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

Film-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 pediatric patients 2 years of age and older, adolescents and adults with moderate to severe atopic dermatitis, who are candidates for systemic therapy. 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.

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.

Alopecia areata
Olumiant is used to treat adults with severe alopecia areata, an autoimmune disease characterized by inflammatory, nonscarring hair loss on the scalp, face and sometimes on other areas of the body that can be recurrent and progressive. 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 hair to regrow on scalp, face and other areas of the body impacted by the disease.

Juvenile idiopathic arthritis
Olumiant is used for the treatment of active juvenile idiopathic arthritis in patients 2 years of age and older who have had an inadequate response or intolerance to one or more prior conventional synthetic or biologic disease-modifying antirheumatic drug (DMARDS):
- Polyarticular juvenile idiopathic arthritis (polyarticular rheumatoid factor positive [RF+] or negative [RF-], extended oligoarticular)
- Enthesitis-related arthritis, and
- Juvenile psoriatic arthritis.

Olumiant may be used as monotherapy or in combination with methotrexate.

Therapeutic group: Immunosuppressants, selective immunosuppressants.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- you are hypersensitive (allergic) to the active ingredient (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 or pharmacist before and during treatment with Olumiant if:

- you are older than 65. Patients aged 65 years and older may be at increased risk of infections, heart problems including heart attack and some types of cancer. Your doctor will discuss with you if Olumiant is appropriate for you.
- 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. If you have diabetes or are older than 65 you may have an increased chance of getting infections.
- you 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.
- you 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.
- you have, or have previously had, hepatitis B or C.
- you are due to have a vaccine. You should not be given certain (live) vaccines while using Olumiant.
- you have or have had cancer, smoke or have smoked in the past, because your doctor will discuss with you if Olumiant is appropriate for you.

- you have poor liver function.
- you have, or have had, heart problems, because your doctor will discuss with you if Olumiant is appropriate for you.
- you have previously had blood clots in the veins of your legs (deep vein thrombosis) or lungs (pulmonary embolism) or have an increased risk for developing this (for example: if you had recent major surgery, if you use hormonal contraceptives/hormonal replacement therapy, or if a coagulation defect is identified in you or your close relatives). Your doctor will discuss with you if Olumiant is appropriate for you. Tell your doctor if you get sudden shortness of breath or difficulty breathing, chest pain or pain in upper back, swelling of the leg or arm, leg pain or tenderness, or redness or discoloration in the leg or arm as these can be signs of blood clots in the veins.
- you have had diverticulitis (a type of inflammation of the large intestine) or ulcers in stomach or intestines (see section 4).
- Non-melanoma skin cancer has been observed in patients taking Olumiant. Your doctor may recommend that you have regular skin examinations while taking Olumiant. If new skin lesions appear during or after therapy or if existing lesions change appearance, tell your doctor.

If you notice any of the following serious side effects, you need to tell a doctor straight away:
- 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
- severe chest pain or tightness (that may spread to arms, jaw, neck, back)
- shortness of breath
- cold sweat
- one-sided weakness in arm and/or leg
- slurred speech.

Children and adolescents
If possible, children and adolescents should be up to date with all vaccinations before using Olumiant.

Do not give this medicine to children younger than 2 years of age.

Do not give this medicine to children and adolescents with alopecia areata under 18 years old, because there is no information on use in this disease.

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.

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 for adults is 2 mg once a day and for children and adolescents the dose should be reduced by half. 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).
- medicines to treat diabetes or if you have diabetes. Your doctor may decide if you need less anti-diabetic medicine while taking Olumiant.

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 do both.

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.

Adults with rheumatoid arthritis, atopic dermatitis and alopecia areata

The usual 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 65 years old or if you have an increased risk of infections, of blood clots, major cardiovascular events or cancer.

If the medicine is working well, your doctor may decide the dose can be reduced.

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

Use in children and adolescents
The usual dose is 4 mg once a day for patients ≥ 30 kg. For patients 10 kg to < 30 kg the recommended dose is 2 mg once a day.

If you have reduced kidney function, the recommended dose of Olumiant should be reduced by half.

For pediatric patients who are unable to swallow whole tablets, the tablets may be dispersed in water:
- Place whole tablet in a container with 5-10 mL of water at room temperature and gently swirl to disperse (break apart) tablet. It may take up to 10 minutes for the tablet to disperse into a cloudy pale pink suspension. Some settling may occur.
- After the tablet is dispersed, gently swirl again and then swallow mixture immediately
- Rinse the container with 5-10 mL of water at room temperature by swirling, and swallow the mixture immediately to ensure full dose is delivered.

Only water should be used to disperse the tablet.

After the tablet is dispersed in water it can be used for up to 4 hours if kept at room temperature.

If a tablet is dispersed in water and only part of the dispersed dose is taken, wait until the next day to take the next scheduled dose.

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.

4. SIDE EFFECTS

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 and uncommon in alopecia areata)
- pneumonia: persistent cough, fever, shortness of breath, and tiredness (this was uncommon in atopic dermatitis and alopecia areata)

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 and alopecia areata)
- headache
- feeling sick in the stomach (nausea; this was uncommon in atopic dermatitis)
- stomach pain (this was uncommon in alopecia areata)
- 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)
- inflammation (swelling) of the hair follicles particularly in the scalp region associated with hair regrowth (observed in alopecia areata).

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 (this was common in alopecia areata)
- 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).

Children and adolescents

- **Polyarticular juvenile idiopathic arthritis, enthesitis-related arthritis and juvenile psoriatic arthritis:** In a study of children 2 years of age and older with polyarticular juvenile idiopathic arthritis, enthesitis-related arthritis and juvenile psoriatic arthritis, headache was very common, low number of white blood cells and blood clots in the lungs were common (1 out of 82 children each).
- **Pediatric atopic dermatitis:** In a study of children 2 years of age and older with atopic dermatitis, side effects were consistent with those seen in adult patients with the exception of low number of white bloods cells (neutrophils), which was more common compared to adults.

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 of 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 blister and on the outer carton. 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, magnesium stearate.
For more information, see section 2 "Important information about some of the ingredients of this medicine".
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.
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 name and address: Eli Lilly and Company, Indianapolis, Indiana, USA.

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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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