



olumiant[®]
(Baricitinib) Tabletten

A Lilly Medicine

**QUESTIONS AND ANSWERS
ABOUT YOUR THERAPY
WITH OLUMIANT[®]**

Information for Patients
with inflammatory-rheumatic diseases of the joints

Your start with Olumiant®

Dear reader,

Your rheumatologist has prescribed Olumiant®, which is used to treat adults with rheumatoid arthritis (RA) and children and adolescents aged 2 years and older with polyarticular juvenile idiopathic arthritis, enthesitis-related arthritis or juvenile psoriatic arthritis. In this brochure we would like to give you information about your new therapy and answer frequently asked questions. We hope that this information will be valuable to you and will answer your most important questions about the drug Olumiant®.

Please also read the package leaflet for Olumiant®.



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Olumiant® for inflammatory rheumatic diseases of the joints

When is Olumiant® used?

In adults, Olumiant® is used to treat moderate to severe active rheumatoid arthritis when your previous treatment has not worked sufficiently well or when you have not tolerated it.

In children and adolescents aged 2 years and above, Olumiant® is used to treat polyarticular juvenile idiopathic arthritis (an inflammatory disease of the joints), enthesitis-associated arthritis (an inflammatory disease of the joints and tendon attachments), or juvenile psoriatic arthritis (an inflammatory disease of the joints that is often associated with psoriasis).

Olumiant® can be used alone or together with methotrexate.

How is Olumiant® taken?

Please take **one whole Olumiant® tablet daily** with water. The medication can be taken regardless of meals and at any time of the day. To make it easier to remember, Olumiant® can be taken at the same time every day.



Our tip for you

Combine taking the tablet with a daily, recurring ritual such as brushing your teeth or eating breakfast. A daily mobile phone reminder can also be very helpful.

Always take Olumiant® exactly as your doctor or pharmacist has told you and ask for advice if you are not sure.



For children and adolescents with swallowing difficulties:

The tablet can be suspended in 1-2 teaspoons (5-10 ml) of water shortly before taking. Make sure that the tablet dissolves completely (this may take up to 10 minutes). Please swirl the cloudy suspension again shortly before drinking. Finally, swirl the container with another 1-2 teaspoons of water and drink this as well.

For treatment success, it is very important to take the tablets for a long period and regularly. This means that even if you feel better, you should not stop taking the tablets without consulting your doctor, as this may actually be an indication that the therapy is working for you. Inflammatory rheumatic diseases are chronic and currently incurable diseases, which is why long-term treatment is necessary.

All Olumiant® tablets have a recess in the middle. This improves the adhesion of the tablet to the skin, similar to a suction cup. This means you can pick up the tablet quite easily even if your fingers are less flexible, or even with the edge of your hand or the ball of your thumb. The tablets cannot be divided.

The tablet is engraved with a 4, a 2 or a 1, which corresponds to the number of milligrams prescribed by your doctor. The word Lilly is embossed on the other side of the tablets.

The days of the week are printed on the tablet blister. This way you can easily see whether you have already taken your daily dose.

If the treatment is working well, your doctor may decide to reduce the dose. Make sure you take the dose prescribed by your doctor.

Examples of Olumiant® 4 mg and Olumiant® 2 mg:



Olumiant® 4 mg film-coated tablets
1× daily



Olumiant® 2 mg film-coated tablets
1× daily



Olumiant® for inflammatory rheumatic diseases of the joints

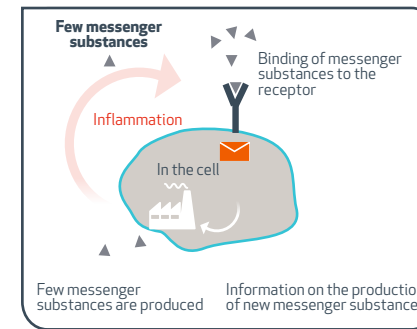
How does Olumiant® work?

Olumiant® contains the active substance baricitinib and belongs to a group of medicinal products known in technical terms as **janus kinase inhibitors**. Janus kinases are enzymes that are involved in the inflammatory process.

Olumiant® specifically counteracts inflammation by reducing the activity of these enzymes. Olumiant® acts in the cells and prevents signals from some inflammatory messenger substances from being transmitted from the cell surface to the cell interior. By temporarily inhibiting the signal, the inflammatory process can be reduced.

