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Tofidence (*tocilizumab*)

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

What is Tofidence and what is it used for?

Tofidence is a medicine used to treat:

- adults with severe rheumatoid arthritis that is getting worse, who have not been previously treated with a medicine called methotrexate;
- adults with moderate to severe active rheumatoid arthritis in whom previous treatments with disease modifying antirheumatic drugs (DMARDs), such as methotrexate or medicines known as tumour necrosis factor (TNF) blockers, have not worked well enough or were not tolerated;
- children from 2 years of age with active systemic juvenile idiopathic arthritis in whom other treatments (anti-inflammatory medicines called NSAIDs and corticosteroids) have not worked well enough;
- children from 2 years of age with juvenile idiopathic polyarthritis in whom treatment with methotrexate has not worked well enough.

Tofidence is used in combination with methotrexate for these conditions but it can be used on its own in patients for whom methotrexate is inappropriate.

Tofidence can also be used in adults with COVID-19 who are receiving treatment with corticosteroids by mouth or injection and require extra oxygen or mechanical ventilation (breathing assisted by a machine).

Tofidence contains the active substance tocilizumab and is a 'biosimilar medicine'. This means that Tofidence is highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Tofidence is RoActemra. For more information on biosimilar medicines, see here.

How is Tofidence used?

Tofidence can only be obtained with a prescription and treatment should be started by a doctor who has experience in the diagnosis and treatment of the relevant condition.

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Tofidence is given by injection under the skin or by infusion (drip) into a vein. How Tofidence is given, the recommended dose and how often it is given depends on the condition it is used to treat. For COVID-19, Tofidence must only be given as an infusion.

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

How does Tofidence work?

The active substance in Tofidence, tocilizumab, is a monoclonal antibody, a type of protein that has been designed to recognise and attach to a specific target (called an antigen) in the body. Tocilizumab attaches to the receptor for a messenger molecule or 'cytokine' called interleukin-6. This messenger is involved in inflammation and is found at high levels in patients with rheumatoid arthritis, systemic juvenile idiopathic arthritis, juvenile idiopathic polyarthritis and COVID-19. By preventing interleukin-6 from attaching to its receptors, tocilizumab reduces the inflammation and other symptoms of these diseases.

What benefits of Tofidence have been shown in studies?

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

In addition, Tofidence was as effective as RoActemra in improving symptoms of rheumatoid arthritis in a study involving 621 adults in whom previous treatment with methotrexate had not worked well enough. After 12 weeks of treatment, the proportion of patients with at least a 20% improvement in symptom score (called ACR20) was 66% with Tofidence and 59% with RoActemra.

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

What are the risks associated with Tofidence?

The safety of Tofidence 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 RoActemra.

The most common side effects with tocilizumab (which may affect more than 5 in 100 people) include upper respiratory tract infections (nose and throat infection), nasopharyngitis (inflammation of the nose and throat), headache, hypertension (high blood pressure) and abnormal liver function tests. The most serious side effects are serious infections, complications of diverticulitis (a disease affecting the gut) and hypersensitivity (allergic) reactions.

In patients with COVID-19, the most common side effects with tocilizumab (which may affect more than 5 in 100 people) include abnormal liver function tests, constipation, and urinary tract infections (infections of the parts of the body that collect and pass out urine).

Tofidence must not be used in patients who have an active, severe infection (except COVID-19). Doctors should monitor patients carefully for signs of infection during treatment, and should prescribe Tofidence with caution in patients who have had recurring or long-term infections, or diseases that could increase the risk of infections, such as diverticulitis or diabetes.

Why is Tofidence authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Tofidence has a highly similar structure, purity and biological activity to RoActemra and is distributed in the body in the same way. In addition, a study in patients with rheumatoid arthritis has shown that Tofidence and RoActemra are equivalent in terms of safety and effectiveness in the treatment of this disease.

All these data were considered sufficient to conclude that Tofidence will have the same effects as RoActemra in its authorised uses. Therefore, the Agency's view was that, as for RoActemra, the benefits of Tofidence outweigh the identified risks and it can be authorised for use in the EU.

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

The company that markets Tofidence must supply all doctors expected to prescribe the medicine for rheumatoid arthritis, systemic juvenile idiopathic arthritis and juvenile idiopathic polyarthritis with an educational pack containing important information on the safety and correct use of Tofidence. The pack will also include a patient alert card with key safety information for patients.

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

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

Other information about Tofidence

Tofidence received a marketing authorisation valid throughout the EU on 20 June 2024.

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

This overview was last updated in 06-2024