www.lilly.ca

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.
- If you develop any sign or symptom 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) contact your healthcare professional.
- Your healthcare professional will closely monitor you for the signs and symptoms of infection during and after the treatment with OLUMIANT.

**Cancers**
- Lymphoma and other cancers have been reported in patients treated with OLUMIANT.

**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.
- If you develop any signs or symptoms of a blood clot in your leg (such as swelling, pain or tenderness in the leg) or in your lung (such as sudden unexplained chest pain or shortness of breath) stop OLUMIANT and seek immediate medical help.

**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.

**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.

**What are the ingredients in OLUMIANT?**
Medicinal ingredient: 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 form:**
Tablets: 2 mg

**Do not use OLUMIANT if:**
• you are allergic to baricitinib or any of the other ingredients in OLUMIANT.

**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. Signs and symptoms of an infection may include:
  • Fever, sweating, or 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
• 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 had blood clots in your legs (deep vein thrombosis) or lungs (pulmonary embolism) or have been told you are at risk of blood clots.
• 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.
• 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) 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.

**Serious Infections**
OLUMIANT can make it harder for your body to fight infections. This means that you might get sick more easily which can lead to serious infections. 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. If you have any signs or symptoms of an infection including fever, sweating, or 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 or feeling very tired, while you are being treated with OLUMIANT contact your healthcare professional immediately.

**Cancers**
OLUMIANT may decrease the activity of your immune system. Medicines that affect the immune system may increase your risk of cancer. Your healthcare professional will monitor you for any signs and symptoms that might mean you have cancer. If you notice any new symptoms while you are being treated with OLUMIANT, including new skin lesions or changes to existing lesions, talk to your healthcare professional.

**Blood Clots**
Blood clots in the legs and lungs can happen in some people taking OLUMIANT. This may be life-threatening and cause death. If you have any signs or symptoms of blood clots while you are being treated with OLUMIANT, including swelling, pain or tenderness in the leg, sudden unexplained chest pain, or shortness of breath, stop OLUMIANT and seek immediate medical help.

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. 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:
• By mouth
• With or without food
• Once a day

**Usual adult dose:** 2 mg once a day

**Overdose:**
If you think you have taken too much OLUMIANT, contact your 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 feel when taking OLUMIANT. If you experience any side effects not listed here, contact 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
- joint pain, muscle spasms
- back pain
- fatigue
- trouble sleeping

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

<table>
<thead>
<tr>
<th>Serious side effects and what to do about them</th>
<th>Talk to your healthcare professional</th>
<th>Stop taking drug and get immediate medical help</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Symptom / effect</strong></td>
<td><strong>Only if severe</strong></td>
<td><strong>In all cases</strong></td>
</tr>
<tr>
<td><strong>COMMON</strong></td>
<td></td>
<td></td>
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<tr>
<td>Shingles (herpes zoster): skin rash or blisters usually on one side of the body with itching, burning or tingling pain.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>UNCOMMON</strong></td>
<td></td>
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<tr>
<td>Blood clots in the leg (deep vein thrombosis): swelling, pain or tenderness in the leg</td>
<td></td>
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<tr>
<td>Blood clot in the lung (pulmonary embolism): chest pain, or shortness of breath</td>
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<td></td>
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<tr>
<td>Pneumonia (lung infection): coughing, fever, fatigue</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urinary tract infections: difficulty or increased need to urinate, pain or</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptom</td>
<td>Description</td>
<td>Risk Factor</td>
</tr>
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<tr>
<td>Burning sensation when passing urine, pain in the pelvis or mid-back, urine that appears cloudy or bloody</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cellulitis (skin infection):</td>
<td>redness, swelling and painful skin</td>
<td>✓</td>
</tr>
<tr>
<td>Anemia:</td>
<td>fatigue, loss of energy, weakness, shortness of breath</td>
<td>✓</td>
</tr>
<tr>
<td>Gastroenteritis (infection of the stomach and intestines):</td>
<td>vomiting, stomach pain, watery or bloody diarrhea, loss of appetite</td>
<td>✓</td>
</tr>
<tr>
<td>Blood clot in the artery of an arm or leg:</td>
<td>cold arm, leg, fingers or hands, muscle pain or spasms, numbness and tingling in the arm or leg</td>
<td>✓</td>
</tr>
<tr>
<td>High blood pressure:</td>
<td>headache, fatigue, vision problems</td>
<td>✓</td>
</tr>
<tr>
<td>Bronchitis:</td>
<td>persistent cough, fatigue, shortness of breath</td>
<td>✓</td>
</tr>
<tr>
<td>Flu:</td>
<td>cough, sore throat, feverish chills</td>
<td>✓</td>
</tr>
<tr>
<td>Skin cancer:</td>
<td>new skin lesions during or after therapy or if an existing lesion changes in appearance</td>
<td>✓</td>
</tr>
</tbody>
</table>

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.

**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/adverse-reaction-reporting.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 healthcare 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° - 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.html); the manufacturer’s website, www.lilly.ca or by calling 1-888-545-5972.

The information in this document is current as of the last revision date shown below. For the most current information please visit our website or contact us directly.
You may need to read this package insert again. Please do not throw it away until you have finished your medicine.

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