

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrOLUMIANT®

baricitinib tablets

Read this carefully before you start taking OLUMIANT 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 about your medical condition and treatment and ask if there is any new information about OLUMIANT.

Serious Warnings and Precautions

Serious Infections

- You should not take OLUMIANT if you have any kind of infection.
- OLUMIANT is a medicine that affects your immune system and can lower the ability of your body to fight infections, such as tuberculosis, and infections caused by other bacteria, fungi or viruses that can spread throughout the body.
- In some cases, these infections may lead to hospitalization or death.
- Most patients taking OLUMIANT who developed these infections were also taking other medicines, such as methotrexate or corticosteroids that may have made it harder to fight infections.
- Contact your healthcare professional if you develop any signs or symptoms of an infection, such as:
 - fever, sweating, chills
 - muscle aches,
 - cough, shortness of breath,
 - blood in spit
 - 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 very tired
- Your healthcare professional will closely monitor you for the signs and symptoms of infection during and after the treatment with OLUMIANT.
- If a serious infection develops, stop taking OLUMIANT and contact your healthcare professional right away.

Cancers and immune conditions

- Lymphoma, lung cancer, and other cancers have been reported in patients treated with OLUMIANT.
- Your healthcare professional will closely monitor you for signs and symptoms of cancer and other serious conditions during treatment with OLUMIANT.

Major heart related problems

- Major heart related problems such as heart attack and stroke have been reported in Rheumatoid Arthritis patients treated with OLUMIANT.

- Talk to your healthcare professional about possible heart disease risk factors before you start taking OLUMIANT.
- Stop taking OLUMIANT and get emergency help right away if you have any symptoms of a heart problem such as heart attack or stroke while taking OLUMIANT. See the [Serious Side Effects table](#) for the symptoms.

Blood clots

- Blood clots in the veins of your legs (deep vein thrombosis, DVT) or lungs (pulmonary embolism, PE) can happen in some people taking OLUMIANT. This may be life-threatening and cause death.
- Stop taking OLUMIANT and seek medical help right away if you develop any signs or symptoms of blood clots in your:
 - leg (such as swelling, pain or tenderness in the leg); or
 - lung (such as sudden unexplained chest pain or shortness of breath).

What is OLUMIANT used for?

OLUMIANT, in combination with methotrexate, is indicated for reducing the signs and symptoms of rheumatoid arthritis (RA), in adult patients with moderately to severely active RA who have not responded well to one or more other medicines called disease modifying anti-rheumatic drugs (DMARDs).

OLUMIANT can be used alone if you cannot tolerate methotrexate.

OLUMIANT is also indicated for the treatment of adult patients with severe alopecia areata (AA). AA is a disease that happens when the immune system attacks hair follicles and causes hair loss.

How does OLUMIANT work?

OLUMIANT is believed to interfere with the activity of an enzyme called Janus Kinase (JAK). Normally JAK enzymes help turn on your immune system when you need it. The immune system then causes swelling and tenderness. This is called inflammation. OLUMIANT attaches to JAK enzymes and can help reduce the swelling and tenderness in people with RA.

In AA, OLUMIANT works by reducing the activity of JAK enzymes, which are involved in inflammation. By reducing the activity of JAK enzymes, OLUMIANT helps hair to regrow on scalp, in eyebrows, and in eyelashes impacted by AA.

What are the ingredients in OLUMIANT?

Medicinal ingredients: Baricitinib.

Non-medicinal ingredients: Croscarmellose sodium, ferric oxide, lecithin (soya), magnesium stearate, mannitol, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc, and

titanium dioxide.

OLUMIANT comes in the following dosage forms:

Tablets: 2 mg and 4 mg

Do not use OLUMIANT if:

- you are allergic to baricitinib or any of the other ingredients in OLUMIANT.
- you are pregnant.

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

- have an infection, or if you often get infections. OLUMIANT can make it harder for your body to fight infections.
- have diabetes, HIV/AIDS, or a weak immune system. People with these conditions have a higher chance of getting infections.
- have or have had tuberculosis (TB), or you have been in close contact with someone with TB.
- have recently traveled to or lived in an area where there is a lot of TB or fungal infections.
- have had a herpes infection, because OLUMIANT may reactivate this condition. Tell your healthcare professional if you develop a painful skin rash with blisters. These can be signs of shingles.
- have, or have previously had, hepatitis B or C.
- have recently received or are scheduled to receive a vaccine. People who take OLUMIANT should not receive live vaccines. Make sure you are up to date with all recommended vaccines before you start treatment with OLUMIANT.
- have or have had any type of cancer.
- have or have had heart problems.
- have had blood clots in your legs (deep vein thrombosis) or lungs (pulmonary embolism) or have been told you are at risk of blood clots. Risk factors may include:
 - older age
 - current or history of smoking
 - obesity
 - use of hormonal contraceptives (birth control) or hormone replacement medications
 - undergoing major surgery
 - immobile for longer periods of time
- have problems with your blood clotting (thrombophilia).
- plan to become pregnant or are pregnant. If you could become pregnant, you should use effective birth control while you are taking OLUMIANT and for at least 1 week after your last dose. If you become pregnant while taking OLUMIANT contact your healthcare professional immediately as it may harm your unborn baby.

