

# ALECENSA®

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## 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.

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### 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"><li>• Remind any doctor, dentist or pharmacist you visit that you are taking Alecensa.</li><li>• Ensure you are using effective contraception (men and women). Even</li></ul>

	<p>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.</p> <ul style="list-style-type: none"> <li>• Tell your doctor straight away if you become pregnant.</li> <li>• Tell your doctor straight away if you experience any new or worsening symptoms or symptoms that concern you.</li> <li>• Alecensa may increase your sensitivity to sunlight so prolonged sun exposure should be avoided. Sunscreen and a lip balm with an SPF of 50 should be used whilst in sunlight.</li> </ul>
<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>• Do not stop taking this medicine, even if you feel well.</li> </ul>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>• Be careful driving and/or operating heavy machinery until you know how Alecensa affects you.</li> </ul>

## Looking after your medicine

- 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 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, unexplained muscle pain, decrease in urine, new or worsening swelling of legs, ankles or around the eyes, chest pain or pressure, severe abdominal or stomach pain. 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*

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## 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.**

**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, the change in the gene causes the body to make an abnormal protein called an ALK fusion protein, which can lead to uncontrolled cell growth and cancer. Alecensa blocks the action of ALK

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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).

## **2. What should I know before I take Alecensa?**

### **Warnings**

#### **Do not take Alecensa if:**

- you are allergic to alectinib hydrochloride, or any of the ingredients listed at the end of this leaflet in Section 7 Product details

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

**It is not known if Alecensa is safe and effective in children younger than 18 years of age.**

## 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;
  - if you have ever had stomach or intestine problems such as holes (perforation);
  - or if you have conditions causing inflammation inside the abdomen (diverticulitis);
  - 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.

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

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



Your doctor will perform a pregnancy test before you start treatment with Alecensa.

This medicine is not recommended for use during pregnancy unless absolutely necessary. Avoid becoming pregnant while being treated with this medicine as it may harm your unborn baby. Your doctor will discuss with you the potential risks of taking Alecensa during pregnancy.

#### Breastfeeding:

It is not known if Alecensa passes into your breast milk. Do not breastfeed during treatment and for one week after your final dose of Alecensa.

#### Contraception in females:

You should avoid becoming pregnant while taking this medicine. If you are able to have children, you must use highly effective contraception (for example, double-barrier contraception such as condom and diaphragm) while on treatment and for at least 5 weeks after stopping treatment.

#### Contraception in males:

Males with female partners of childbearing potential must use effective contraception during treatment and for at least 3 months after completion of treatment.

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?

Your healthcare provider will perform a test to make sure that Alecensa is right for you.

### How much to take

- Follow the instructions provided by your doctor and take Alecensa until your doctor tells you to stop. The recommended dose is 600 mg (4 capsules) taken by mouth, twice daily.

### When and how to take Alecensa

- Alecensa is usually taken twice a day 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 times 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.
- Alecensa capsules should be swallowed whole with a glass of water and must not be opened, chewed or dissolved.
- Do not change your dose or stop taking Alecensa unless your healthcare provider tells you to. Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with Alecensa. If you are taking Alecensa for lung cancer after surgery, you may receive Alecensa for up to 2 years.

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

Alecensa should be taken regularly at the same time each day. If you miss your dose at the usual time, 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 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **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.**

**If you become pregnant while taking this medicine, or within 1 week of stopping this medicine, tell your doctor immediately. Ensure you are using effective contraception (see further details above under Section 2).**

**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.**

**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 changing the amount you take 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**

Store Alecensa at room temperature (below 30°C) in a dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- 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.

**Keep it where young children cannot reach it.**

## **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.

Do not take this medicine after the expiry date which is stated on the blister pack and outer carton after "EXP". The expiry date refers to the last day of that month.

## **6. Are there any 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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### **Less serious side effects**

<b>Less serious side effects</b>	<b>What to do</b>
<b>Gut-related:</b> <ul style="list-style-type: none"><li>• diarrhoea and/or constipation</li><li>• nausea and/or vomiting</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you, or if</b>

<b>Less serious side effects</b>	<b>What to do</b>
<p><b>Skin-related:</b></p> <ul style="list-style-type: none"> <li>● rash</li> </ul> <p><b>Eye-related:</b></p> <ul style="list-style-type: none"> <li>● blurred or impaired vision, black dots or white spots in your vision, double vision</li> </ul> <p><b>Symptoms of high uric acid levels in your blood (hyperuricaemia):</b></p> <ul style="list-style-type: none"> <li>● red, hot or swollen joints</li> <li>● pain below the ribs or around the stomach area</li> <li>● cloudy or dark urine</li> </ul> <p><b>Other:</b></p> <ul style="list-style-type: none"> <li>● tiredness</li> <li>● dizziness</li> <li>● headache</li> <li>● sensitivity to sunlight</li> <li>● inflammation in your mouth</li> <li>● change in sense of taste</li> <li>● weight gain</li> </ul>	<p><b>they do not go away or get worse.</b></p>



<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• swelling of hands, feet, legs or around the eyes</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Gut-related:</b></p> <ul style="list-style-type: none"> <li>• severe stomach or abdominal pain, fever, chills, sickness, vomiting, or abdominal rigidity or bloating. These could be symptoms of a hole in the wall of your gut, and could happen even after you stop taking Alecensa</li> </ul> <p><b>Breathing-related:</b></p> <ul style="list-style-type: none"> <li>• shortness of breath or difficulty breathing</li> <li>• cough and/or fever</li> </ul> <p><b>Liver-related:</b></p> <ul style="list-style-type: none"> <li>• yellowing of your skin or the whites of your eyes</li> </ul> <p><b>Heart-related:</b></p>	<p><b>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.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● slow heart beat (bradycardia)</li> </ul> <p><b>Muscle-related:</b></p> <ul style="list-style-type: none"> <li>● new or worsening signs and symptoms of muscle problems, including unexplained muscle pain that does not go away, tenderness or weakness</li> </ul> <p><b>Kidney-related:</b></p> <ul style="list-style-type: none"> <li>● decrease in urine, confusion, new or worsening swelling of legs, ankles or around the eyes, tiredness, nausea, chest pain or pressure</li> </ul> <p><b>Abnormal breakdown of red blood cells (haemolytic anaemia):</b></p> <ul style="list-style-type: none"> <li>● tiredness, weakness or dizziness, yellow skin (jaundice), shortness of breath</li> </ul>	

**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.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). 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**

<b>Active ingredient (main ingredient)</b>	alectinib hydrochloride
<b>Other ingredients (inactive ingredients)</b>	lactose monohydrate, hyprolose, 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

**Do not take this medicine if you are allergic to any of these ingredients.**

## **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).

(AUST R 272115).

## **Who distributes Alecensa**

Alecensa is distributed in Australia by:

Roche Products Pty Ltd

ABN 70 000 132 865

Level 8, 30-34 Hickson Road

Sydney NSW 2000

Medical enquiries: 1800 233 950

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