

MEDICATION GUIDE
OLUMIANT® (O-loo-me-ant)
(baricitinib)
tablets, for oral use

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

OLUMIANT may cause serious side effects, including:

1. Serious infections.

OLUMIANT is a medicine that affects your immune system. OLUMIANT can lower the ability of your immune system to fight infections. Some people have had serious infections while taking OLUMIANT, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses that can spread throughout the body. Some people have died from these infections.

- Your healthcare provider should test you for TB before starting treatment with OLUMIANT for rheumatoid arthritis or alopecia areata.
- Your healthcare provider should watch you closely for signs and symptoms of TB during treatment with OLUMIANT.

You should not start taking OLUMIANT if you have any kind of infection unless your healthcare provider tells you it is okay. You may be at a higher risk of developing shingles.

Before starting OLUMIANT, tell your healthcare provider if you:

- are being treated for an infection
- have an infection that does not go away or that keeps coming back
- have diabetes, chronic lung disease, HIV, or a weak immune system. People with these conditions have a higher chance for infections
- have TB or have been in close contact with someone with TB
- have had shingles (herpes zoster)
- have had hepatitis B or C
- live or have lived, or have traveled to certain parts of the country (such as the Ohio and Mississippi River valleys and the Southwest) where there is an increased chance for getting certain kinds of fungal infections. These infections may happen or become more severe if you use OLUMIANT. Ask your healthcare provider if you do not know if you have lived in an area where these infections are common.
- think you have an infection or have symptoms of an infection such as:
 - fever, sweating, or chills
 - muscle aches
 - cough
 - shortness of breath
 - blood in your phlegm
 - weight loss
 - warm, red, or painful skin or sores on your body
 - diarrhea or stomach pain
 - burning when you urinate or urinating more often than normal
 - feeling tired

After starting OLUMIANT, call your healthcare provider right away if you have any symptoms of an infection.

OLUMIANT can make you more likely to get infections or, make worse any infection that you have. If you get a serious infection, your healthcare provider may stop your treatment with OLUMIANT until your infection is controlled.

2. Increased risk of death in people 50 years of age and older who have at least 1 heart disease (cardiovascular) risk factor and are taking a medicine in the class of medicines called Janus kinase (JAK) inhibitors.

OLUMIANT is a JAK inhibitor medicine.

3. Cancer and immune system problems.

OLUMIANT may increase your risk of certain cancers by changing the way your immune system works.

- Lymphoma and other cancers including skin cancers can happen in people taking OLUMIANT. People taking a medicine in the class of medicines called Janus kinase (JAK) inhibitors have a higher risk of certain cancers including lymphoma and lung cancer, especially if you are a current or past smoker.
- Tell your healthcare provider if you have ever had any type of cancer. Follow your healthcare provider's advice about having your skin checked for skin cancer during treatment with OLUMIANT.

4. Increased risk of major cardiovascular events such as heart attack, stroke or death in people 50 years of age and older who have at least 1 heart disease (cardiovascular) risk factor and taking a medicine in the class of medicines called JAK inhibitors, especially if you are a current or past smoker.

Get emergency help right away if you have any symptoms of a heart attack or stroke while taking OLUMIANT, including:

- discomfort in the center of your chest that lasts for more than a few minutes, or that goes away and comes back
- severe tightness, pain, pressure, or heaviness in your chest, throat, neck, or jaw
- pain or discomfort in your arms, back, neck, jaw, or stomach
- shortness of breath with or without chest discomfort
- breaking out in a cold sweat
- nausea or vomiting
- feeling lightheaded
- weakness in one part or on one side of your body
- slurred speech

5. Blood Clots.

Blood clots in the veins of your legs (deep vein thrombosis, DVT) or lungs (pulmonary embolism, PE) and arteries (arterial thrombosis) can happen in some people taking OLUMIANT. This may be life-threatening and cause death. Blood clots in the veins of the legs (deep vein thrombosis, DVT) and lungs (pulmonary embolism, PE) have happened more often in people who are 50 years of age and older and with at least 1 heart disease (cardiovascular) risk factor taking a medicine in the class of medicines called Janus kinase (JAK) inhibitors.

- Tell your healthcare provider if you have had blood clots in the veins of your legs or lungs in the past.
- Stop taking OLUMIANT and tell your healthcare provider or get emergency help right away if you have any signs and symptoms of blood clots during treatment with OLUMIANT, including: swelling, pain or tenderness in the leg, sudden unexplained chest pain, or shortness of breath.

6. Allergic Reactions.

Symptoms such as rash (hives), trouble breathing, feeling faint or dizzy, or swelling of your lips, tongue, or throat, that may mean you are having an allergic reaction have been seen in people taking OLUMIANT. Some of these reactions were serious. If any of these symptoms occur during treatment with OLUMIANT, stop taking OLUMIANT and get emergency help right away.

7. Tears (perforation) in the stomach or intestines.

- Tell your healthcare provider if you have had diverticulitis (inflammation in parts of the large intestine) or ulcers in your stomach or intestines. Some people taking OLUMIANT can get tears in their stomach or intestines. This happens most often in people who also take nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, or methotrexate.
- Tell your healthcare provider right away if you have fever and stomach-area pain that does not go away, and a change in your bowel habits.

