

OLUMIANT FILM-COATED TABLETS

Baricitinib (2 mg, 4 mg)

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What Olumiant is used for

Rheumatoid arthritis

Olumiant is used to treat adults with moderate to severe rheumatoid arthritis, an inflammatory disease of the joints, if previous therapy did not work well enough or was not tolerated. Olumiant can be used alone or together with some other medicines, such as methotrexate.

Atopic dermatitis

Olumiant is used to treat children from the age of 2 years, adolescents and 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.

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.

Children and adolescents

Polyarticular juvenile idiopathic arthritis, enthesitis-related arthritis and juvenile psoriatic arthritis

Olumiant is used for the treatment of active polyarticular juvenile idiopathic arthritis, an inflammatory disease of the joints, in children 2 years of age and older.

Olumiant is also used for the treatment of active enthesitis-related arthritis, an inflammatory disease of the joints and the places where tendons join the bone, in children 2 years of age and older.

Olumiant is also used for the treatment of active juvenile psoriatic arthritis, a condition that is an inflammatory disease of the joints often accompanied by psoriasis, in children 2 years of age and older.

Olumiant can be used alone or together with methotrexate.

How Olumiant works

Olumiant contains the active substance baricitinib. It belongs to a group of medicines called Janus kinase inhibitors, which help to reduce inflammation.

Rheumatoid arthritis

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 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 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.

Before you use Olumiant

- When you must not use it

Do not take Olumiant:

- if you are allergic to baricitinib or

any of the other ingredients of this medicine (see section **Product description**).

- if you are pregnant or think you may be pregnant.

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.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, 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 breast-feeding as it is not known if this medicine passes into milk. You and your doctor should decide if you will breast-feed or use Olumiant. You should not do both.

- Before you start to use it

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
- have an infection, or if you often get infections. Tell your doctor if you have a wound and are experiencing symptoms such as fever and feeling more tired than usual as they might be sign of an infected wound. Olumiant can

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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

- 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 increase the chances of 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 or have had cancer, smoke or have smoked in the past, because your doctor will discuss with you if Olumiant is appropriate for you.
- have poor liver function.
- have, or have had, heart problems, because your doctor will discuss with you if Olumiant is appropriate for you.
- have previously had blood clots in the vein 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.
- have had diverticulitis (a type of inflammation of the large

intestine) or ulcers in stomach or intestines.

- 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.

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 (anaemia), low white blood cell count (neutropaenia or lymphopaenia), high blood fat (cholesterol) or high levels of liver enzymes, to ensure that treatment with Olumiant is not causing problems.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken, or might take, any other medicines.

In particular, tell your doctor or pharmacist before taking Olumiant if you are taking any other medicine such as:

- 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
- 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 (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 **Side effects**).

- medicines to treat diabetes or if you have diabetes. Your doctor may decide if you need less anti-diabetic medicine while taking Olumiant.

How to use Olumiant

- How much to use

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.

Adult with rheumatoid arthritis, atopic dermatitis and alopecia areata

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 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 recommended dose of Olumiant is 2 mg once a day.

Use in children and adolescents

The recommended 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.

For children weighing less than 30 kg taking OAT3 inhibitors or with moderate kidney failure, the dose should not exceed 1 mg once daily. However, as this dose strength is not available, Olumiant is not recommended for these patients.

For paediatric 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

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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.

- When to use it

Olumiant is for oral use. You should swallow your tablet with a glass 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.

- How long to use it

Do not stop using Olumiant unless your doctor tells you to stop taking it.

- If you forget to use it

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.

- If you use too much (overdose)

If you take more Olumiant than you should, contact your doctor. You may get some of the side effects described in the **Side effects** section.

While you are using Olumiant

- Things you must do

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

- Things you must not do

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

- Things to be careful of

Driving and using machines

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

Blood clots

Olumiant may cause a condition in which a blood clot forms in your leg that may travel to your lungs. Inform your doctor immediately if you experience any of the following symptoms:

- Swelling or pain in one leg
- Warmth or redness in one leg
- Shortness of breath which is unexpected
- Rapid breathing
- Chest pain

Side effects

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

Like all medicines, this medicine can cause side effects, although not everybody gets 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.

Other side effects

Very common (may affect more than 1 in 10 people):

- throat and nose infections
- high levels of blood fat (cholesterol) shown by blood test

Common (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 (may affect up to 1 in 100 people):

- low number of white blood cells (neutrophils), shown by blood test

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- 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).

- **Paediatric 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 blood cells (neutrophils), which was more common compared to adults.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Olumiant

- Storage

Keep this medicine out of the sight and reach of children.

Store below 30°C.

Do not use this medicine after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.

- Disposal

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.

Product Description

- What it looks like

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 round and have hollow sides to help you pick them up.

Olumiant 2 mg and 4 mg are available in packs of 1 x 7 and 4 x 7 tablets in perforated unit dose blisters. Not all pack sizes may be marketed.

- Ingredients

- **Active ingredient:**

The active substance is baricitinib.

- Olumiant 2 mg film-coated tablets: Each tablet contains 2 milligrams of baricitinib.
- Olumiant 4 mg film-coated tablets: Each tablet contains 4 milligrams of baricitinib.

- **Inactive ingredients**

The other ingredients are microcrystalline cellulose, croscarmellose sodium, (see “Olumiant contains sodium”) magnesium stearate, mannitol, iron oxide red (E172), lecithin (soya) (E322), macrogol, poly (vinyl alcohol), talc and titanium dioxide (E171).

Olumiant contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that

is to say essentially “sodium-free”.

- MAL number

Olumiant 2 mg film-coated tablets – MAL18086128ARZ

Olumiant 4 mg film-coated tablets – MAL18086127ARZ

Manufacturer

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Product Registration Holder

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Date of Revision

09/07/2025

Serial Number

NPRA(R1/AI5)17032025/006

NPRA (R1/7) 19122023/213