

BARICITINIB

What are the aims of this leaflet?

This leaflet has been written to help you understand more about baricitinib It tells you what it is, how it works, how it is used to treat skin conditions, and where you can find out more about it.

What is baricitinib and how does it work?

It is a type of drug known as a Janus kinase (JAK) inhibitor. It works by blocking the activity of pathways of inflammation involved in <u>atopic eczema</u> or atopic dermatitis. In doing so, it suppresses the immune system.

What skin conditions are treated with baricitinib?

It is currently licensed to treat moderate to severe <u>atopic eczema</u> or atopic dermatitis.

Why have I been selected for treatment with baricitinib?

Baricitinib is used in patients with moderate to severe <u>atopic eczema</u> who have tried standard immunosuppressive treatments for <u>atopic eczema</u> but have failed to benefit from them, were unable to tolerate them, or the treatments were unsuitable.

How long will I need to take baricitinib before it has an effect?

Many people who benefit from this treatment will notice an improvement within the first few weeks of starting this medication, but some people may see more gradual and further improvements over the first six months of treatment.

Your response to treatment will be assessed from 8 weeks after starting baricitinib and if your response to treatment is inadequate after 16 weeks, then treatment may be stopped.

How do I take baricitinib?

Baricitinib is a tablet taken by mouth once daily with or without food and at any time of the day.

What dose should I take?

The recommended dose of baricitinib is 4 mg once daily.

If you are 75 years or older, have reduced kidney function or have a history of long standing or recurrent infections such as pneumonia, a lower dose of 2 mg once daily may be considered.

Patients who have their <u>atopic eczema</u> well controlled with a 4 mg once daily dose, may consider reducing their dose of baricitinib to 2 mg once daily.

What are the common side effects of baricitinib?

<u>Herpes simplex</u> skin infection was more commonly seen in atopic eczema patients taking baricitinib. It is a common viral infection that presents with blisters most commonly located on the mouth (known as cold sores) and in the genital area.

<u>Shingles</u> was also a common side effect. It is a painful blistering rash, typically on one side of the body, caused by the varicella zoster (or chicken pox) virus.

Other common infections seen in patients taking baricitinib are those affecting the nose, throat or chest, those causing vomiting or diarrhoea (gastroenteritis) and urinary tract infections. There was a higher risk of infections in patients taking the 4mg rather than the 2mg dose. Other common side effects reported high levels of cholesterol.

We do not have enough information to know if treatment with baricitinib is associated with an increased risk of cancer. You should protect yourself from too much exposure to sunlight by not sunbathing, wearing suitable clothing (e.g. long sleeves and hat that protects your face and ears), and using sunscreens with a sun protection factor (SPF) of at least 30 and a star rating of at least 4.

If you detect any new swellings or lumps, or changes in your skin, which last more than two weeks, you should inform your doctor as soon as possible.

What are the rare side effects of baricitinib?

Rare side effects include low numbers of a type of white blood cells known as neutrophils, or blood clots in the blood vessels of the lungs (called pulmonary embolism) or the legs (deep vein thrombosis).

How will I be monitored for the side effects of baricitinib treatment?

Before you start taking baricitinib, you will have a consultation with your dermatologist. You will be asked about any current or past infections (such as human immunodeficiency virus (HIV) infection, viral hepatitis, tuberculosis, frequent cold sores, and shingles), and blood tests for some of these will be performed before starting. It is important to tell your dermatologists if: you are or planning to become pregnant and if you are breastfeeding

During treatment with baricitinib, you will have blood test monitoring regularly to check your full blood count and liver function while you are taking baricitinib. Your lipid profile, which includes your cholesterol and triglyceride levels, will be performed before starting treatment and repeated a few months after starting treatment.

Can I still use topical steroids?

Yes, you can use steroid creams or ointments whilst taking baricitinib. Clinical trials showed that when combined with steroid creams/ointments, patients experienced improvement in atopic eczema more quickly.

Can I have immunisations (vaccinations) whilst on baricitinib?

Patients on baricitinib should not be given live vaccines, such as those for polio, rubella (German measles), and yellow fever. Inactivated or non-live vaccinations such as Covid, a pneumococcal and flu vaccinations (except the nasal flu vaccine) are safe.

You should always check with your healthcare professional when having a vaccination and make them aware that you are on baricitinib. (For further information on immunisations for people on immune-suppressing medicines, please see the patient information leaflet here).

Does baricitinib affect fertility or pregnancy/ breastfeeding?

You should not take baricitinib if you are pregnant or breastfeeding. Women of childbearing potential must use effective contraception during treatment and for at least 1 week after treatment. There is little information on its effect on human fertility, but non-human studies suggest that it has the potential to decrease female fertility.

Can I drink alcohol while taking baricitinib?

Alcohol may be consumed during treatment with baricitinib. To keep health risks from alcohol to a low level, it is safest not to drink more than 14 units of alcohol per

week regularly (https://www.nhs.uk/Live-well/alcohol-advice/calculating-alcohol-units/).

Can I take other medicines at the same time as baricitinib?

Before you start treatment with baricitinib, please let your dermatologist know of the medicines you are taking, including prescribed and over-the-counter supplements or herbal treatments. After starting baricitinib, you should let any doctor treating you know that you are taking this medication.

Taking other medicines that suppress the immune system together with baricitinib has not been studied, and it is currently not recommended.

If you are taking a medication called probenecid, often used for gout, it is advised that you take baricitinib 2 mg once a day as probenecid may increase your blood levels of baricitinib.

Where can I get more information about baricitinib?

You should speak to your prescribing doctor or pharmacist if you want to know more about treatment with baricitinib.

There is also a drug information sheet that is provided as an insert in the packaging of the medication. It can also be obtained online at https://www.medicines.org.uk/emc/search?q=%22baricitinib%22.

This leaflet aims to provide accurate information about the subject and is a consensus of the views held by representatives of the British Association of Dermatologists and the British Hair and Nail Society: individual patient circumstances may differ, which might alter both the advice and course of therapy given to you by your doctor.



This leaflet has been assessed for readability by the British Association of Dermatologists' Patient Information Lay Review Panel

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