

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking Alecensa?

Alecensa contains the active ingredient alectinib hydrochloride. Alecensa is used to treat patients who have a certain type of cancer - known as anaplastic lymphoma kinase (ALK)-fusion positive lung cancer. For more information, see Section [1. Why am I taking Alecensa?](#) in the full CMI.

2. What should I know before I take Alecensa?

Do not take Alecensa if you have ever had an allergic reaction to Alecensa or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I take Alecensa?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Alecensa and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take Alecensa?

- Alecensa is taken by mouth (orally) twice a day. Alecensa capsules should be swallowed whole with a glass of water and must not be opened or chewed. Alecensa should be taken with food.
- If you get side effects, your doctor may change your dose, temporarily stop, or permanently stop treatment.

More instructions can be found in Section [4. How do I take Alecensa?](#) in the full CMI.

5. What should I know while taking Alecensa?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist who treats you that you are taking Alecensa.• Ensure you are using highly effective contraception (men and women). Even if you stop treatment you should continue to use effective contraception for at least 5 weeks if you are a woman and 3 months if you are a man.• Tell your doctor straight away if you become pregnant.• Tell your doctor straight away if you experience any new or worsening symptoms or symptoms that concern you.• Alecensa may increase your sensitivity to sunlight so prolonged sun exposure should be avoided. Sunscreen and lip balm with an SPF of 50 should be used whilst in sunlight.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking this medicine, even if you feel well.
Driving or using machines	<ul style="list-style-type: none">• Be careful driving and/or operating heavy machinery until you know how Alecensa affects you.
Looking after your medicine	<ul style="list-style-type: none">• Store Alecensa in a cool, dry place where children cannot access it. Alecensa should be stored in a cool dry place where the temperature stays below 30°C.• If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

For more information, see Section [5. What should I know while taking Alecensa?](#) in the full CMI.

6. Are there any side effects?

Alecensa can cause side effects that you need to tell your doctor about straight away. Tell your doctor or pharmacist if you experience any side effects which concern you. Symptoms of serious side effects include difficulty breathing, shortness of breath, fever, yellowing of your skin or the whites of your eyes, dark and/or less urine than usual, itchy skin, nausea or vomiting, bleeding or bruising more easily than normal, unexplained muscle pain, new or worsening swelling of legs, ankles or around the eyes, chest pain or pressure, severe abdominal/stomach pain or a slowed heartbeat. Some side effects might only be detected by blood tests or other tests. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ALECENSA (ALI-SENS-A)

Active ingredient(s): *alectinib hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking Alecensa. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking Alecensa.**

Keep this leaflet with the medicine. You may need to read it again.

Where to find information in this leaflet:

- [1. Why am I taking Alecensa?](#)
- [2. What should I know before I take Alecensa?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take Alecensa?](#)
- [5. What should I know while taking Alecensa?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking Alecensa?

Alecensa contains the active ingredient alectinib hydrochloride. Alecensa is a cancer medicine. In patients whose cancer is due to an altered anaplastic lymphoma kinase (ALK) gene, which can lead to uncontrolled cell growth and cancer, Alecensa blocks the action of ALK fusion proteins and may help to slow or stop your cancer from growing. It may also help to shrink your cancer.

Alecensa is used to treat adults who have non-small cell lung cancer, caused by ALK genes.

Alecensa can be given to you when the lung cancer has not spread to other parts of the body. Treatment will be given after surgery takes place (adjuvant treatment). Alecensa can also be given to you if you have lung cancer that is advanced or has spread to other parts of your body (metastatic).

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

2. What should I know before I take Alecensa?

Warnings

Do not take Alecensa if:

- you are allergic to alectinib, or any of the ingredients listed at the end of this leaflet

Always check the ingredients to make sure you can use this medicine. Some symptoms of an allergic reaction 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 give Alecensa to children under the age of 18 years. Safety and effectiveness in children have not been established.

Check with your doctor if you:

- take any medicines for any other condition
- have or have had any of the following medical conditions:
 - 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;

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes. If you have not told your doctor about any of the above, tell him/her before you start taking Alecensa. If you are not sure whether you should start taking this medicine, talk to your doctor.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take this medicine if 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.

Ensure you tell your doctor if you are pregnant or plan to become pregnant.

Breastfeeding:

Do not breastfeed if you are taking this medicine.

Talk to your doctor if you are breastfeeding or plan to breastfeed.

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

Contraception in females:

If you are a woman who could become pregnant, use highly effective contraception (for example, double-barrier contraception such as condom and diaphragm) during treatment, and for at least 5 weeks after taking the last capsule.

Contraception in males:

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.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Alecensa.

4. How do I 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.

When and how to take Alecensa

- Swallow the capsules whole with a full glass of water. Do not open or dissolve the capsules.
- Alecensa capsules should be taken with food.
- 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.

