



## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

S4

**Alecensa® 150 mg** (Hard capsule)

Alectinib

Contains sugar, lactose monohydrate 33,67 mg

### Read all of this leaflet carefully before you start using Alecensa

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- Alecensa has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

### What is in this leaflet

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

#### 1. What Alecensa is and what it is used for

Alecensa is a cancer medicine that contains the active ingredient alectinib.

Alecensa blocks the action of an enzyme called 'ALK tyrosine kinase'. Abnormal forms of this enzyme (due to fault in the gene that makes it) help encourage cancer cell growth. Alecensa may slow down or stop the growth of your cancer. It may also help to shrink your cancer.

Alecensa is used to treat adults with a type of lung cancer called 'non-small cell lung cancer' ('NSCLC'). It is used if your lung cancer:

- is 'ALK-positive' - this means your cancer cells have a fault in a gene that makes an enzyme called ALK ('anaplastic lymphoma kinase'), see 'How Alecensa works'
- and is advanced.

Alecensa can be prescribed to you as first treatment of your lung cancer, or if you have been previously treated with a medicine containing 'crizotinib'.

## 2. What you need to know before you take Alecensa

### Do not use Alecensa:

- If you are allergic to alectinib or to any of the other ingredients of this medicine, listed in "What Alecensa contains". If you are not sure, talk to your doctor or nurse before taking Alecensa.
- If you are pregnant or are breastfeeding your baby.

### Warnings and precautions

Talk to your doctor or healthcare professional before you take Alecensa:

- if you have an inherited problem called 'galactose intolerance', 'congenital lactase deficiency' or 'glucose-galactose malabsorption'.

Alecensa can cause side effects that you need to tell your doctor about straight away. These include:

- Liver injury (hepatotoxicity). Your doctor will take blood tests before you start treatment, then every 2 weeks for the first 3 months of your treatment and then less often. This is to check you do not have any liver problems while taking Alecensa. Tell your doctor straight away if you get any of the following signs: yellowing of your skin or the whites of your eyes, pain on the right side of your stomach area, dark urine, itchy skin, feeling less hungry than usual, nausea or vomiting, feeling tired, bleeding or bruising more easily than normal.



- Slow heart beat (bradycardia).
- Lung inflammation (pneumonitis). Alecensa may cause severe or life-threatening swelling (inflammation) of the lungs during treatment. The signs may be similar to those from your lung cancer. Tell your doctor straight away if you have any new or worsening signs including difficulty in breathing, shortness of breath, or cough with or without mucous, or fever.
- Severe muscle pain, tenderness, and weakness (myalgia). Your doctor will do blood tests at least every 2 weeks for the first month and as needed during treatment with Alecensa. Tell your doctor straight away if you get new or worsening signs of muscle problems, including unexplained muscle pain or muscle pain that does not go away, tenderness, or weakness.
- Haemolytic anaemia (breakdown of healthy red blood cells earlier than normal) can happen in some people who take Alecensa. If this happens, you may not have enough healthy red blood cells. Your healthcare provider may temporarily stop Alecensa and do blood tests, if needed, to check for this problem. If you develop haemolytic anaemia, your healthcare provider may either restart you on Alecensa at a lower dose when the haemolytic anaemia goes away, or may stop your treatment with Alecensa. Tell your healthcare provider right away if you experience yellow skin (jaundice), weakness or dizziness, or shortness of breath.

Look out for these while you are taking Alecensa. See 'Side effects' for more information.

### **Sensitivity to sunlight**

Do not expose yourself to the sun for any long period of time while you are taking Alecensa and for 7 days after you stop. You need to apply sunscreen and lip balm with a Sun Protection Factor of 50 or higher to help prevent sunburn.

### **Children and adolescents**

Alecensa has not been studied in children or adolescents. Do not give this medicine to children or adolescents under the age of 18 years.

### **Tests and checks**

When you take Alecensa your doctor will do blood tests before you start treatment, then every 2 weeks for the first 3 months of your treatment and then less often. This is to check you do not have any liver or muscle problems while taking Alecensa.

**Taking other medicines with Alecensa:**

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Alecensa can affect the way some other medicines work. Also, some other medicines can affect the way Alecensa works.

