

Package leaflet: Information for the patient

Olumiant® 2 mg film-coated tablets

Olumiant® 4 mg film-coated tablets

Baricitinib

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, or pharmacist or nurse.
- 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.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Olumiant is and what it is used for
2. What you need to know before you take Olumiant
3. How to take Olumiant
4. Possible side effects
5. How to store Olumiant
6. Contents of the pack and other information

1. What Olumiant is and what it is used for

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

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.

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.

2. What you need to know before you take Olumiant

Do not take Olumiant:

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

Warnings and precautions

Talk to your doctor or pharmacist 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

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.

Children and adolescents

Olumiant is not for use in children and adolescents under 18 years old because there is no information on use in this age group.

Other medicines and Olumiant

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:

- 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
- 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, such as ruxolitinib

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.

Driving and using machines

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

3. How to take Olumiant

Treatment should be started by a doctor experienced in the diagnosis and treatment of rheumatoid arthritis. Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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.

Olumiant is 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.

If you take more Olumiant than you should

If you take more Olumiant than you should, contact your doctor. You may get some of the side effects described in section 4.

If you forget to take Olumiant

- 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 stop taking Olumiant

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

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

4. Possible side effects

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

Infection such as shingles, 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

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 diarrhoea (gastroenteritis)
- urinary infection
- pneumonia
- high number of platelets (cells involved in blood clotting), shown by blood test
- feeling sick in the stomach (nausea)
- high levels of liver enzymes, shown by blood test

Uncommon side effects (may affect up to 1 in 100 people):

- low number of white blood cells (neutrophils), shown by blood test
- increase in an enzyme called creatine kinase, shown by blood test
- high levels of blood fat (triglycerides), shown by blood test
- acne
- weight gain

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via **Ireland:** HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517; website: www.hpra.ie; e-mail: medsafety@hpra.ie, **Malta:** ADR Reporting, Website: www.medicinesauthority.gov.mt/adrportal, **United Kingdom:** Yellow Card Scheme; website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Olumiant

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

This medicine does not require any special storage conditions.

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.

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. Contents of the pack and other information

What Olumiant contains

- The **active** substance is baricitinib. Each tablet contains 2 or 4 milligrams of baricitinib.
- The **other** ingredients are: microcrystalline cellulose, croscarmellose sodium, magnesium stearate, mannitol, iron oxide red (E172), lecithin (soya) (E322), macrogol, poly (vinyl alcohol), talc and titanium dioxide (E171).

What Olumiant looks like and contents of the pack

Olumiant 2 mg film-coated tablets are light pink, oblong tablets, with "Lilly" on one side and "2" on the other.

Olumiant 4 mg film-coated tablets are medium pink, 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 the pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Eli Lilly Nederland B.V., Papendorpseweg 83, 3528BJ, Utrecht, The Netherlands.

Manufacturer: Lilly S.A., Avda. de la Industria 30, 28108 Alcobendas, Madrid, Spain.

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Ireland

Eli Lilly and Company (Ireland) Limited
Tel: + 353-(0) 1 661 4377

Malta

Charles de Giorgio Ltd.
Tel: + 356 25600 500

United Kingdom

Eli Lilly and Company Limited
Tel: + 44-(0) 1256 315000

This leaflet was last revised in September 2018.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:

<http://www.ema.europa.eu>.

www.olumiant.eu

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

<p>Information for Patients about OLUMIANT® (baricitinib) This document contains important information you should be aware of before and during treatment with Olumiant.</p> <p>Keep this information with you and share it with other healthcare professionals involved in your medical care or treatment.</p> <p>Your name: _____</p> <p>Doctor's name (who prescribed Olumiant): _____</p> <p>Doctor's phone number: _____</p>	<p><u>Pregnancy</u></p> <ul style="list-style-type: none"> Do not take Olumiant if you are pregnant or suspect you may be pregnant. Use effective contraception while taking Olumiant (and for 1 week after, if you stop treatment). Tell your doctor immediately if you become (or wish to become) pregnant. <p><u>Infections:</u> 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:</p> <ul style="list-style-type: none"> 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. <p><u>Blood fat:</u> Your doctor may check for levels of fat in the blood, such as cholesterol, while you are taking Olumiant.</p>
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