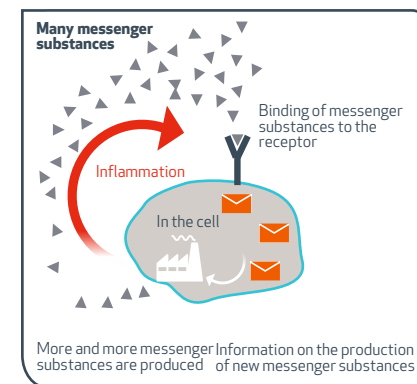
The effect of Olumiant® can alleviate pain, stiffness and swelling in your joints, reduce fatigue, and delay damage to bones and cartilage in the joints. Olumiant® can help you to carry out your normal daily activities and improve the quality of life affected by the disease.

Schematic representation of the operating principle



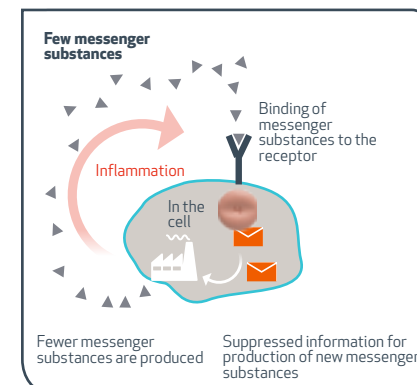
Without a rheumatic disease

Messenger substances that promote inflammation also occur in healthy people. As part of a healthy immune system, they protect against disease. Inflammation is a completely normal defence reaction to allow the healing process to proceed in a controlled manner.



With rheumatic disease and uncontrolled inflammation

Here, the body produces a lot of messenger substances. The system becomes unbalanced and inflammation continues.



With rheumatic disorder and reduced inflammation with Olumiant®

Olumiant® temporarily inhibits the production of messenger substances and can reduce inflammation .

Important instructions

What do I need to consider when using Olumiant®?

Do not take Olumiant® if you are allergic to the active substance baricitinib or any other ingredient. It is also not approved for use by children with juvenile idiopathic arthritis under 2 years of age and pregnant women.

Please tell your doctor before starting and during use if any of the following apply to you:

- I currently have an infection or have frequent infections
- I have tuberculosis or have had a tuberculosis infection before
- I have had a herpes zoster infection (shingles) before
- I have or have had a hepatitis B or C infection
- I have had diverticulitis (a type of colon inflammation) or stomach or intestinal ulcers
- I have poor liver values
- I need a vaccination
- I have or have had cancer
- I am 65 years or older
- I smoke or have smoked in the past
- I have or have had heart problems in the past
- I have had a blood clot in the veins of my legs or lungs before or am at increased risk of developing one*

If one or more of the above statements apply to you, your doctor must decide whether you can take Olumiant®, or take it at a reduced dosage.

* There is an increased risk of a blood clot, e.g., after a recent major surgical procedure, with hormonal contraceptives/hormone replacement therapy, or if you/close relatives are known to have a coagulation disorder

Can I take Olumiant® with other medicines?

Tell your doctor if and what other medicines you are taking. This is because interactions may occur when taken at the same time as baricitinib, the active ingredient in Olumiant®. This applies particularly to:

- Probenecid for the treatment of gout
- Drugs that are injected for the treatment of rheumatoid arthritis
- Medicines used to inhibit the body's immune response, such as azathioprine, tacrolimus or ciclosporin
- Other janus kinase inhibitors, such as ruxolitinib for the treatment of myelofibrosis (a disease of the bone marrow)
- Medications that may increase your risk of diverticulitis (risk of a type of colon inflammation), such as nonsteroidal anti-inflammatory drugs and/or opioids (for treating severe pain) and/or corticosteroids



Our tip for you

Carry your Olumiant® patient card ("Information for Patients") with you. Take your patient card with you to every doctor's appointment and show it. This will enable your doctor to select medications or vaccinations that are appropriate for you.



Important instructions

What should I do if I forget to take Olumiant®?

Take the forgotten dose as soon as possible. However, if you do not notice this until the next day, simply skip the missed tablet and continue taking it as usual. In other words, do not take two tablets at the same time.

