

ALECENSA[®] Hard Capsules

Alectinib (150 mg)

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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 and 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.

Before you use ALECENSA

- *When you must not use it*

If you are allergic to alectinib or any of the other ingredients of this medicine (listed in Product Description).

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

- *Before you start to use it*

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'.

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.

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.

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.

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

- *Taking other medicines*

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 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 phenobarbital)
- medicines used to treat tuberculosis (e.g. rifampicin, rifabutin)
- nefazodone, a medicine used to treat depression

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

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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.

How to use 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 use

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.

- When to use it

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 a dose of ALECENSA, do not take an extra dose, just take your next dose at the usual time.

- How long to use it

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.

- If you forget to use it

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 use too much (overdose)

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

While you are using it

- Things you must do

If you become pregnant when taking the medicine or during the 3 months after taking your last dose, tell your doctor straight away.

- Things you must not do

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.

- Things to be careful of

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.
- abnormal breakdown of red blood cells (haemolytic anaemia). Tell

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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' for more information.

- 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.
- 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.

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:

- 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.

- Feeling tired, weak or short of breath (potential signs of an abnormal breakdown of red blood cells, known as haemolytic anaemia).

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

- blurred vision, loss of sight, black dots or white spots in your vision, and seeing double (problems with your eyes)
- 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)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI))

Storage and Disposal of ALECENSA

- Storage

Do not store above 30°C. Store in the original package to protect from light and moisture.

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 the blister 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.

- Disposal

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.

Product Description

- What it looks like

ALECENSA capsules are white to yellowish white in colour with "ALE" printed in black on the cap and "150 mg" printed in black on the body.

- Ingredients

- Active Ingredients

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Each ALECENSA capsule contains 150 mg of alectinib (equivalent to 161.3 mg alectinib hydrochloride).

- **Inactive Ingredients**

The capsule fill contains:

- Lactose monohydrate
- Hydroxypropylcellulose
- Sodium lauryl sulfate
- Magnesium stearate
- Carboxymethylcellulose calcium

The capsule shell contains

- Hypromellose
- Carrageenan
- Potassium chloride
- Titanium dioxide (E171)
- Corn starch
- Carnauba wax
- Red iron oxide (E172)
- Yellow iron oxide (E172)
- FD&C Blue No. 2 aluminum lake (E132)
- White shellac
- Glyceryl monooleate

- **MAL number:**

ALECENSA capsule
MAL18086130ACRZ

Manufacturer

Made for F. Hoffmann-La Roche
Ltd, Basel, Switzerland
By Excella GmbH
Production site Feucht, Germany

Product Registration Holder

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Date of revision

4 April 2025
MYPILAleccensa20250404CDS10.0
(Eng)

Serial Number

NPRA (R1/2) 04042025/067