

Package leaflet: Information for the patient

Alecensa 150 mg hard capsules alectinib

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 Alecensa is and what it is used for
2. What you need to know before you take Alecensa
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1. What Alecensa is and what it is used for

What Alecensa is

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

What Alecensa is used for

Alecensa is used to treat adults with a type of lung cancer called 'non-small cell lung cancer' ('NSCLC') that is 'ALK-positive' - this means your cancer cells have a fault in a gene that makes an enzyme called ALK ('anaplastic lymphoma kinase') fusion, see 'How Alecensa works', below.

Alecensa can be prescribed to you:

- after removal of your cancer as a post-surgical (adjuvant) treatment, or
- as the first treatment of your lung cancer that has spread to other parts of the body (advanced), or if you have been previously treated with a medicine containing 'crizotinib'.

How Alecensa works

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 prevent the tumour from coming back after removal by surgery. It may also help to shrink your cancer.

If you have any questions about how Alecensa 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 Alecensa

Do not take Alecensa

- if you are allergic to alectinib or any of the other ingredients of this medicine (listed in section 6). If you are not sure, talk to your doctor, pharmacist or nurse before taking Alecensa.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Alecensa:

- if you have ever had stomach or intestine problems as holes (perforation), or if you have conditions causing inflammation inside the abdomen (diverticulitis), or if you have spread of cancer inside the abdomen (metastasis). It is possible that Alecensa may increase the risk of developing holes in the wall of your gut.
- if you have an inherited problem called ‘galactose intolerance’, ‘congenital lactase deficiency’ or ‘glucose-galactose malabsorption’.

If you are not sure, talk to your doctor, pharmacist or nurse before taking Alecensa.

Talk to your doctor right away after having taken Alecensa:

- if you are experiencing severe stomach or abdominal pain, fever, chills, sickness, vomiting, or abdominal rigidity or bloating, as these could be symptoms of a hole in the wall of your gut.

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 mucus, 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.
- abnormal breakdown of red blood cells (haemolytic anaemia). Tell your doctor straight away if you feel tired, weak or short of breath.

Look out for these while you are taking Alecensa. See ‘Side effects’ in section 4 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 (SPF) of 50 or higher to help prevent sunburn.

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.

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.

Other medicines and Alecensa

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

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- digoxin, a medicine used to treat heart problems
- dabigatran etexilate, a medicine used to treat blood clots
- methotrexate, a medicine used to treat severe joint inflammation, cancer and the skin disease psoriasis
- 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 multiple sclerosis (a disease that affects the central nervous system which damages the coating that protects the nerves)
- everolimus, a medicine used to treat certain types of cancer or used to prevent the body's immune system from rejecting an organ transplant
- sirolimus, a medicine used to prevent the body's immune system from rejecting an organ transplant
- topotecan, a medicine used to treat certain types of cancer
- medicines used to treat acquired immunodeficiency syndrome/human immunodeficiency virus (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 phenobarbital)
- 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.

Alecensa with food and drink

Tell your doctor or pharmacist if you drink grapefruit juice or eat grapefruit or Seville oranges while on treatment with Alecensa as they may change the amount of Alecensa in your body.

Contraception, pregnancy, and breast-feeding

Contraception – information for women

- 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 5 weeks after stopping treatment. If you take Alecensa whilst using oral contraceptives, the oral contraceptives may be less effective.

Contraception - information for men

- You should not father a child while taking this medicine. If your female partner is 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.

Pregnancy

- Do not take Alecensa if you are pregnant. This is because it may harm your baby.
- If you become pregnant while taking the medicine or during the 5 weeks after taking your last dose, tell your doctor straight away.

- If your female partner becomes pregnant while you are taking the medicine or during the 3 months after taking your last dose, tell your doctor straight away, and your female partner should seek medical advice.

Breast-feeding

- Do not breast-feed while taking this medicine. This is because it is not known if Alecensa can pass over into breast milk and could therefore harm your baby.

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.

Alecensa contains lactose

Alecensa contains lactose (a type of sugar). If you have been told by your doctor that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.

Alecensa contains sodium

This medicine contains 48 mg sodium (main component of cooking/table salt) per recommended daily dose (1200 mg). This is equivalent to 2.4% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Alecensa

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

How much to take

- The recommended dose is 4 capsules (600 mg) twice a day.
- This means you take a total of 8 capsules (1200 mg) each day.

If you have severe liver problems before starting your treatment with Alecensa:

- The recommended dose is 3 capsules (450 mg) twice a day.
- This means you take a total of 6 capsules (900 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.

If you vomit after taking Alecensa

If you vomit after taking a dose of Alecensa, do not take an extra dose, just take your next dose at the usual time.

If you take more Alecensa than you should

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

If you forget to take Alecensa

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

If you stop taking Alecensa

Do not stop taking this medicine without talking to your doctor first. It is important to take Alecensa twice a day for as long as your doctor prescribes it for you.

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. The following side effects may happen with this medicine.

Some side effects could be serious.

Tell your doctor straight away if you notice any of the following side effects. Your doctor may lower your dose, stop your treatment for a short time or stop your treatment completely:

- New or worsening signs including difficulty in breathing, shortness of breath, or cough with or without mucus, 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.
- 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).
- Feeling tired, weak or short of breath (potential signs of an abnormal breakdown of red blood cells, known as haemolytic anaemia).

Other side effects

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

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

- 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)
- abnormal results of blood tests to check for liver disease or bone disorders (high level of alkaline phosphatase)
- 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
- diarrhoea
- nausea
- rash
- swelling caused by fluid build-up in the body (oedema)
- weight gain.

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

- abnormal results of blood tests to check kidney function (high level of creatinine)
- 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

- problem with your eyes including blurred vision, loss of sight, black dots or white spots in your vision, and seeing double
- increased levels of uric acid in the blood (hyperuricaemia)

Uncommon (may affect up to 1 in 100 people):

- kidney problems including rapid loss of kidney function (acute kidney injury)

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 Alecensa

- Keep this medicine out of the sight and reach of children.
- Do not take this medicine after the expiry date which is stated on the carton and either the blister or the bottle after EXP. The expiry date refers to the last day of that month.
- If Alecensa is packed in blisters, store in the original package in order to protect from moisture.
- If Alecensa is packed in bottles, store in the original package and keep the bottle tightly closed to protect from moisture.
- 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 Alecensa contains

- The active substance is alectinib. Each hard capsule contains alectinib hydrochloride equivalent to 150 mg alectinib.
- The other ingredients are:
 - *Capsule content:* lactose monohydrate (see section 2 ‘Alecensa contains lactose’), hydroxypropylcellulose, sodium laurilsulfate (see section 2 ‘Alecensa contains sodium’), magnesium stearate and carmellose calcium
 - *Capsule shell:* hypromellose, carrageenan, potassium chloride, titanium dioxide (E171), maize starch and carnauba wax
 - *Printing ink:* red iron oxide (E172), yellow iron oxide (E172), indigo carmine aluminium lake (E132), carnauba wax, white shellac and glyceryl monooleate.

What Alecensa looks like and contents of the pack

Alecensa hard capsules are white, with ‘ALE’ printed in black ink on the cap and ‘150 mg’ printed in black ink on the body.

The capsules are provided in blisters and are available in cartons containing 224 hard capsules (4 packs of 56). The capsules are also available in plastic bottles containing 240 hard capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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