

Alecensa[®]

alectinib hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Alecensa. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Alecensa against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Alecensa is used for

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

- is ALK-positive – this means your cancer cells have a fault in a gene called anaplastic lymphoma kinase (ALK)
- is advanced or has spread to another part of your body (metastatic)

Alecensa contains the active ingredient alectinib.

Alecensa belongs to a group of medicines called anti-neoplastic (or anti-cancer) agents, which are used to treat cancer.

Alecensa prevents the activity of the ALK protein. This protein is known to be involved in the growth and spread of cancer cells.

Alecensa may slow down or stop the growth of your cancer. It may also help to shrink your cancer.

Some people may experience side effects not yet known or mentioned in this leaflet. If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

Ask your doctor if you have any questions about why Alecensa has been prescribed for you.

Your doctor may have prescribed it for another reason.

Alecensa is not addictive.

This medicine is available only with a doctor's prescription.

Before you take Alecensa

When you must not take it

Do not take Alecensa if you have an allergy to:

- any medicine containing alectinib
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breastfeed if you are taking this medicine.

Do not give Alecensa to children under the age of 18 years.

Safety and effectiveness in children have not been established.

Do not take Alecensa after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- you are pregnant or plan to become pregnant

Alecensa may be harmful to an unborn baby when taken by a pregnant woman. You should not take Alecensa while you are pregnant.

If you are a woman who could become pregnant, use highly effective contraception (birth control) during treatment, and for at least 1 week after taking the last capsule.

If you are the partner of a woman who could become pregnant, use highly effective contraception during treatment, and for at least 3 months after taking the last capsule.

Talk to your doctor about the right methods of contraception for you and your partner.

- you are breastfeeding or plan to breastfeed

It is not known whether alectinib passes into breast milk. It is not recommended that you breastfeed while taking Alecensa and for 1 week after taking the last capsule.

- you have liver problems

Your doctor will do blood tests before treatment to check your liver function.

- you cannot tolerate lactose, or you have an inherited problem called galactose intolerance, congenital lactase deficiency or glucose-galactose malabsorption.
- 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 not told your doctor about any of the above, tell him/her before you start taking Alecensa.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Alecensa may interfere with some medicines. These include some medicines with a narrow therapeutic index (meaning

medicines that need tight control of the dose to produce the desired effects without causing severe or fatal problems).

These include:

- digoxin, used to treat heart disease
- dabigatran, used to prevent or treat blood clots
- methotrexate, used to treat rheumatoid arthritis and some cancers

These medicines may be affected by Alecensa or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Alecensa

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

How much to take

Your doctor will tell you how many capsules you need to take each day. This may depend on your condition, whether you are taking any other medicines and whether you experience side effects.

The normal dose of Alecensa is 4 capsules twice a day, taken with food.

How to take it

Swallow the capsules whole with a full glass of water. Do not open or dissolve the capsules.

Alecensa capsules should be taken with food.

When to take it

Take 4 capsules in the morning (i.e. with breakfast), then 4 capsules in the evening (i.e. with dinner).

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it

The duration of treatment with Alecensa varies, depending on the nature of your illness and your individual response to treatment.

Continue taking Alecensa until your doctor tells you to stop.

If you forget to take Alecensa

If you forget to take a dose, or if you vomit after taking a dose, skip the dose you missed and take your next dose

when you are meant to. Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Australia - telephone 13 11 26; New Zealand - telephone 0800 764 766 or 0800 POISON) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Alecensa. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep telephone numbers for these places handy.

If you are not sure what to do, contact your doctor or pharmacist.

While you are using Alecensa

Things you must do

Tell all doctors, dentists, and pharmacists who treat you that you are taking Alecensa.

Use highly effective contraception to prevent pregnancy while you are being treated with Alecensa.

Women must avoid pregnancy during treatment with Alecensa and for at least 1 week after taking the last dose. Men must avoid fathering a child during treatment with Alecensa and for at least 3 months after taking the last dose.

