

PATIENT INFORMATION

ALECENSA® (a-le-sen-sah)
(alectinib)
capsules

What is the most important information I should know about ALECENSA?

ALECENSA may cause serious side effects, including:

- **Liver problems (hepatotoxicity).** Liver problems are common with ALECENSA and can be severe. Your healthcare provider will do blood tests at least every 2 weeks for the first 3 months, and then 1 time each month and as needed during treatment with ALECENSA to check your liver function. **Tell your healthcare provider right away if you get any of the following signs and symptoms:**
 - feeling tired
 - feeling less hungry than usual
 - yellowing of your skin or the whites of your eyes
 - dark urine
 - itchy skin
 - nausea or vomiting
 - pain on the right side of your stomach area
 - bleeding or bruising more easily than normal
- **Lung problems.** ALECENSA may cause severe or life-threatening swelling (inflammation) of the lungs during treatment. Symptoms may be similar to those symptoms from lung cancer. Tell your healthcare provider right away if you have any new or worsening symptoms, including trouble breathing, shortness of breath, cough, or fever.
- **Kidney problems.** ALECENSA may cause severe kidney problems that can lead to death. Tell your healthcare provider right away if you have a change in the amount or color of your urine, or if you get new or worsening swelling in your legs or feet.
- **Slow heartbeat (bradycardia).** ALECENSA may cause very slow heartbeats that can be severe. Your healthcare provider will check your heart rate and blood pressure during treatment with ALECENSA. Tell your healthcare provider right away if you feel dizzy, lightheaded, or if you faint during treatment with ALECENSA. Tell your healthcare provider if you take any heart or blood pressure medicines.
- **Severe muscle pain, tenderness, and weakness (myalgia).** Muscle problems are common with ALECENSA and can be severe. Your healthcare provider will do blood tests at least every 2 weeks for the first month and as needed during treatment with ALECENSA. Tell your healthcare provider 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.
- **Breakdown of healthy red blood cells earlier than normal (hemolytic anemia).** Hemolytic anemia can happen in some people who take ALECENSA. If this happens, you may not have enough healthy red blood cells. Your healthcare provider may temporarily stop ALECENSA and do blood tests, if needed, to check for this problem. If you develop hemolytic anemia, your healthcare provider may either restart you on ALECENSA at a lower dose when the hemolytic anemia goes away, or may stop your treatment with ALECENSA. Tell your healthcare provider right away if you experience yellow skin (jaundice), weakness or dizziness, or shortness of breath.

See “What are the possible side effects of ALECENSA?” for more information about side effects.

What is ALECENSA?

ALECENSA is a prescription medicine used to treat adults with non-small cell lung cancer (NSCLC) that is caused by an abnormal anaplastic lymphoma kinase (ALK) gene:

- to help prevent your lung cancer from coming back after your tumor has been removed by surgery (adjuvant), **or**
- as treatment when your lung cancer has spread to other parts of your body (metastatic).

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

It is not known if ALECENSA is safe and effective in children.

Before you take ALECENSA, tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems
- have lung or breathing problems
- have a slow heartbeat
- are pregnant or plan to become pregnant. ALECENSA can harm your unborn baby.

Females who are able to become pregnant:

- Your healthcare provider will do a test to see if you are pregnant before starting treatment with ALECENSA.
- You should use effective birth control (contraception) during treatment with ALECENSA and for 5 weeks after the last dose of ALECENSA.
- Tell your healthcare provider right away if you become pregnant during treatment with ALECENSA or think you may be pregnant.

Males who have female partners that are able to become pregnant should use effective birth control (contraception) during treatment with ALECENSA and for 3 months after the last dose of ALECENSA.

- are breastfeeding or plan to breastfeed. It is not known if ALECENSA passes into your breast milk. Do not breastfeed during treatment with ALECENSA and for 1 week after the last dose of ALECENSA. Talk to your healthcare provider about the best way to feed your baby during this time.

Tell your healthcare provider about all the medicines you take, including prescription medicines, over-the-counter medicines, vitamins, or herbal supplements.

How should I take ALECENSA?

- Take ALECENSA exactly as your healthcare provider tells you to take it. 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 have side effects.
- Take ALECENSA 2 times a day.
- Take ALECENSA with food.
- Swallow ALECENSA capsules whole. Do not open or dissolve the capsule contents.
- If you miss a dose of ALECENSA, do not take the missed dose. Take your next dose at your regular time.
- If you vomit after taking a dose of ALECENSA, do not take an extra dose. Take your next dose at your regular time.

What should I avoid while taking ALECENSA?

Avoid spending time in the sunlight during treatment with ALECENSA and for 7 days after the last dose of ALECENSA. Your skin may be sensitive to the sun (photosensitivity) and you may burn more easily and get severe sunburns. Use sun protecting measures, such as sunscreen and lip balm with an SPF 50 or greater to help protect against sunburn.

What are the possible side effects of ALECENSA?

ALECENSA may cause serious side effects, including:

- See “What is the most important information I should know about ALECENSA?”

The most common side effects of ALECENSA include:

- constipation
- tiredness
- swelling in your hands, feet, ankles, face and eyelids
- rash
- cough

These are not all of the possible side effects of ALECENSA. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ALECENSA?

- Do not store ALECENSA at temperatures above 86°F (30°C).
- Store ALECENSA capsules in the original container.
- Keep ALECENSA capsules dry and away from light.

Keep ALECENSA and all medicines out of the reach of children.

General information about the safe and effective use of ALECENSA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use ALECENSA for a condition for which it was not prescribed. Do not give ALECENSA to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about ALECENSA that is written for health professionals.

What are the ingredients in ALECENSA?

Active ingredient: alectinib

Inactive ingredients: lactose monohydrate, hydroxypropylcellulose, sodium lauryl sulfate, magnesium stearate and carboxymethylcellulose calcium. Capsule shell contains: hypromellose, carrageenan, potassium chloride, titanium dioxide, corn starch, and carnauba wax. Printing ink contains: red iron oxide (E172), yellow iron oxide (E172), FD&C Blue No. 2 aluminum lake (E132), carnauba wax, white shellac, and glyceryl monooleate.

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For more information, go to www.ALECENSA.com or call 1-800-253-2367.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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