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EPAR summary for the public

Flixabi

infliximab

This is a summary of the European public assessment report (EPAR) for Flixabi. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Flixabi.

For practical information about using Flixabi, patients should read the package leaflet or contact their doctor or pharmacist.

What is Flixabi and what is it used for?

Flixabi is an anti-inflammatory medicine. It is used in adults, usually when other medicines or treatments have failed or cannot be used, for the treatment of the following diseases:

- rheumatoid arthritis (an immune-system disease causing inflammation of the joints). Flixabi is used with methotrexate (a medicine that acts on the immune system);
- Crohn's disease (a disease causing inflammation of the gut), when the disease is moderate to severe or causes fistulae (abnormal passageways between the gut and other organs);
- ulcerative colitis (a disease causing inflammation and ulcers in the lining of the gut);
- ankylosing spondylitis (a disease causing inflammation and pain in the joints of the spine);
- psoriatic arthritis (a disease causing red, scaly patches on the skin and inflammation of the joints);
- psoriasis (a disease causing red, scaly patches on the skin).

Flixabi is also used in patients aged between 6 and 17 years with severe Crohn's disease or ulcerative colitis, when they have not responded to or cannot take other medicines or treatments.

For further information see the summary of product characteristics (also part of the EPAR).

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Flixabi contains the active substance infliximab and is a 'biosimilar medicine'. This means that Flixabi is similar to a biological medicine (also known as the 'reference medicine') that is already authorised in the European Union (EU). The reference medicine for Flixabi is Remicade. For more information on biosimilar medicines, see the question-and-answer document here.

How is Flixabi used?

Flixabi treatment should be started and supervised by a specialist doctor who has experience in the diagnosis and treatment of the diseases that Flixabi is used to treat. The medicine can only be obtained with a prescription.

Flixabi is usually given as 3 mg per kilogram body weight in rheumatoid arthritis, although the dose can be increased if necessary. The dose is 5 mg per kilogram for the other diseases. How often the treatment is repeated depends on which disease is being treated, and on the patient's response to the medicine.

Flixabi is given as an infusion lasting one or two hours. All patients are monitored for any reactions during the infusion and for at least one to two hours afterwards. To reduce the risk of infusion-related reactions, patients may be given other medicines before or during treatment with Flixabi or the infusion time may be slowed down. For further information, see the package leaflet.

How does Flixabi work?

The active substance in Flixabi, infliximab, is a monoclonal antibody (a type of protein) that has been designed to attach to a protein called tumour necrosis factor-alpha (TNF-alpha) and block its activity. TNF-alpha is involved in causing inflammation and is found at high levels in patients with the diseases that Flixabi is used to treat. By blocking TNF-alpha, infliximab improves the inflammation and other symptoms of these diseases.

What benefits of Flixabi have been shown in studies?

Studies were carried out to show that Flixabi is comparable to Remicade, including a study to show that it produces similar levels of the active substance in the body to Remicade.

Flixabi was also compared with Remicade in one main study involving 584 patients with moderate to severe rheumatoid arthritis who had received previous treatment with methotrexate. The main measure of effectiveness was the proportion of patients who achieved at least a 20% reduction in ACR scores (a measure of painful, swollen joints and other symptoms) after 30 weeks of treatment. Results of this study showed that Flixabi was as effective as Remicade in reducing symptoms of rheumatoid arthritis: 64% of those treated with Flixabi (148 of 231 patients) had at least a 20% reduction in ACR scores, compared with 66% of those given Remicade (163 out of 247).

What are the risks associated with Flixabi?

The most common side effects with Flixabi (seen in more than 1 patient in 10) are viral infections (such as flu or cold sores), headache, upper-respiratory-tract infection (colds), sinusitis (inflammation of the sinuses), nausea (feeling sick), abdominal pain (stomach ache), infusion-related reactions and pain. Some side effects, including infections, may be more common in children than in adults. For the full list of all side effects reported with Flixabi, see the package leaflet.

Flixabi must not be used in patients who are hypersensitive (allergic) to infliximab, mouse proteins or any of the other ingredients of Flixabi. Flixabi must also not be used in patients with tuberculosis, other

severe infections, or moderate or severe heart failure (an inability of the heart to pump enough blood around the body).

Why is Flixabi approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Flixabi has been shown to have a comparable quality, safety and effectiveness to Remicade. Therefore, the CHMP's view was that, as for Remicade, the benefit outweighs the identified risk. The Committee recommended that Flixabi be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Flixabi?

A risk management plan has been developed to ensure that Flixabi is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Flixabi, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, the company that markets Flixabi will provide an alert card for patients and educational material for prescribers, summarising the safety information about the medicine. In particular, information will be provided for doctors who intend to prescribe the medicine to children with Crohn's disease or ulcerative colitis, to explain that these patients may be at an increased risk of developing infections and to remind of the importance of keeping vaccinations up to date.

Other information about Flixabi

The European Commission granted a marketing authorisation valid throughout the European Union for Flixabi on 26 May 2016.

The full EPAR for Flixabi can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Flixabi, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 05-2016.