Patient Leaflet in Accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a physician's prescription only

OLUMIANT 2 MG
OLUMIANT 4 MG

Coated Tablets

Active ingredient - baricitinib
Each tablet of Olumiant 2 mg contains 2 mg of baricitinib.
Each tablet of Olumiant 4 mg contains 4 mg of baricitinib.

Inactive ingredients and allergens in the preparation: see section "important information about some of the ingredients of this medicine" in chapter 2 and chapter 6 "Additional Information".
Read the entire leaflet carefully before using this medicine. This leaflet contains concise information regarding this medicine.
If you have any further questions, contact your doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

In addition to the leaflet, Olumiant has a patient safety information card. This card contains important safety information that you need to know, before starting treatment and during treatment with Olumiant, and act on it. You must refer to the patient safety information card and patient leaflet before using the product. The card should be kept for further reference if necessary.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Rheumatoid Arthritis
Olumiant is used to treat adults with moderate to severe rheumatoid arthritis, when previous therapy with one or more anti-rheumatic drugs from the disease-modifying anti-rheumatic drug (DMARD) group did not work well enough or was not tolerated. Olumiant can be used alone or in combination with methotrexate.

Olumiant works by reducing the activity of an enzyme in the body called 'Janus kinase', which is involved in inflammation. By reducing the activity of this enzyme, Olumiant helps to reduce pain, stiffness and swelling in your joints, tiredness, and helps to slow damage to the bone and cartilage in the joints. These effects can help you to do normal daily activities and so improve the health-related quality of life for patients with rheumatoid arthritis.

Atopic Dermatitis
Olumiant is used to treat adults with moderate to severe atopic dermatitis, who are candidates for systemic therapy.

Olumiant works by reducing the activity of an enzyme in the body called 'Janus kinase', which is involved in inflammation. By reducing the activity of this enzyme, Olumiant helps to improve the condition of your skin and reduce itching. In addition, Olumiant helps improve your sleep disturbance (due to itch) and overall quality of life. Olumiant has also been shown to improve symptoms of skin pain, anxiety, and depression associated with atopic dermatitis. Atopic dermatitis is also known as

atopic eczema. Olumiant may be used with eczema medicines that you apply to the skin, or it may be used on its own.

Therapeutic group: Selective immunosuppressants.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- you are hypersensitive (allergic) to baricitinib or any of the other ingredients of this medicine (listed in section 6).
- you are pregnant or think you may be pregnant.

Special warnings regarding the use of this medicine
Talk to your doctor before and during treatment with Olumiant if you:

- have an infection, or if you often get infections. Tell your doctor if you get symptoms such as fever, wounds, feeling more tired than usual or dental problems as these can be signs of infection. Olumiant can reduce your body's ability to fight infections and may make an existing infection worse or increase the chance of you getting a new infection.
- have, or have previously had, tuberculosis. You may need tests to check for tuberculosis before you are given Olumiant. Tell your doctor if you get persistent cough, fever, night sweats and weight loss during Olumiant treatment as these can be signs of tuberculosis.
- have had a herpes infection (shingles), because Olumiant may allow it to come back. Tell your doctor if you get painful skin rash with blisters during Olumiant treatment as these can be signs of shingles.
- have, or have previously had, hepatitis B or C.
- are due to have a vaccine. You should not be given certain (live) vaccines while using Olumiant.
- have cancer, because your doctor will have to decide if you can still be given Olumiant.
- have poor liver function.
- have previously had blood clots in the veins of your legs (deep vein thrombosis) or lungs (pulmonary embolism). Tell your doctor if you get a painful swollen leg, chest pain, or shortness of breath as these can be signs of blood clots in the veins.
- have had diverticulitis (a type of inflammation of the large intestine) or ulcers in stomach or intestines (see section 4).

- If you notice any of the following serious side effects, you need to tell a doctor straight away:
  - chest tightness
  - wheezing
  - severe dizziness or light-headedness
  - swelling of the lips, tongue or throat
  - hives (itching or skin rash)
  - severe abdominal pain especially accompanied with fever, nausea and vomiting.

Children and adolescents
Do not give this medicine to children and adolescents under 18 years old because there is no information on use in this age group.

Tests and follow-up
You may need blood tests before you start Olumiant, or 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, to ensure that treatment with Olumiant is not causing problems.