The duration of treatment with Alecensa varies, depending on the nature of your illness and your individual response to treatment. If you are taking Alecensa for lung cancer after surgery, you may receive Alecensa for up to 2 years.

Continue taking Alecensa until your doctor tells you to stop.

If you forget to take Alecensa

Alecensa should be taken regularly at the same time each day. 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 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 Alecensa

If you think that you have taken too much Alecensa, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre **by calling 0800 POISON (0800 764766)**, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

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.

5. What should I know while taking Alecensa?

Things you should 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 5 weeks 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 should not do

- Do not take Alecensa to treat any other complaints unless your doctor tells you to
- Do not stop taking your medicine or change the dosage without checking with your doctor
- Do not give your medicine to anyone else, even if they have the same condition as you

Driving or using machines

Be careful before you drive or use any machines or tools 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

Looking after your medicine

Keep your capsules inside the carton in a cool dry place where the temperature stays below 30°C; for example, do not store it in the bathroom or near a sink, in the car or on window sills.

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. Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe 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.

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

6. Are there any 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. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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:

Less serious side effects

Less serious side effects	What to do
Gut problems: <ul style="list-style-type: none">• diarrhoea and/or constipation• nausea and/or vomiting Skin problems: <ul style="list-style-type: none">• rash Eye problems: <ul style="list-style-type: none">• blurred or impaired vision, black dots or white spots in your vision, double vision Blood test problems: <ul style="list-style-type: none">• abnormal results of blood tests to check for liver problems; muscle damage; liver disease or bone disorders; kidney function; and levels of uric acid in the blood Other: <ul style="list-style-type: none">• tiredness• dizziness• headache• sensitivity to sunlight• inflammation in your mouth	Speak to your doctor if you have any of these less serious side effects and they worry you, or if they do not go away or get worse.

Less serious side effects	What to do
<ul style="list-style-type: none"> change in sense of taste weight gain swelling of hands, feet, legs or around the eyes red, hot or swollen joints pain below the ribs or around the stomach area cloudy or dark urine 	

Serious side effects

Serious side effects	What to do
<p>Breathing problems:</p> <ul style="list-style-type: none"> shortness of breath or difficulty breathing cough and/or fever. These could be symptoms of swelling (inflammation) of the lungs. The signs may be similar to those from your lung cancer <p>Liver problems:</p> <ul style="list-style-type: none"> 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. This could be a sign of liver injury (hepatotoxicity) <p>Heart problems:</p> <ul style="list-style-type: none"> slow heartbeat (bradycardia) <p>Muscle problems:</p> <ul style="list-style-type: none"> new or worsening signs and symptoms of muscle problems, including unexplained muscle pain that does not go away, tenderness or weakness. This could be a sign of myalgia. <p>Kidney problems:</p> <ul style="list-style-type: none"> decrease in urine, confusion, new or worsening swelling of legs, ankles or around the eyes, tiredness, nausea, chest pain or pressure, or abnormal results of blood tests to check kidney function. This could be a sign of a kidney injury. <p>Blood problems:</p> <ul style="list-style-type: none"> Tired, weak or short of breath. This could be a sign of abnormal breakdown of red blood cells (haemolytic anaemia) 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>Severe increase in blood triglycerides (a type of fat in the blood):</p> <ul style="list-style-type: none"> Sudden, severe abdominal pain, accompanied by nausea, vomiting, fast heart rate, fast breathing and/or fever, as these symptoms could be signs of inflammation of the pancreas (pancreatitis) 	

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 else that may be making you feel unwell.

Other side effects not listed here may 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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Centre for Adverse Reactions Monitoring (CARM) online at <https://pophealth.my.site.com/carmreportnz/s/>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Alecensa contains

Active ingredient (main ingredient)	Alecensa contains 150 mg of alectinib, equivalent to 161.3 mg of alectinib hydrochloride, as the active ingredient.
Other ingredients (inactive ingredients)	lactose monohydrate, hypromellose, sodium lauryl sulfate, carmellose calcium, magnesium stearate Capsule shell: carrageenan, potassium chloride, titanium dioxide, carnauba wax, maize starch, hypromellose Printing ink: iron oxide red (E172), iron oxide yellow (E172), indigo carmine

	aluminium lake, carnauba wax, shellac, glyceryl monooleate
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Do not take this medicine if you are allergic to any of these ingredients.

Alecensa capsules do not contain gluten.

What Alecensa 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).

Who distributes Alecensa

Alecensa is distributed in New Zealand by:

Roche Products (NZ) Limited

PO Box 109113 Newmarket

Auckland 1149

NEW ZEALAND

Medical enquiries: 0800 276 243

This leaflet was prepared on 28th of May 2026.