

PRODUCT MONOGRAPH
INCLUDING PATIENT MEDICATION INFORMATION

Pr **ALECENSARO**[®]

alectinib (as alectinib hydrochloride)

Capsule, 150 mg

Protein Kinase Inhibitor (L01XE)

Hoffmann-La Roche Limited
7070 Mississauga Road
Mississauga, Ontario, Canada
L5N 5M8
www.rochecanada.com

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PATIENT MEDICATION INFORMATION

ALECENSARO[®]

Alectinib (as alectinib hydrochloride) capsules

Read this carefully before you start taking ALECENSARO and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional (doctor, pharmacist or nurse) about your medical condition and treatment and ask if there is any new information about ALECENSARO.

Serious Warnings and Precautions

ALECENSARO should only be prescribed and used under the supervision of a healthcare professional experienced with drugs used to treat cancer.

Serious side effects with ALECENSARO include:

- Life-threatening tear in the stomach or intestine (gastrointestinal perforation)
- Liver problems
- Lung problems
- Slow heart beat

ALECENSARO has not been studied in patients with severe kidney problems.

What is ALECENSARO used for?

ALECENSARO is used to treat adult patients with anaplastic lymphoma kinase (ALK)-positive, **locally advanced** (a cancer that cannot be surgically removed or treated with chemotherapy or radiation for cure) or **metastatic** (a cancer that has spread to other parts of the body) non-small cell lung cancer (NSCLC) who have gotten worse on or are unable to take crizotinib.

ALECENSARO is also used as the first treatment option for your **locally advanced** or **metastatic** ALK positive non-small cell lung cancer.

How does ALECENSARO work?

ALECENSARO belongs to a group of anti-tumor medicines which stop cancer from making new cells if the cancer is caused by a defect in a gene called anaplastic lymphoma kinase (ALK). By doing so, ALECENSARO may slow down the growth and spread of non-small cell lung cancer (NSCLC).

What are the ingredients in ALECENSARO?

Medicinal ingredients: alectinib (as alectinib hydrochloride)

Non-medicinal ingredients (in alphabetical order): carboxymethylcellulose calcium, carnauba wax, carrageenan, corn starch, hydroxypropylcellulose, hypromellose, lactose monohydrate,

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magnesium stearate, potassium chloride, sodium lauryl sulfate, titanium dioxide and traces of printing ink.

ALECENSARO comes in the following dosage form and appearance:

Capsules: 150 mg (white, with “ALE” printed in black ink on the cap and “150 mg” printed in black ink on the body).

Do not use ALECENSARO if you:

- are allergic to alectinib or any of the other ingredients in ALECENSARO

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ALECENSARO. Talk about any health conditions or problems you may have, including if you:

- are intolerant to lactose, as ALECENSARO contains lactose.
- are younger than 18 years of age. The effects of ALECENSARO in people younger than 18 years old are not known.
- are taking medicine to lower your blood pressure or control your heart rate.
- have a history of slow heart rate or fainting.
- have a history of heart problems including irregular heartbeat, heart disease and heart failure.
- have a history of problems with your gut, such as inflammation in the intestines (diverticulitis), a previous tear in your stomach or intestines or cancer that has spread to your gut.
- are pregnant or plan on becoming pregnant. Do not become pregnant while taking ALECENSARO, as it can harm your unborn baby.
 - Female patients who take ALECENSARO must use effective birth control during treatment and for at least 3 months after stopping ALECENSARO.
 - Talk to your healthcare professional about birth control methods that may be right for you.
 - Tell your healthcare professional right away if you become pregnant during treatment with ALECENSARO.
- are a male patient with a female partner who is able to become pregnant.
 - Male patients should use effective birth control during treatment and for at least 3 months after stopping ALECENSARO.
 - Tell your healthcare professional right away if your partner becomes pregnant while you are receiving treatment with ALECENSARO
- are breast-feeding or planning to breast-feed. Do not breast-feed while taking ALECENSARO.

Other warnings you should know about during treatment:

Life-threatening Tear in the Stomach or Intestines

ALECENSARO may cause a tear (perforation) in the stomach or intestine. Seek immediate medical help if you experience severe stomach or abdominal pain, fever, chills, or changes in bowel habits.

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Serious Liver Problems

ALECENSARO may cause liver injury. Your healthcare professional will take blood tests before you start treatment, then every 2 weeks for the first 3 months of your treatment and then less often. Tell your healthcare professional right away if you start to notice yellowing of your skin or the whites of your eyes, pain on the right side of your stomach area, dark urine, itchy skin, feeling tired, feeling less hungry than usual, nausea or vomiting or if you are bleeding or bruising more easily.

Serious Lung Problems

ALECENSARO may cause severe or life-threatening swelling of the lungs during treatment. The signs may be similar to those from your lung cancer. Seek immediate medical help if you have any new or worsening lung problems including difficulty in breathing, shortness of breath, or cough with or without mucous, or fever.

Slow Heart Beat

ALECENSARO may cause very slow heartbeats. Your healthcare professional will check your heart rate and blood pressure during treatment with ALECENSARO. Tell your healthcare professional right away if you feel dizzy or faint or have abnormal heartbeats.