Interactions / Drug interactions
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including nonprescription medications and nutritional supplements.
Especially if you are taking:
- probenecid (for gout), since this medicine may increase the levels of Olumiant in your blood. If you are taking probenecid, the recommended dose of Olumiant is 2 mg once a day. Consult your doctor before use
- injectable anti-rheumatic medicine
- injectable medicines that depress the immune system, including so called targeted biologic (antibody) therapies
- medicines which are used to control the body's immune response, such as azathioprine, tacrolimus or ciclosporin
- other medicines belonging to the group of Janus kinase inhibitors
- medicines that may increase your risk of diverticulitis such as a non-steroidal anti-inflammatory medicines (NSAIDs, usually used to treat painful and/or inflammatory conditions of muscle or joints) and/or opioids (used to treat severe pain), and/or corticosteroids (usually used to treat inflammatory conditions) (See section 4).

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, ask your doctor or pharmacist for advice before taking this medicine.

You should use an effective method of contraception to avoid becoming pregnant during treatment with Olumiant and for at least one week after the last Olumiant treatment. You must tell your doctor if you become pregnant, as Olumiant should not be used during pregnancy.

You should not use Olumiant while breastfeeding as it is not known if this medicine passes into milk. You and your doctor should decide if you will breastfeed or use Olumiant. You should not breastfeed and use Olumiant at the same time.

Driving and using machines
Olumiant has no effect on the ability to drive and use machines.

Important information about some of the ingredients of this medicine
Olumiant contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium-free".

3. HOW TO USE THIS MEDICINE?

Always use this preparation according to the doctor's instructions.

Treatment should be started by a doctor experienced in the diagnosis and treatment of your condition. Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure about the dosage and manner of treatment with this preparation. The dosage and manner of treatment will be determined by the doctor only.

Rheumatoid arthritis and atopic dermatitis

The recommended dose is 4 mg once a day. Your doctor may give you a lower dose of 2 mg once a day, particularly if you are over 75 years old or if you have an increased risk of infections. If the medicine is working well, your doctor may decide the dose can be reduced.

If you have reduced kidney function, the recommended dose of Olumiant is 2 mg once a day.

Do not exceed the recommended dosage.

Olumiant is intended for oral use. You should swallow your tablet with a drink of water.
You can take the tablets either with or without food. To help you remember to take Olumiant, you may find it easier to take it at the same time every day.
Do not crush or split Olumiant tablets. The tablets are not intended for distribution to smaller doses. If you try to split the tablet, you may not get the whole dose prescribed to you by your doctor.
There is no information on the use of this drug in a nasogastric tube.

If you have accidentally taken a higher dose or if a child accidentally swallowed the medicine, proceed immediately to the doctor or a hospital Emergency Room and bring the package of the medicine with you. You may suffer from some of the side effects described in section 4.

If you forgot to take the medicine

- If you miss a dose, take it as soon as you remember.
- If you forget your dose for an entire day, just skip the missed dose and take only a single dose as usual the following day.
- Do not take a double dose to make up for a forgotten tablet.

Treatment should be continued as recommended by the doctor.

If you stop taking the medicine
Do not stop taking Olumiant unless your doctor tells you to stop taking it.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take your medicine. Wear glasses if you need them.
If you have any further questions regarding the use of this medicine, consult the doctor or pharmacist.

<u>4. SIDE EFFECTS</u>

As with any medicine, the use of Olumiant may cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not experience any of them.

Serious side effects

Infection such as shingles and pneumonia, which may affect up to 1 in 10 people: Tell your doctor or seek medical help immediately if you get the following symptoms, which may be signs of:
- shingles (herpes zoster): painful skin rash with blisters and fever (this was very rare in atopic dermatitis)
- pneumonia: persistent cough, fever, shortness of breath, and tiredness (this was uncommon in atopic dermatitis)

Serious pneumonia and serious herpes zoster were uncommon.

