

Package leaflet: Information for the patient

Baricitinib Lilly 1 mg film-coated tablets
Baricitinib Lilly 2 mg film-coated tablets
Baricitinib Lilly 4 mg film-coated tablets
baricitinib

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

1. What Baricitinib Lilly is and what it is used for

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

Rheumatoid arthritis

Baricitinib Lilly 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. Baricitinib Lilly can be used alone or together with some other medicines, such as methotrexate.

Baricitinib Lilly 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, Baricitinib Lilly 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

Baricitinib Lilly 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. Baricitinib Lilly may be used with eczema medicines that you apply to the skin or it may be used on its own.

Baricitinib Lilly 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, Baricitinib Lilly helps to improve the condition of your skin and reduce itching. In addition, Baricitinib Lilly helps improve your sleep disturbance (due to itch) and overall quality of life. Baricitinib Lilly has also been shown to improve symptoms of skin pain, anxiety, and depression associated with atopic dermatitis.

Alopecia areata

Baricitinib Lilly 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.

Baricitinib Lilly 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, Baricitinib Lilly helps hair to regrow on scalp, face and other areas of the body impacted by the disease.

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

Baricitinib Lilly 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.

Baricitinib Lilly 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.

Baricitinib Lilly 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.

Baricitinib Lilly can be used alone or together with methotrexate.

2. What you need to know before you take Baricitinib Lilly

Do not take Baricitinib Lilly

- 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 Baricitinib Lilly 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 Baricitinib Lilly is appropriate for 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. Baricitinib Lilly 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
- have, or have previously had, tuberculosis. You may need tests to check for tuberculosis before you are given Baricitinib Lilly . Tell your doctor if you get persistent cough, fever, night sweats and weight loss during Baricitinib Lilly treatment as these can be signs of tuberculosis
- have had a herpes infection (shingles), because Baricitinib Lilly may allow it to come back. Tell your doctor if you get painful skin rash with blisters during Baricitinib Lilly 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 Baricitinib Lilly
- have or have had cancer, smoke or have smoked in the past, because your doctor will discuss with you if Baricitinib Lilly is appropriate for you
- have poor liver function
- have, or have had, heart problems, because your doctor will discuss with you if Baricitinib Lilly is appropriate for 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 Baricitinib Lilly 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 (see section 4)
- Non-melanoma skin cancer has been observed in patients taking Baricitinib Lilly. Your doctor may recommend that you have regular skin examinations while taking Baricitinib Lilly. 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

You may need blood tests before you start Baricitinib Lilly, 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 Baricitinib Lilly is not causing problems.

Children and adolescents

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

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.

Other medicines and Baricitinib Lilly

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 Baricitinib Lilly if you are taking any other medicine such as:

- probenecid (for gout), since this medicine may increase the levels of Baricitinib Lilly in your blood. If you are taking probenecid, the recommended dose of Baricitinib Lilly for adults is 2 mg once a day and for children and adolescents the dose should be reduced by half.
- 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 section 4)
- medicines to treat diabetes or if you have diabetes. Your doctor may decide if you need less anti-diabetic medicine while taking Baricitinib Lilly

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 Baricitinib Lilly and for at least one week after the last Baricitinib Lilly treatment. You must tell your doctor if you become pregnant as Baricitinib Lilly should not be used during pregnancy.

You should not use Baricitinib Lilly 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 Baricitinib Lilly. You should not do both.

Driving and using machines

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

Baricitinib Lilly contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially “sodium-free”.

3. How to take Baricitinib Lilly

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.

Adults 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 Baricitinib Lilly 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.

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

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 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.

Method of administration

Baricitinib Lilly 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 Baricitinib Lilly, you may find it easier to take it at the same time every day.

If you take more Baricitinib Lilly than you should

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

If you forget to take Baricitinib Lilly

- 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 Baricitinib Lilly

Do not stop taking Baricitinib Lilly 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.

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 diarrhoea (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
- 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.

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 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 Baricitinib Lilly

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 Baricitinib Lilly contains

- The active substance is baricitinib. Each tablet contains 1, 2 or 4 milligrams of baricitinib.
- The other ingredients are: microcrystalline cellulose, croscarmellose sodium (see section 2 "Baricitinib Lilly contains sodium"), magnesium stearate, mannitol, iron oxide red (E172), lecithin (soya) (E322), macrogol, poly (vinyl alcohol), talc and titanium dioxide (E171).

What Baricitinib Lilly looks like and contents of the pack

Baricitinib Lilly 1 mg film-coated tablets are very light pink, 6.75 mm round tablets, with “Lilly” on one side and “1” on the other.

Baricitinib Lilly 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.

Baricitinib Lilly 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.

Baricitinib Lilly 1 mg is available in blister packs of 14 and 28 tablets in calendar blisters and 28 x 1 tablets in perforated unit dose blisters. Baricitinib Lilly 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

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:

United Kingdom

Eli Lilly and Company Limited

Tel: + 44-(0) 1256 315000

This leaflet was last revised in September 2024.

OL056

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

Information for Patients about BARICITINIB LILLY (baricitinib)

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

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 Baricitinib Lilly):

Doctor's phone number:

Pregnancy:

- Do not take Baricitinib Lilly if you are pregnant or suspect you may be pregnant.
- Use effective contraception while taking Baricitinib Lilly (and for 1 week after, if you stop treatment).
- Tell your doctor immediately if you become (or wish to become) pregnant.

Infections:

Baricitinib Lilly may make an existing infection worse or increase the chance of you getting a new infection or increase the chance of viral reactivation. If you have diabetes or are older than 65 you may have an increased chance of getting infections. The infection can become serious if not treated. 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.

Non-melanoma skin cancer:

Non-melanoma skin cancer has been observed in patients taking Baricitinib Lilly . If new skin lesions appear during or after therapy or if existing lesions change appearance, tell your doctor.

Blood clots:

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

Heart attack or stroke:

Inform your doctor immediately if you experience any of the following:

	<ul style="list-style-type: none">• 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
--	--