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Ilumetri (*tildrakizumab*)

An overview of Ilumetri and why it is authorised in the EU

What is Ilumetri and what is it used for?

Ilumetri is a medicine that acts on the immune system and is used to treat plaque psoriasis, a disease causing red, scaly patches on the skin. It is used in adults with moderate to severe disease for whom treatments applied to the skin are not suitable.

Ilumetri contains the active substance tildrakizumab.

How is Ilumetri used?

Ilumetri can only be obtained with a prescription and should be used under the supervision of a doctor experienced in diagnosing and treating plaque psoriasis.

Ilumetri is available as a solution in pre-filled syringes for injection under the skin. The recommended dose is one 100 mg injection, followed by a further dose after 4 weeks and then an injection every 12 weeks. The dose may be increased to 200 mg in certain patients, for example patients badly affected by the disease or with bodyweight over 90 kg. The doctor may decide to stop treatment if the condition does not improve after 28 weeks.

After training, patients may inject Ilumetri themselves if the doctor considers it appropriate.

For more information about using Ilumetri, see the package leaflet or contact your doctor or pharmacist.

How does Ilumetri work?

The active substance in Ilumetri, tildrakizumab, is a monoclonal antibody (a type of protein) which is designed to attach to interleukin 23 and block its activity. Interleukin 23 is a substance that controls the growth and maturation of some types of T cells. These T cells, which are part of the immune system (the body's natural defences), are involved in causing inflammation that is linked to the development of plaque psoriasis. By blocking the action of interleukin 23, Ilumetri reduces inflammation and symptoms associated with the disease.

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What benefits of Ilumetri have been shown in studies?

Two main studies involving adults found Ilumetri effective for treating moderate to severe plaque psoriasis in patients for whom treatments applied to the skin did not work well enough.

The first study involving 771 patients compared Ilumetri with placebo (a dummy treatment). After 12 weeks, 64% and 62% of patients given 100 mg and 200 mg Ilumetri respectively had at least a 75% improvement in disease severity compared with 6% of those given placebo. Additionally, 58% of those given 100 mg and 59% of those given 200 mg had almost complete skin clearance compared with 7% given placebo.

The second study involving 1,090 patients compared Ilumetri with placebo and with etanercept (another psoriasis medicine). After 12 weeks, 61% and 66% of patients given 100 mg and 200 mg Ilumetri respectively had at least 75% improvement in severity compared with 48% of those given etanercept and 6% given placebo. Of those given Ilumetri, 55% (for 100 mg) and 59% (for 200 mg) had almost complete skin clearance compared with 48% given etanercept and 5% given placebo.

What are the risks associated with Ilumetri?

The most common side effects with Ilumetri are upper respiratory tract (nose and throat) infections (which may affect more than 1 in 10 people). Headache, gastroenteritis (diarrhoea and vomiting), nausea (feeling sick), diarrhoea, pain at the site of the injection and back pain may affect up to 1 in 10 people.

Ilumetri must not be used in patients who have a serious ongoing infection such as tuberculosis. For the full list of side effects and restrictions with Ilumetri, see the package leaflet.

Why is Ilumetri authorised in the EU?

Ilumetri is effective in treating psoriasis and some patients can experience total clearing of their psoriasis. Patients do not experience many side effects. Information on the use of Ilumetri in the long term is limited and studies are ongoing. The European Medicines Agency decided that Ilumetri's benefits are greater than its risks and it can be authorised for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Ilumetri have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Ilumetri are continuously monitored. Side effects reported with Ilumetri are carefully evaluated and any necessary action taken to protect patients.

Other information about Ilumetri

Ilumetri received a marketing authorisation valid throughout the EU on 17 September 2018.

Further information on Ilumetri can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports.

This overview was last updated in 09-2018.