Serious Muscle Problems

Muscle problems are common with ALECENSARO and can be severe. Your healthcare professional will do blood tests at least every 2 weeks for the first month and as needed during treatment with ALECENSARO. Tell your healthcare professional right away if you get new or worsening signs and symptoms of muscle problems, including unexplained muscle pain or muscle pain that does not go away, tenderness, or weakness.

Serious Kidney Problems

ALECENSARO may cause severe or life-threatening kidney problems. Tell your healthcare professional right away if you have a change in the amount or colour of your urine, or if you get new or worsening swelling in your legs or feet.

Sensitivity to Sunlight

ALECENSARO can cause your skin to become very sensitive to sunlight. You should limit your exposure to the sun and tanning beds while you are taking ALECENSARO and for 7 days after stopping. If sun exposure is unavoidable a broad spectrum UVA/UVB sunscreen and lipbalm must be used to protect against sunburn.

Driving or using machines

ALECENSARO may influence your ability to drive and use machines. If you feel dizzy, weak, or tired, or have problems with your eyes while taking ALECENSARO, do not drive or use tools or machines.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with ALECENSARO:

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- Digoxin, used for heart problems
- Dabigatran, used to thin the blood to prevent blood clots
- Methotrexate, used to treat cancer and immune system disorders
- Drugs used to lower heart rate
- St. John's wort, a herbal medicine used to treat depression
- Grapefruit, grapefruit juice, products containing grapefruit extract, star fruit, pomegranate, Seville oranges or other similar fruit

How to take ALECENSARO:

- Always take ALECENSARO exactly as your doctor or pharmacist has told you. Check with your healthcare professional if you are not sure.
- ALECENSARO is taken by mouth. Swallow each capsule whole. Do not open or dissolve the capsules.
- You should take ALECENSARO with food.

Usual dose:

The recommended dose of ALECENSARO is 600 mg (4 capsules) taken twice daily (total of 8 capsules, 1200 mg per day).

Sometimes your doctor may lower your dose, stop your treatment for a short time or stop your treatment completely if you feel unwell.

Overdose:

If you think you have taken too much ALECENSARO, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to take ALECENSARO:

- Take your next dose at your regular time.
- Do not take a double dose to make up for a missed dose.

Vomiting:

If you vomit (throw up) after taking ALECENSARO, do not take an extra dose of ALECENSARO, just take your next dose at the usual time.

What are possible side effects from using ALECENSARO?

These are not all the possible side effects you may experience when taking ALECENSARO. If you experience any side effects not listed here, contact your healthcare professional. Please also see the warnings above.

Side effects of ALECENSARO may include:

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- constipation
- diarrhea
- nausea
- vomiting
- abnormal or metallic taste in the mouth
- inflammation of the mucous membrane of the mouth
- weight gain
- headache
- dizziness
- sensitivity to sunlight
- problems with your eyes such as blurred vision, loss of sight, black dots or white spots in your vision, and seeing double.
- dry skin
- rash
- hair loss
- itching
- numbness and tingling in the hands and feet
- muscle ache and pain, joint pain
- fatigue
- swelling caused by fluid build-up in the body (edema)

ALECENSARO can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Serious Muscle Problems: unexplained muscle pain or muscle pain that does not go away, tenderness, or weakness		✓	
Serious Anemia: fatigue, dizziness, fast heart rate, shortness of breath		✓	
Slow Heart Beat: dizziness, lightheadedness, slow heart beat, fainting		✓	
UNCOMMON			
Life-threatening Tear in the Stomach or Intestines: severe stomach or abdominal pain, fever, chills, or changes in bowel habits, death.			✓

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Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Serious Lung Problems: new or worsening difficulty breathing, shortness of breath, cough with or without mucous, or fever.			✓
Serious Liver Problems: yellowing of your skin or the whites of your eyes, pain on the right side of your stomach area, dark urine, itchy skin, feeling tired, feeling less hungry than usual, nausea or vomiting, bleeding or bruising more easily than normal.		✓	
Serious Kidney Problems: change in the amount or colour of your urine, new or worsening swelling in your legs or feet.		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

<p>Reporting Side Effects</p> <p>You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.</p> <p>3 ways to report:</p> <ul style="list-style-type: none"> • Online at MedEffect (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html); • By calling 1-866-234-2345 (toll-free); • By completing a Consumer Side Effect Reporting Form and sending it by: <ul style="list-style-type: none"> - Fax to 1-866-678-6789 (toll-free), or - Mail to: Canada Vigilance Program Health Canada, Postal Locator 1908C Ottawa, ON K1A 0K9 <p>Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html).</p> <p><i>NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.</i></p>

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Storage:

- Store ALECENSARO between 15-30°C.
- Store in the original package in order to protect from light and moisture.
- Keep out of reach and sight of children.
- Do not take this medicine after the expiry date which is stated on the bottle after “EXP”. The expiry date refers to the last day of that month.
- Do not throw away any unused medicine in the garbage or down the drain or toilet. Therefore, ask your pharmacist how to best dispose of medicines that you no longer require. These measures will help to protect the environment.

If you want more information about ALECENSARO:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website \(https://www.canada.ca/en/health-canada.html\)](https://www.canada.ca/en/health-canada.html); the manufacturer’s website (www.rochecanada.com), or by calling 1-888-762-4388.

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Hoffmann-La Roche Limited Mississauga, ON L5N 5M8