What happens if I take Olumiant® too often?

Taking a larger amount of Olumiant® could cause side effects to occur. If you have taken more Olumiant® than you should contact your doctor.

How long does therapy with Olumiant® last?

Rheumatoid arthritis is a chronic disease that is currently incurable but usually easy to treat. If treatment with Olumiant® works for you, you will notice an improvement in your symptoms after a certain period of time.

To permanently reduce disease activity and pain, stiffness and swelling in your joints, the medication must be taken regularly and over a long period of time.

How long will it take until I notice that I am feeling better?

Everyone has their own medical history. Therefore, it is not possible to predict exactly how each individual will respond to treatment with Olumiant® or how quickly the drug will take effect.

However, it is known that typical symptoms in people with rheumatoid arthritis who took Olumiant® once daily and who responded to treatment experienced improvement **within the first one to twelve weeks of treatment**. Then, for example, they had less pain or their joints were more mobile.

No special storage conditions are required for Olumiant®. Keep this medicine out of the sight and reach of children. Do not dispose of medicinal products in sewage or with household waste. Ask your pharmacist how to dispose of medicines you no longer use. In this way, you are helping to protect the environment.



Side effects and precautions



What side effects can occur during treatment with Olumiant®?

As with all medicines, Olumiant® can cause side effects, although these do not occur in all patients. The most commonly observed side effects include throat and nose infections and high blood fat levels (cholesterol). Headaches were very common in children aged 2 years and older. All other side effects can be found in the package leaflet. If you have any further questions, ask your doctor.

What should I do if I notice side effects?

If you notice any side effects, please tell your doctor so that he or she can advise you. This also applies to side effects that are not listed in the package leaflet. Typical side effects may include fever, signs of a cold, cough, night sweats, skin rash or tiredness.

Tell your doctor if you suspect an infection. Typical symptoms may include fever, wounds, feeling more tired than normal or dental problems. You should also contact your doctor if new skin changes occur during or after treatment, or if existing ones change .

When should I see a doctor quickly?

In special situations, it is advisable to act quickly in order to avoid possible risks or to treat them at an early stage. Tell a doctor immediately if you notice any of the following serious side effects:

- Wheezing
- Severe dizziness or light-headedness
- Swelling of the lips, tongue or throat
- Hives (itching or rash)
- Severe abdominal pain, especially in association with fever, nausea and vomiting
- Severe chest pain or tightness (which may spread to the arms, jaw, neck, back)
- Shortness of breath
- Cold sweat
- Unilateral weakness in one arm and/or leg
- Slurred speech

Special situations

Can I take Olumiant® during pregnancy and breastfeeding?

Olumiant® must not be taken during pregnancy or breastfeeding. Please inform your rheumatologist immediately if you suspect you are pregnant or if you are confirmed to be pregnant. Consult your doctors if you want to become pregnant. Use a reliable method of contraception during Olumiant® treatment and for at least one week after treatment has stopped. Please seek advice from your gynaecologist on this matter.

Can I get vaccinated during treatment with Olumiant®?

Drugs that affect the immune system, such as Olumiant®, are generally well tolerated. However, there is a slightly increased susceptibility to infection. Therefore, for patients with rheumatoid arthritis, **regular booster vaccinations are recommended** to prevent serious infections.

If possible, all vaccinations in children and adolescents should be brought up to date before treatment with Olumiant®.



Our tip for you

If you need a vaccination, please contact your doctor. During treatment with Olumiant®, no vaccinations containing weakened pathogens (live vaccines) should be administered.

What do I need to consider when planning a trip?

Olumiant® does not require any special storage or refrigeration, so you can simply take the tablets with you in your luggage. When travelling by plane, you should take your medication with you in your hand luggage. Make sure you take enough tablets with you so that you can continue taking them daily while you travel, and also plan to have a **reserve** in case your return journey is delayed.

Depending on the country you are travelling to, you may need to consider **special vaccinations**. In this case, please inform your doctor and discuss with him whether and how such vaccinations can be carried out during treatment with Olumiant®. If you are unsure whether you need vaccinations or if you have any other questions about Olumiant® treatment while travelling, talk to your doctor.



Olumiant® package leaflet, latest version.

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your treating physician

Practice

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A MEDICINE COMPANY

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