mg) or round (30 mg). They are convex on the upper and lower side.

Alunbrig 30 mg:
- Each 30 mg tablet contains 30 mg brigatinib.
- The film-coated tablets are approximately 7 mm in diameter with “U3” on one side and plain on the other side.

Alunbrig 90 mg:
- Each 90 mg tablet contains 90 mg brigatinib.
- The film-coated tablets are approximately 15 mm long with “U7” on one side and plain on the other side.

Alunbrig 180 mg:
- Each 180 mg tablet contains 180 mg brigatinib.
- The film-coated tablets are approximately 19 mm long with “U13” on one side and plain on the other side.

Alunbrig is available in plastic foil strips (blisters) packed in a carton with:
- Alunbrig 30 mg: 28, 56 or 112 film-coated tablets
- Alunbrig 90 mg: 7 or 28 film-coated tablets
- Alunbrig 180 mg: 28 film-coated tablets

Alunbrig is available in plastic bottles with child resistant screw top closures. Each bottle contains one canister of a desiccant and is packed in a carton with:
- Alunbrig 30 mg: 60 or 120 film-coated tablets
- Alunbrig 90 mg: 7 or 30 film-coated tablets
- Alunbrig 180 mg: 30 film-coated tablets

Alunbrig is available as a treatment initiation pack. Each pack consists of an outer carton with two inner cartons containing:
- Alunbrig 90 mg film-coated tablets
  1 plastic foil strip (blister), containing 7 film-coated tablets
- Alunbrig 180 mg film-coated tablets
  3 plastic foil strips (blisters), containing 21 film-coated tablets

Keep the desiccant canister in the bottle.

Not all pack sizes may be marketed.

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency website: http://www.ema.europa.eu.