- plan to breastfeed or are breastfeeding. You and your healthcare provider should decide if you will take OLUMIANT or breastfeed. You should not do both.
- have or have had inflammation in parts of the large intestine (diverticulitis), tears in your stomach or intestines (gastrointestinal perforations) or ulcers in your stomach or intestines. Some people using OLUMIANT get tears in their stomach or intestine. This happens most often in people who also take medicines such as nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, or methotrexate.
- have or have had liver problems.
- have or have had kidney problems.
- have or have had lung problems, including interstitial lung disease.
- have or have had muscle pain or muscle weakness.
- have low blood counts. Treatment with OLUMIANT can be associated with low red blood cell counts (anemia) and low white blood cell counts (neutrophils or lymphocytes).
- have high cholesterol.
- are 65 years of age or older. You may be more likely to get certain side effects.

Other warnings you should know about:

Blood Tests

You will need blood tests before you start OLUMIANT, and while you are taking it, to check if you have a low red blood cell count (anemia), low white blood cell count (neutropenia or lymphopenia), high blood fat (cholesterol), high creatine phosphokinase (an enzyme that increases in the blood when there is muscle damage) or high levels of liver enzymes, and to ensure that treatment with OLUMIANT is not causing problems. Your healthcare professional will decide when to perform blood tests and will interpret the results.

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 OLUMIANT:

- probenecid, used to treat gout, since this medicine may increase the levels of OLUMIANT in your blood.
- medicines which are used to control the body's immune response, such as azathioprine, tacrolimus or cyclosporine.
- any other medicines to treat your RA or your AA. For example, you should not take rituximab, etanercept, infliximab, anakinra, adalimumab, abatacept, certolizumab, golimumab, tocilizumab, tofacitinib or sarilumab while you are taking OLUMIANT. Using OLUMIANT with these medicines may increase your risk of infection.

How to take OLUMIANT:

- Always take OLUMIANT exactly as your healthcare professional tells you
- OLUMIANT can be taken with or without food
- Your healthcare professional may prescribe OLUMIANT alone or in combination with other medication(s). If you receive treatment with another drug, your healthcare professional will tell you how to take it. Be sure to read the package leaflets for the other drugs as well as this one.

Usual dose:

Adults with alopecia areata: 2 mg or 4 mg, taken by mouth once daily.
 Adults with rheumatoid arthritis: 2 mg, taken by mouth once daily.

Overdose:

If you think you, or a person you are caring for, have taken too much OLUMIANT, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you miss a dose of OLUMIANT, take your dose as soon as you remember. Do not take more than 1 tablet per day.

What are possible side effects from using OLUMIANT?

These are not all the possible side effects you may have when taking OLUMIANT. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- upper respiratory tract infections (common cold, sinus infections nose or throat infection with runny or stuffy nose, cough)
- mouth and throat pain
- headaches, nausea (feeling sick to your stomach), vomiting, diarrhea, stomach pain
- constipation, indigestion (heartburn or upset stomach)
- dizziness
- cold sores
- acne, rash, hives, swelling of the face
- high number of platelets (cells involved in blood clotting), shown by blood test
- muscle aches, muscle weakness, joint pain, muscle spasms, pain, stiffness
- fatigue or trouble sleeping

OLUMIANT can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and 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			
Shingles (herpes zoster): skin rash or blisters usually on one side of the body with itching, burning or tingling pain.			✓

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	
Gastroenteritis (infection of the stomach and intestines): vomiting, stomach pain, watery or bloody diarrhea, loss of appetite		✓	
High blood pressure: headache, fatigue, vision problems	✓		
Bronchitis: persistent cough, fatigue, shortness of breath		✓	
UNCOMMON			
Blood clots in the leg (deep vein thrombosis): swelling, pain or tenderness in the leg			✓
Liver problems: yellowing of the skin or eyes, dark urine, abdominal or back pain, nausea, vomiting, loss of appetite, itching			✓
Vulvovaginal candidiasis (vaginal yeast infection): severe itching, burning, soreness, irritation and a whitish-grey cottage cheese-like discharge		✓	
Blood clot in the lung (pulmonary embolism): chest pain, or shortness of breath			✓
Pneumonia (lung infection): coughing, fever, fatigue		✓	
Urinary tract infections: difficulty or increased need to urinate, pain or burning sensation when passing urine, pain in the pelvis or mid-back, urine that appears cloudy or bloody		✓	
Cellulitis (skin infection): redness, swelling and painful skin		✓	
Anemia: fatigue, loss of energy, weakness, shortness of breath		✓	
RARE			
Blood clot in the artery of an arm or leg: cold arm, leg, fingers or hands, muscle pain or spasms,			✓

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	
numbness and tingling in the arm or leg			
Flu: cough, sore throat, feverish chills		✓	
Skin cancer: new skin lesions during or after therapy or if an existing lesion changes in appearance		✓	
Cancers involving different body organs		✓	
UNKNOWN			
Major heart related problems such as heart attack and stroke: shortness of breath, 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 arms, back, stomach, chest, throat, neck, or jaw, breaking out in cold sweat, nausea or vomiting, feeling lightheaded, weakness in one part or on one side of your body and slurred speech.			✓
Allergic reactions: trouble breathing, chest tightness, wheezing, severe dizziness or lightheadedness, swelling of the lips, tongue or throat, hives			✓
Gastrointestinal perforations: (a hole or tear in your gastrointestinal tract)			✓

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

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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.

Storage:

Store at room temperature between 15° and 30°C

Keep out of reach and sight of children.

If you want more information about OLUMIANT:

- 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/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.lilly.ca, or by calling 1-888-545-5972.

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