8. Changes in certain laboratory test results.

Your healthcare provider should do blood tests before you start taking OLUMIANT and while you take OLUMIANT to check for the following:

- **low neutrophil and lymphocyte counts.** Neutrophils and lymphocytes are types of white blood cells that help the body fight off infections.
- **low red blood cell counts.** This may mean that you have anemia, which may make you feel weak and tired.
- **increased cholesterol levels.** If you are being treated for rheumatoid arthritis or alopecia areata, your healthcare provider should do blood tests to check your cholesterol levels approximately 12 weeks after you start taking OLUMIANT, and as needed.
- **elevated liver enzymes.** Liver enzymes help to tell if your liver is functioning normally. Elevated liver enzymes may indicate that your healthcare provider needs to do additional tests on your liver.

You should not take OLUMIANT if your lymphocyte count, neutrophil count, or red blood cell count is too low or your liver tests are too high. Your healthcare provider may stop your OLUMIANT treatment for a period of time if needed because of changes in these blood test results.

See "**What are the possible side effects of OLUMIANT?**" for more information about side effects.

What is OLUMIANT?

OLUMIANT is a prescription medicine that is a Janus Kinase (JAK) inhibitor. OLUMIANT is used to treat:

- adults with moderately to severely active rheumatoid arthritis after treatment with 1 or more medicines called tumor necrosis factor (TNF) blockers have been used and did not work well enough or could not be tolerated
- adult patients hospitalized with coronavirus disease 2019 (COVID-19) requiring oxygen or assistance with breathing.
- adults with severe alopecia areata

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

Before taking OLUMIANT, tell your healthcare provider about all your medical conditions, including if you:

- See "**What is the most important information I should know about OLUMIANT?**"
- have an infection
- are a current or past smoker
- have had a heart attack, other heart problems or stroke
- have kidney problems
- have liver problems
- have low red or white blood cell counts
- have recently received or are scheduled to receive a vaccine. People who take OLUMIANT should not receive live vaccines.
- have any stomach area (abdominal) pain or been diagnosed with diverticulitis or ulcers in your stomach or intestines
- are pregnant or plan to become pregnant. It is not known if OLUMIANT will harm an unborn baby. If you become pregnant during treatment with OLUMIANT call Eli Lilly and Company at 1-800-545-5979 to report the pregnancy.
- are breastfeeding or plan to breastfeed. It is not known if OLUMIANT passes into your breast milk. You should not breastfeed during treatment with OLUMIANT and for 4 days after the last dose. Talk to your healthcare provider about the best way to feed your baby during treatment with OLUMIANT.

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

OLUMIANT and other medicines may affect each other causing side effects.

Especially tell your healthcare provider if you take:

- a medicine called probenecid
 - medicines that affect your immune system such as biologic medications, other JAK inhibitors, and strong immunosuppressants (such as azathioprine and cyclosporine) as these medicines may increase your risk of infection.
- Ask your healthcare provider or pharmacist if you are not sure if you are taking one of these medicines. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take OLUMIANT?

- Take OLUMIANT exactly as your healthcare provider tells you to take it.
- For people with rheumatoid arthritis or alopecia areata, take OLUMIANT 1 time a day by mouth with or without food.
- For people with COVID-19, OLUMIANT will be given to you 1 time a day by mouth with or without food, for up to 14 days or until you are discharged from the hospital (whichever comes first), as instructed by your healthcare provider.
- Talk to your healthcare provider if you cannot swallow tablets whole.
- If you take too much OLUMIANT, call your healthcare provider or poison control center at 1-800-222-1222, or go to the nearest hospital emergency room right away.

What are the possible side effects of OLUMIANT?

OLUMIANT may cause serious side effects including:

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

The most common side effects of OLUMIANT in people treated for rheumatoid arthritis include:

- upper respiratory tract infections (common cold, sinus infections)
- nausea
- herpes simplex virus infections, including cold sores
- shingles (herpes zoster)

The most common side effects of OLUMIANT in people treated for COVID-19 include:

- increased liver enzyme levels
- increased platelets in your blood (thrombocytosis)
- increased blood creatine phosphokinase
- low white blood cell count (neutropenia)
- blood clots in the veins of your legs (DVT)
- blood clot in your lungs (pulmonary embolism)
- urinary tract infection

The most common side effects of OLUMIANT in people treated for alopecia areata include:

- upper respiratory tract infections (common cold, sinus infections)
- headache
- acne
- increased blood cholesterol
- increased blood creatine phosphokinase
- urinary tract infection
- increased liver enzyme levels
- inflammation of hair follicles (folliculitis)
- tiredness
- lower respiratory tract infections
- nausea
- genital yeast infection
- low red blood cell count (anemia)
- low number of certain types of white blood cells (neutropenia)
- stomach-area (abdominal) pain
- shingles (herpes zoster)
- increased weight

These are not all of the possible side effects of OLUMIANT.

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 OLUMIANT?

Store OLUMIANT at room temperature between 68°F to 77°F (20°C to 25°C).

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

General Information about the safe and effective use of OLUMIANT.

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

What are the ingredients in OLUMIANT?

Active ingredient: baricitinib

Inactive ingredients: croscarmellose sodium, magnesium stearate, mannitol, microcrystalline cellulose, ferric oxide, lecithin (soya), polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide.

OLUMIANT is a registered trademark of Eli Lilly and Company.

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For more information, call 1-800-545-5979 or go to the following website: www.olumiant.com.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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