Talk to your doctor before taking Alecensa if you are taking:

- digoxin, a medicine used to treat heart problems
- dabigatran etexilate, a medicine used to treat blood clots
- methotrexate, a medicine used to treat certain types of cancer or to treat autoimmune diseases (e.g. rheumatoid arthritis)
- nilotinib, a medicine used to treat certain types of cancer
- lapatinib, a medicine used to treat certain types of breast cancer
- mitoxantrone, a medicine used to treat certain types of cancer or autoimmune diseases (e.g. multiple sclerosis)
- everolimus, a medicine used to treat certain types of cancer or used to prevent the body's immune system from rejecting a transplanted kidney, heart or liver
- sirolimus, a medicine used to prevent the body's immune system from rejecting a transplanted kidney, heart or liver
- topotecan, a medicine used to treat certain types of cancer
- medicines used to treat AIDS/HIV (e.g. ritonavir, saquinavir)

- medicines used to treat infections. These include medicines that treat fungal infections (antifungals such as ketoconazole, itraconazole, voriconazole, posaconazole) and medicines that treat certain types of bacterial infection (antibiotics such as telithromycin)
- St. John's Wort, a herbal medicine used to treat depression
- medicines used to stop seizures or fits (anti-epileptics such as phenytoin, carbamazepine, or phenobarbitone)
- medicines used to treat tuberculosis (e.g. rifampicin, rifabutin)
- nefazodone, a medicine used to treat depression

### **Oral contraceptives**

If you take Alecensa whilst using oral contraceptives, the oral contraceptives may be less effective.

### **Taking Alecensa with food and drink**

You should use caution when drinking grapefruit juice or eating grapefruit or Seville oranges while on treatment with Alecensa as they may change the amount of Alecensa in your body. See also section 3 "How to take Alecensa".

### **Pregnancy and breastfeeding**

Alecensa is not for use in women who are pregnant, may become pregnant or plan to breastfeed their babies.

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

### **Contraception**

- You should not become pregnant while taking this medicine. If you are able to become pregnant, you must use highly effective contraception while on treatment and for at least 3 months after stopping treatment. Talk to your doctor about the right methods of contraception

for you and your partner. If you take Alecensa whilst using oral contraceptives, the oral contraceptives may be less effective.

- Male patients receiving Alecensa, who have female partners of child-bearing potential. The female partner must use highly effective contraceptive methods during treatment and for at least 3 months following the last dose of Alecensa.

### **Pregnancy**

- Do not take Alecensa if you are pregnant. This is because it may harm your baby.
- If you become pregnant when taking the medicine or during the 3 months after taking your last dose, tell your doctor straight away.

### **Breastfeeding**

- Do not breastfeed while taking this medicine.

If you are pregnant or breastfeeding your baby, please consult your doctor or other healthcare professional for advice before taking this medicine.

### **Driving and using machines**

Take special care when driving and using machines as you may develop problems with vision or slowing of the heartbeat or low blood pressure that can lead to fainting or dizziness while you are taking Alecensa.

### **Important information about some of the ingredients of Alecensa:**

Alecensa contains lactose monohydrate. Patients with the rare hereditary conditions of lactose intolerance eg. galactosaemia, should not take Alecensa.

Alecensa contains sodium. The recommended daily dose of Alecensa (1 200 mg) contains 48 mg of sodium. Please take this amount into consideration if you are on a controlled sodium diet.

## **3. How to take Alecensa**

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

Always take Alecensa exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

### **How much to take**

- The recommended dose is 4 capsules (600 mg) twice a day.
- This means you take a total of 8 capsules (1 200 mg) each day.
- Sometimes your doctor may lower your dose, stop your treatment for a short time or stop your treatment completely if you feel unwell.

### **How to take**

- Alecensa is taken by mouth. Swallow each capsule whole. Do not open or dissolve the capsules.
- You must take Alecensa with food.

Your doctor will tell you how long your treatment with Alecensa will last. Do not stop treatment early if you are sick (vomit) after taking Alecensa. Do not take an extra dose of Alecensa on that day. Continue to take Alecensa as normal, the next day. If you have the impression that the effect of Alecensa is too strong or too weak, tell your doctor or pharmacist.

### **If you take more Alecensa than you should**

If you take more Alecensa than you should, talk to a doctor straight away. Take the medicine package and this leaflet with you.

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

### **If you forget to take Alecensa**

- If it is more than 6 hours before your next dose, take the missed dose as soon as you remember.
- If it is less than 6 hours before your next dose, skip the missed dose. Then take the next dose at the usual time.
- Do not take a double dose to make up for a missed dose.

### **Effects when treatment with Alecensa is stopped**

It is important to keep taking Alecensa twice a day for as long as your doctor prescribes it.

