

Baricitinib factsheet

Baricitinib, also known as Olumiant[®], is a treatment for moderate to severe atopic eczema (also known as atopic dermatitis) in adults. It's a type of drug known as a Janus kinase (JAK) inhibitor. Baricitinib was the first JAK-inhibitor licensed for atopic eczema in the UK and is taken orally, as a tablet.

Baricitinib calms the immune system and reduces eczema inflammation (red or darker areas of active eczema) and itch. Most people who benefit from baricitinib will notice some improvement in their eczema within the first eight weeks of treatment.

How does it work?

JAK-inhibitors are named after the messaging pathway that they block within cells. In eczema, there is excessive inflammation in the skin. Multiple small signals, called cytokines, drive that inflammation. Cytokines promote inflammation by attaching to receptors on cells, like a key fitting into a lock. Once attached, they trigger the production of even more cytokines resulting in worsening eczema symptoms. The JAK pathway is key in this process and forms an important target that can be blocked by drugs to reduce the unwanted excessive inflammation. There are different kinases; JAK1, JAK2, JAK3 and TYK2. Baricitinib targets JAK1 and JAK2 and works by blocking the activity of specific pathways within the cells, which can cause the symptoms of atopic eczema.

What has the research shown?

Clinical trials of baricitinib have shown that it can rapidly improve eczema symptoms, including itch. In the BREEZE-AD trial, adults with moderate to severe eczema were randomised to either baricitinib or placebo. Baricitinib taken as 4 mg tablets was almost four times more effective in clearing eczema compared to placebo. One of the most commonly reported improvements was the reduction in itch sensation, which was noticed as early as the first week.

These results were echoed in a similar study where baricitinib was trialled in combination with topical steroids compared to placebo. In this study, patients

found that they needed to use less topical steroid to manage flare-ups while taking baricitinib.

Is it available on the NHS?

Yes. Baricitinib was approved for routine use in adults in England, Wales, Scotland and Northern Ireland in 2021. It can only be initiated by a dermatologist, so you would need a secondary care referral to dermatology to access it.

Who is it for?

Baricitinib is licensed for the treatment of adults with moderate to severe eczema who are possible candidates for systemic medication (these are medications that affect the whole body, rather than being localised to a specific area or organ). The more severe the eczema, the more likely you are to be considered for an advanced therapy such as baricitinib. To be eligible for baricitinib, you will usually need to have tried at least one systemic medication (azathioprine, ciclosporin, methotrexate or mycophenolate mofetil) and this needs to have not worked effectively for you. You may also be eligible for baricitinib if you are unable to tolerate systemic medications, or if they are not suitable for you.

If you're aged 65 or older, have an already increased risk of major cardiovascular problems or cancer, or if you smoke or have smoked in the past for a long time, your doctor will only offer you treatment with baricitinib or another JAK-inhibitor if nothing else is suitable for you.

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This is because these factors may put you at greater risk of developing certain serious side effects while taking baricitinib (see 'What are the risks of baricitinib?' below).

How do I go about getting it?

If you think you might be eligible for baricitinib, speak to your dermatologist about the possibility of trying it. If you're not currently under the care of a dermatologist, ask your GP for a dermatology referral. You need to be referred to see a specialist dermatologist in a hospital to access this treatment.

How is it taken?

Baricitinib is taken as a tablet once a day – with or without food, at any time of the day. It comes in 2 mg and 4 mg tablets. The recommended dose of baricitinib is usually 4 mg once daily. In some circumstances, such as if you have certain risk factors or have experienced repeated infections, your doctor may decide to give you the 2 mg daily dose instead. Your 4 mg dose may also be reduced to 2 mg once daily if your eczema has seen a sustained improvement since starting treatment.

If you take more than the recommended dose by mistake, contact your doctor straight away. If you miss a dose, carry on with the usual dose the next day – do not double it.

Before you start baricitinib, you will have a full medical assessment and blood tests, including a lipid profile with cholesterol and triglyceride levels. During treatment you will have regular blood test monitoring to check your full blood count, liver function and lipids. If you have any abnormal results, your treatment with baricitinib will be reviewed, and may be discontinued.

How long do you take it for?

Baricitinib is an ongoing treatment rather than a treatment that is used for a fixed amount of time. Patients are reviewed after eight weeks to see how effectively the treatment is working for them. If your eczema hasn't responded adequately to baricitinib at 16 weeks, the treatment may be stopped.

Can people taking baricitinib still use emollients and topical steroids?

Yes, patients taking baricitinib will be expected to use emollients and topical steroids to manage their eczema alongside baricitinib. Clinical trials have shown that using topical steroids to manage eczema flare-ups when taking baricitinib can actually improve eczema more quickly.

Can I take it while breastfeeding or pregnant?

Baricitinib is not recommended if you're pregnant, planning to become pregnant or breastfeeding. If you could become pregnant, you should use effective contraception while being treated with baricitinib and for at least a week after stopping the treatment. Baricitinib has the potential to decrease female fertility, but has no effect on male fertility.

What are the risks of baricitinib?

Since baricitinib affects the immune system, it can make you more likely to pick up non-serious infections, including throat, nose and chest infections. Baricitinib doesn't remain in the body for as long as some other eczema treatments after you stop taking it, so people are able to regain their full ability to fight infection quickly if needed after stopping treatment. Other common side effects include cold sores, shingles, infections causing vomiting or diarrhoea, urinary tract infections and high cholesterol.

In clinical trials for rheumatoid arthritis, there was an increased incidence of major cardiovascular problems (such as heart attack or stroke), cancer, blood clots in the lungs and in the deep veins of the body, serious infections and death in patients with certain risk factors who were taking JAK-inhibitors compared with the group taking a comparable drug (a tumour necrosis factor (TNF)-alpha inhibitor). Following this, the Medicines and Healthcare products Regulatory Agency has issued a warning for all JAK-inhibitors, not just the one used in the clinical trials for rheumatoid arthritis (tofacitinib).

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The risk of experiencing these serious side effects is greater if you are aged 65 or older, have an already increased risk of major cardiovascular problems or cancer, or if you smoke or have smoked in the past for a long time. People with these risk factors will not be offered baricitinib unless there is no alternative.

People taking baricitinib are advised to examine their skin periodically and let their doctor or nurse know if they notice any new growths or changes to moles (including itching, shape and discharge, which might not be as obvious on darker skin tones). These might need to be investigated for possible skin cancer.

Let your doctor or nurse know if you experience any side effects. It's particularly important that you contact your doctor or seek urgent medical advice if you experience chest pain or tightness (which may spread to arms, jaw, neck and back), shortness of breath, cold sweats, light-headedness, sudden dizziness, weakness in arms and legs or slurred speech.

Can I have vaccinations while on baricitinib?

It's best to discuss vaccinations, including any you may need if you're planning to travel abroad, with your dermatology team. If possible, have any vaccinations you may need before starting baricitinib.

It's generally recommended that people on baricitinib avoid live vaccines. These include measles, mumps and rubella (MMR), tuberculosis (BCG), yellow fever and shingles.

Pneumococcal vaccines, which help protect against pneumonia, and yearly flu vaccines – except the nasal flu vaccine – are fine and are usually recommended.

Further information

Electronic Medicines Compendium: Olumiant[®]

<https://www.medicines.org.uk/emc/search?q=Olumiant>

British Association of Dermatologists' patient information leaflet on baricitinib

<https://www.bad.org.uk/patient-information-leaflets/>

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