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Zessly (*infliximab*)

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

What is Zessly and what is it used for?

Zessly is an anti-inflammatory medicine for treating the following diseases:

- rheumatoid arthritis (disease causing inflammation of the joints);
- Crohn's disease (disease causing inflammation of the gut);
- ulcerative colitis (inflammation and ulcers in the lining of the gut);
- ankylosing spondylitis (inflammation of spine causing back pain);
- psoriasis (red, scaly patches on the skin);
- psoriatic arthritis (psoriasis with inflammation of the joints).

Zessly is used mainly in adults, usually when other medicines or treatments have failed or cannot be used. For Crohn's disease and ulcerative colitis, it is also used in children from 6 years of age. For some conditions, Zessly is also used in combination with another medicine, methotrexate.

Zessly is a 'biosimilar medicine'. This means that it is highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Zessly is Remicade. For more information on biosimilar medicines, see here.

Zessly contains the active substance infliximab.

How is Zessly used?

Zessly is given as an infusion (drip) into a vein over 2 hours. After each infusion, the patient should be monitored for 1 to 2 hours in case they have an allergic reaction, such as swelling of the mouth, face and throat, skin rash, and difficulty breathing.

To reduce the risk of infusion reactions, patients may be given other medicines before or during treatment with Zessly or the infusion may be slowed down.

The dose of Zessly and how often it is given depends on the patient's weight and the condition being treated. After the initial doses, it is usually given once every 8 weeks. For more information about using Zessly, see the package leaflet or contact your doctor or pharmacist.

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

How does Zessly work?

The active substance in Zessly, infliximab, is a monoclonal antibody (a type of protein) that attaches to a substance in the body called tumour necrosis factor alpha (TNF-α). This substance is involved in causing inflammation and is found at high levels in patients with the diseases that Zessly is used to treat. By attaching to TNF-α, infliximab blocks its activity and thereby reduces inflammation and other symptoms of the diseases.

What benefits of Zessly have been shown in studies?

Laboratory studies comparing Zessly with Remicade have shown that the active substance in Zessly is highly similar to that in Remicade in terms of structure, purity and biological activity. Studies have also shown that giving Zessly produces similar levels of the active substance in the body to giving Remicade.

In addition, Zessly was as effective as Remicade in a study of 650 rheumatoid arthritis patients whose previous treatment with methotrexate alone had not worked well enough. The study looked at the proportion of patients who achieved at least a 20% reduction in ACR scores (a measure of painful, swollen joints and other symptoms) after 14 weeks of treatment. A similar proportion of patients achieved a 20% reduction with both medicines (around 61.1% with Zessly and 63.5% with Remicade).

Because Zessly is a biosimilar medicine, the studies on effectiveness and safety carried out with Remicade do not all need to be repeated for Zessly.

What are the risks associated with Zessly?

The safety of Zessly has been evaluated, and on the basis of all the studies carried out the side effects of the medicine are considered to be comparable to those of the reference medicine Remicade.

The most common side effects with Zessly (in which may affect more than 1 in 10 people) are viral infections (such as flu and cold sores), headache, upper respiratory tract infection (nose and throat infection), sinusitis (inflammation of the sinuses), nausea (feeling sick), abdominal pain (belly ache), infusion-related reactions and pain. For the full list of side effects of Zessly, see the package leaflet.

Zessly must not be used in patients who are hypersensitive (allergic) to infliximab, mouse proteins or any of the other ingredients of Zessly. Zessly must also not be used in patients with tuberculosis, other severe infections, or moderate or severe heart failure (when the heart does not pump blood as well as it should).

Why is Zessly authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Zessly has a highly similar structure, purity and biological activity to Remicade and is distributed in the body in the same way. In addition, studies in patients with rheumatoid arthritis have shown that the safety and effectiveness of Zessly are equivalent to those of Remicade.

All these data were considered sufficient to conclude that Zessly will behave in the same way as Remicade in terms of effectiveness and safety in its authorised uses. Therefore, the Agency's view was

that, as for Remicade, the benefit of Zessly outweighs the identified risk and it can be authorised for use in the EU.

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

The company that markets Zessly will provide a reminder card for patients. The card will include safety information about the medicine and results of specific tests that the patient has had so these can be shared with any treating doctor.

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

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

Other information about Zessly

Zessly received a marketing authorisation valid throughout the EU on 18 May 2018.

Further information on Zessly can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/zessly.

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