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

#### **4. Possible side effects**

Alecensa can have side effects.

Not all side effects reported for Alecensa are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

**Tell your doctor straight away or go to casualty department or hospital if you notice any of the following side effects:**

- Yellowing of your skin or the whites of your eyes, pain on the right side of your stomach area, dark urine, itchy skin, feeling less hungry than usual, nausea or vomiting, feeling tired, bleeding or bruising more easily than normal (potential signs of liver problems)
- New or worsening signs of muscle problems, including unexplained muscle pain or muscle pain that does not go away, tenderness, or weakness (potential signs of muscle problems).
- Fainting, dizziness and low blood pressure (potential signs of slow heart beat)
- New or worsening signs including difficulty in breathing, shortness of breath, or cough with or without mucous, or fever - the signs may be similar to those from your lung cancer (potential signs of lung inflammation – pneumonitis). Alecensa can cause severe or life-threatening inflammation of the lungs during treatment.
- Breakdown of healthy red blood cells earlier than normal (haemolytic anaemia). Haemolytic anaemia can happen in some people who take Alecensa. Tell your healthcare provider right away if you experience yellow skin (jaundice), weakness or dizziness, or shortness of breath.

These are all serious side effects. You may need urgent medical attention.

#### **Other side effects**

Tell your doctor, pharmacist or nurse if you notice any of the following side effects:

**Frequent:**

- abnormal results of blood tests to check for liver problems (high levels of alanine aminotransferase, aspartate aminotransferase and bilirubin)
- abnormal results of blood tests to check for muscle damage (high level of creatine phosphokinase)
- you may feel tired, weak or short of breath due to a reduction in the number of red blood cells, known as anaemia
- vomiting – if you vomit after taking a dose of Alecensa, do not take an extra dose, just take your next dose at the usual time
- constipation
- diarrhea
- nausea
- rash
- swelling caused by fluid build-up in the body (oedema)
- weight gain.
- abnormal results of blood tests to check kidney function (high level of creatinine)
- blurred vision, loss of sight, black dots or white spots in your vision, and seeing double (problems with your eyes)
- abnormal results of blood tests to check for liver disease or bone disorders (high level of alkaline phosphatase)
- inflammation of the mucous membrane of the mouth
- sensitivity to sunlight – do not expose yourself to the sun for any long period of time while you are taking Alecensa and for 7 days after you stop. You need to apply sunscreen and lip balm with a Sun Protection Factor of 50 or higher to help prevent sunburn.
- alteration in sense of taste
- rapid loss of kidney function (kidney problems).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

### **Reporting of side effects**

If you get side effects, talk to your doctor 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 Alecensa.

### **5. How to store Alecensa**

Store all medicines out of reach of children.

Store at or below 30 °C.

Store in the original package.

Keep the container in the outer carton to protect from light and moisture.

Do not use after the expiry date on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

### **6. Contents of the pack and other information**

#### **What Alecensa contains**

The active substance is alectinib. Each tablet contains 150 mg alectinib.

The other ingredients are:

- Carboxymethylcellulose calcium, hydroxypropylcellulose, lactose monohydrate, magnesium stearate, sodium lauryl sulphate.
- The capsule shell contains carnauba wax, carrageenan, corn starch, hypromellose, potassium chloride, titanium dioxide (E171).



- The printing ink contains red iron oxide (E172), yellow iron oxide (E172), FD and C Blue 2 (aluminium lake, E132), carnauba wax, white shellac, glyceryl monooleate, 1-butanol and dehydrated ethyl alcohol.
- Contains sugar (lactose monohydrate 33,67 mg).

### **What Alecensa looks like and contents of the pack**

Alecensa hard capsules are white to yellowish white, size 1 capsules with "ALE" printed in black ink on the cap and "150 mg" printed in black ink on the body.

Alecensa hard capsules are packaged in aluminium foil push-through blisters consisting of three-layered oriented polyamide/aluminium/polyvinyl chloride film and hard-tempered aluminium foil. Each multipack pack contains 224 capsules of 4 individual packs each containing 56 capsules (7 x blisters of 8 capsules each).

### **Holder of Certificate of Registration**

Roche Products (Pty) Ltd

90 Bekker Road, Hertford Office Park,

Building E, Vorna Valley, Midrand

Johannesburg, 1686

South Africa

Roche Ethical Assistance Line toll-free: 0800 21 21 25

**This leaflet was last revised on 25 August 2022**

### **Registration number**

53/32.16/0183