If you or your partner becomes pregnant while taking Alecensa, tell your doctor immediately.

Avoid prolonged exposure to the sun while you are taking Alecensa and for at least 7 days after you stop. Apply sunscreen and a lip balm with a SPF of 50 or higher and cover your arms, legs and head to reduce exposure to sunlight.

Alecensa may increase your sensitivity to sunlight.

Tell your doctor right 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.

Muscle problems are common with Alecensa and sometimes these can be severe.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor will do blood tests and other tests from time to time to monitor your progress and check for side effects. If necessary, your doctor may decide to reduce your dose, temporarily interrupt your treatment or stop it altogether.

Things you must not do

Do not take Alecensa to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or change the dosage without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Alecensa affects you.

Alecensa may cause problems with vision or slowing of the heartbeat or low blood pressure that can lead to dizziness or fainting in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

If you experience any of these problems and they continue or get worse, talk to your doctor.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Alecensa.

Alecensa helps people with non-small cell lung cancer, but it may have unwanted side effects. All medicines can have side effects. Sometimes they are serious; most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- rash
- diarrhoea or constipation
- tiredness
- dizziness
- nausea and/or vomiting
- swelling of hands, feet, legs or around the eyes

- problems with your eyes such as blurred or impaired vision, black dots or white spots in your vision, double vision
- headache
- sensitivity to sunlight
- inflammation in your mouth
- change in sense of taste
- weight gain

The above list includes the more common side effects of your medicine.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- shortness of breath or difficulty breathing, cough and/or fever
- yellowing of your skin or the whites of your eyes
- slow heart beat (bradycardia)
- new or worsening signs and symptoms of muscle problems, including unexplained muscle pain that does not go away, tenderness or weakness
- decrease in urine, confusion, new or worsening swelling of legs, ankles or around the eyes, tiredness, nausea, chest pain or pressure

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some side effects can only be found when your doctor does blood tests or other tests. These tests could show a change in the liver, kidneys, levels of blood cells or changes in heart rate or blood pressure.

After using Alecensa

Tell your doctor or pharmacist if you are experiencing severe stomach or abdominal pain, fever, chills, sickness, vomiting, or abdominal rigidity or bloating.

These these could be symptoms of a hole in the wall of your gut.

Storage

Keep your capsules inside the original package until it is time to take them.

If you take the capsules out of the package they may not keep well.

Keep your capsules inside the carton in a cool dry place where the temperature stays below 30°C.

Do not store Alecensa or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Alecensa 150 mg capsules are white and are printed with "ALE" on the cap and "150 mg" printed on the body in black ink.

The capsules are provided in blisters and are available in multipacks containing 224 hard capsules (4 packs of 56).

Ingredients

Alecensa contains 150 mg of alectinib, equivalent to 161.3 mg of alectinib hydrochloride, as the active ingredient.

The capsules also contain:

- lactose monohydrate
- hypolose
- sodium lauryl sulfate
- carmellose calcium
- magnesium stearate

The capsule shell contains:

- carrageenan
- potassium chloride
- titanium dioxide
- carnauba wax
- maize starch
- hypromellose

The printing ink contains:

- iron oxide red (E172)
- iron oxide yellow (E172)
- indigo carmine aluminium lake
- carnauba wax

- shellac
- glyceryl monooleate

Alecensa capsules do not contain gluten.

Manufacturer

Alecensa is distributed in Australia by:

Roche Products Pty Limited

ABN 70 000 132 865

Level 8, 30 - 34 Hickson Road

Sydney NSW 2000

AUSTRALIA

Medical enquiries: 1800 233 950

Please check with your pharmacist for the latest Consumer Medicine Information.

Australian Registration Number:

AUST R 272115

Alecensa is distributed in New Zealand by:

Roche Products (NZ) Limited

PO Box 109113 Newmarket

Auckland 1149

NEW ZEALAND

Medical enquiries: 0800 276 243

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