Approved ALUNBRIG™ Patient Information Leaflet

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM ALUNBRIG™ 30 mg (FILM-COATED TABLETS)

ALUNBRIG™ 90 mg (FILM-COATED TABLETS)

ALUNBRIG™ 180 mg (FILM-COATED TABLETS)

Contains sugar: lactose monohydrate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do not share **ALUNBRIG™** with any other person
- Ask your doctor, pharmacist, nurse if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

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, of the adenenocarcinoma cell type. It is given to patients whose lung cancer is related to an abnormal form of a gene called anaplastic lymphoma kinase (*ALK*).

***ALUNBRIG™** is used to treat patients whose lung cancer is related to an abnormal form of a gene called ALK, previously not treated with an ALK inhibitor.*

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).
- if you are a woman who is pregnant or are planning to become pregnant within four months.
- if you are a man planning to father a child within three months.
- a woman should not breastfeed her baby while taking **ALUNBRIG™**

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
- 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
- phenobarbitone, 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
- cyclosporin, 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 for use during pregnancy. 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™**.

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. Do not share medicines prescribed for you with any other person.

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

This medicine can cause side effects.

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

Frequent side effects:

- 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.

- 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

Frequent side effects:

- 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
- 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

Less common frequent side effects:

- 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 or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. 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.

Store at or below 30 °C. For bottle: Keep bottle tightly closed. For blisters: Keep blisters enclosed in carton until required for use.

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 clear 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 white plastic bottles with child resistant white 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 clear plastic foil strip (blister), containing 7 film-coated tablets

- **ALUNBRIG™** 180 mg film-coated tablets

3 clear plastic foil strips (blisters), containing 21 film-coated tablets

Keep the desiccant canister in the bottle.

Not all pack sizes may be marketed.

REGISTRATION NUMBER

ALUNBRIG™ 30 mg film coated tablets

52/26/0353

ALUNBRIG™ 90 mg film coated tablets

52/26/0354

ALUNBRIG™ 180 mg film coated tablets

52/26/0355

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THIS LEAFLET WAS LAST REVISED IN:

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