Abrocitinib factsheet

Abrocitinib, also known as Cibinqo®, is a treatment for moderate to severe atopic eczema (also known as atopic dermatitis) in adults and children aged 12 years and older. It's a type of drug known as a Janus kinase (JAK) inhibitor. Abrocitinib is taken orally, as a tablet. It calms the immune system and reduces eczema inflammation (red or darker areas of active eczema) and itch.

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 crucial 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. Abrocitinib primarily targets JAK1 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 abrocitinib have shown that it can quickly improve eczema severity and itch. In the JADE MONO-1 and JADE MONO-2 clinical trials, adults and adolescents with moderate to severe atopic eczema took either a daily dose of abrocitinib 100 mg or 200 mg, or a daily dose of placebo (a dummy drug) for 12 weeks.

At the end of the 12 weeks, abrocitinib was found to be significantly more effective than placebo at reducing the amount of body area affected by eczema, inflammation and itch. Improvements in these areas were seen as early as the second week of treatment and carried on until the end of the trial. In the JADE MONO-2 trial, abrocitinib reduced itch severity compared with placebo within 24 hours of starting treatment.

Is it available on the NHS?

Yes. Abrocitinib was approved for routine use in adults and children aged 12 years and older in England, Wales and Scotland in 2022. In Northern Ireland, abrocitinib has been approved for routine use in adults only. Abrocitinib can only be prescribed and monitored by a dermatologist, so you need to be under the care of a dermatology team to access this treatment. Ask your GP for a dermatology referral if needed.

Who is it for?

Abrocitinib is licensed for the treatment of adults and children aged 12 years and older with moderate to severe atopic 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 a newer therapy such as abrocitinib.

To be eligible for abrocitinib, you will usually need to have tried at least one systemic immunosuppressive medication (azathioprine, ciclosporin, methotrexate or mycophenolate mofetil) and found that it was not effective for you. You may also be eligible for abrocitinib if you are unable to tolerate the immunosuppressive medications listed above, 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 abrocitinib or

another JAK-inhibitor if nothing else is suitable for you. This is because these factors may put you at greater risk of developing certain serious side effects while taking abrocitinib (see 'What are the risks of abrocitinib?' below).

How do I go about getting it?

If you think you might be eligible for abrocitinib, 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 will need to see a specialist dermatologist in a hospital to access this treatment.

How is it taken?

Abrocitinib is taken as a tablet once a day – with or without food, at any time of the day. If it makes you feel sick, it might help to take it with food. Swallow your tablet whole with water.

Abrocitinib comes in 50 mg, 100 mg and 200 mg tablets. Adults will be prescribed a dose of either 100 mg or 200 mg. This daily dose may be increased or decreased depending on how well abrocitinib works for the adult taking it. For children aged 12 years and older, and people aged 65 and older, the recommended dose is 100 mg once daily. If you have certain medical conditions, such as moderate to severe kidney problems, or you are taking certain other medications, you may be given a daily dose of 50 mg.

If you take more than the recommended dose by mistake, contact your doctor straight away. If you forget to take it for a day, carry on with the usual dose the next day – do not take a double dose to make up for the forgotten tablet.

Before you start abrocitinib, you will have a full medical assessment and blood tests to check levels are normal and that you don't have a low red blood cell count (anaemia), a low white blood cell count (neutropaenia or lymphopaenia) or a low platelet count (platelets are important for blood clotting and wound healing). During treatment you will have regular complete blood count monitoring. If you have any abnormal results, your treatment with abrocitinib will be reviewed, and may be discontinued. Your doctor will also need to check whether you've ever been exposed to tuberculosis (TB). If the bacteria that cause TB are still present in the body, you may need a course of treatment for this before starting abrocitinib. In addition, you will be screened for viral hepatitis before and during treatment.

How long do you take it for?

Abrocitinib is an ongoing treatment rather than a treatment that is used for a fixed amount of time. If a patient's eczema has not responded to abrocitinib after 12 weeks of starting the treatment, it may be stopped.

Can people taking abrocitinib still use emollients and topical steroids?

Yes, people taking abrocitinib will be expected to use emollients and topical steroids to manage their eczema alongside abrocitinib. The JADE-TEEN trial assessed abrocitinib when used in combination with topical therapy in 12-17-year-olds. 'Topical therapy' here means emollients, topical steroids and other topical treatments. This trial showed that using abrocitinib in combination with topical therapy has a beneficial effect compared to placebo with topical therapy.

Can I take it while pregnant or breastfeeding?

Abrocitinib 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 abrocitinib and for at least four weeks after your last dose. Abrocitinib may cause fertility problems in females.

What are the risks of abrocitinib?

Since abrocitinib affects the immune system, it can reduce your body's ability to fight infection. Abrocitinib should not be taken if you have an active serious infection. Common side effects of abrocitinib include feeling sick, cold sores, headaches, dizziness, vomiting, upper abdominal pain, acne, shingles and elevation in blood creatine phosphokinase (CPK) level. CPK is an enzyme found mainly in the muscles, heart and brain. It plays an important role in energy production and muscle contraction.

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).

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 abrocitinib unless there is no alternative.

People taking abrocitinib 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 seek urgent medical advice if you experience any of the following:

- a painful skin rash with blisters and fever
- a rapidly spreading painful rash, blisters or sores (with or without fever)
- a painful swollen leg, chest pain or shortness of breath
- 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 abrocitinib?

It's best to discuss vaccinations with your dermatology team, including any vaccines you may need if you're planning to travel abroad. If possible, have any vaccines you may need for travelling abroad, or that you're due to have, before starting abrocitinib.

It's recommended that you avoid live vaccines when taking abrocitinib. These include measles, mumps and rubella (MMR), tuberculosis (BCG), yellow fever and shingles.

Seek advice from your dermatology team about pneumococcal vaccines, which help protect against pneumonia, and yearly flu vaccines.

Further information

Electronic Medicines Compendium: Cibinqo®

https://www.medicines.org.uk/emc/search?q=cibinqo

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National Eczema Society is the UK charity for everyone affected by eczema. We help support people with eczema, providing information and advice, which we deliver through our website, social media, campaigns, publications and nurse-supported Helpline. We also provide a voice for people with eczema, raising awareness of the condition, supporting research into new treatments and campaigning for better medical care.

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