Additional side effects

Very common side effects (may affect more than 1 in 10 people):
- throat and nose infections
- high levels of blood fat (cholesterol) shown by blood test

Common side effects (may affect up to 1 in 10 people):
- cold sores (herpes simplex)
- infection causing a sick stomach or diarrhea (gastroenteritis)
- urinary infection
- high number of platelets (cells involved in blood clotting), shown by blood test (this was uncommon in atopic dermatitis)
- headache
- feeling sick in the stomach (nausea; this was uncommon in atopic dermatitis)
- stomach pain
- high levels of liver enzymes, shown by blood test (this was uncommon in atopic dermatitis)
- rash
- acne (this was uncommon in rheumatoid arthritis)
- increase in an enzyme called creatine kinase, shown by a blood test (this was uncommon in rheumatoid arthritis)

Uncommon side effects (may affect up to 1 in 100 people):
- low number of white bloods cells (neutrophils), shown by blood test
- high levels of blood fat (triglycerides), shown by blood test
- high levels of liver enzymes, shown by blood test
- weight gain
- swelling of the face
- urticaria
- blood clots in the blood vessels of the lungs
- blood clot in the veins of the legs or pelvis, called a deep vein thrombosis (DVT)
- diverticulitis (painful inflammation of small pockets in the lining of your intestine)

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult your doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting Side Effects due to Drug Treatment" that can be found on the Home Page

of the Ministry of Health's website (www.health.gov.il), which refers to the online form for reporting side effects, or via the following link: https://sideeffects.health.gov.il

5. HOW TO STORE THIS MEDICINE?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the outer carton and on the blister. The expiry date refers to the last day of that month.

Storage conditions

- Store below 30°C.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, the medicine also contains:
microcrystalline cellulose, mannitol, croscarmellose sodium (see section 2 "Olumiant contains sodium"), magnesium stearate,

Film coating, color mixture pink 85G140008 (2 mg)/85G140009(4 mg):

- polyvinyl alcohol
- titanium dioxide
- macrogol
- talc
- lecithin
- iron oxide red

What does the medicine look like and contents of the pack:
Olumiant 2 mg film coated tablets are light pink, 9 x 7.5 mm oblong tablets, with "Lilly" on one side and "2" on the other.

Olumiant 4 mg film coated tablets are medium pink, 8.5 mm round tablets, with "Lilly" on one side and "4" on the other.

The tablets are rounded and have hollow sides to help you pick them up.

Olumiant 2 mg and 4 mg are available in blister packs of 14, 28, 35, 56, 84 and 98 tablets in calendar blisters and 28 x 1 and 84 x 1 tablets in perforated unit dose blisters.
Not all pack sizes may be marketed.

Registration holder and address: Eli Lilly Israel, Ltd., 4 HaSheizaf Street, P.O.Box 4246, Ra'anana 4366411.

Manufacturer and address: Lilly S.A., Alcobendas, Madrid, Spain.

Revised in December 2021 according to MoH's guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Olumiant 2 mg: 161-15-35738-00
Olumiant 4 mg: 161-16-35739-00

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Please remove this portion of the patient leaflet and keep it with you.

Information for Patients about Olumiant (baricitinib).

This document contains important information you should be aware of before and during treatment with Olumiant.

Olumiant is used

- to treat adults with moderate to severe rheumatoid arthritis, when previous therapy with one or more anti-rheumatic drugs from the disease-modifying anti-rheumatic drug (DMARD) group did not work well enough or was not tolerated. Olumiant can be used alone or in combination with methotrexate.
- to treat adults with moderate to severe atopic dermatitis, also known as atopic eczema. Olumiant may be used with eczema medicines that you apply to the skin or it may be used on its own.

Keep this information with you and share it with other healthcare professionals involved in your medical care or treatment.

Your name:

_____

Doctor's name (who prescribed Olumiant):

Infections:

Olumiant may make an existing infection worse or increase the chance of you getting a new infection or increase the chance of viral reactivation. Inform your doctor immediately if you get symptoms of infection, such as:

- Fever, wounds, feeling more tired than usual, or dental problems.
- A cough that won't go away, night sweats, and weight loss. These could be symptoms of tuberculosis (an infectious disease of the lungs).
- A painful skin rash with blisters. This could be a sign of a herpes zoster infection.

Blood fat:

The use of Olumiant may increase the level of fat in the blood.

Your doctor may check for levels of fat in the blood, such as cholesterol, while you are taking Olumiant.

Blood clots in the veins:
Before and during treatment with Olumiant, tell your doctor if you have previously had blood clots in the veins of your legs (deep vein thrombosis) or lungs (pulmonary embolism).

_____ **Doctor's phone number:** _____	• Tell your doctor if you get a painful swollen leg, redness or warmth in the leg, chest pain, or shortness of breath as these can be signs of blood clots in the veins. **Pregnancy:** • Do not take Olumiant if you are pregnant or suspect you may be pregnant. • Use effective contraception while taking Olumiant (and for one week after if you stop treatment). • Tell your doctor immediately if you become (or wish to become) pregnant.