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Tyenne (*tocilizumab*)

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

What is Tyenne and what is it used for?

Tyenne 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 whose 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 1 year of age with active systemic juvenile idiopathic arthritis in whom other treatments (anti-inflammatory medicines called NSAIDs and corticosteroids medicines by mouth or injection) 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.

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

Tyenne is also used to treat:

- adults with giant cell arteritis, a disease in which arteries, usually of the head, are swollen;
- adults and children from 2 years of age with severe or life-threatening cytokine release syndrome (CRS, a condition that can cause nausea, vomiting, pain and low blood pressure). CRS is a side effect of certain cancer treatments and Tyenne is used for CRS caused by medicines known as chimeric antigen receptors (CAR) T-cell medicines.

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

Tyenne contains the active substance tocilizumab and is a 'biosimilar medicine'. This means that Tyenne is highly similar to another biological medicine (the 'reference medicine') that is already

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authorised in the EU. The reference medicine for Tyenne is RoActemra. For more information on biosimilar medicines, see here.

How is Tyenne used?

Tyenne 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.

Tyenne is available as a solution to be injected under the skin and as a concentrate for making a solution for infusion (drip) into a vein. How Tyenne is given, its dose and how often it is given depends on the condition it is used to treat. For COVID-19 and CRS, Tyenne must only be given as an infusion.

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

How does Tyenne work?

The active substance in Tyenne, 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, giant cell arteritis, CRS 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 Tyenne have been shown in studies?

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

In addition, Tyenne was as effective as RoActemra in reducing disease in a study involving 604 adults with moderately to severely active rheumatoid arthritis for whom previous treatment with at least one DMARD had not worked well enough. After 24 weeks of treatment, the DAS28 score (a measure of disease activity in rheumatoid arthritis) had decreased by an average of 3.5 both in patients receiving Tyenne and in those receiving RoActemra.

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

What are the risks associated with Tyenne?

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

For the complete list of side effects and restrictions of Tyenne, see the package leaflet.

The most common side effects with tocilizumab include upper respiratory tract infections (nose and throat infection) and nasopharyngitis (inflammation of the nose and throat), which may affect more than in 1 in 10 people, and headache, hypertension (high blood pressure) and abnormal liver function tests, which may affect up to in 1 in 10 people. 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 up to in 1 in 10 people) include abnormal liver function tests, constipation, and urinary tract infections (infections of the parts of the body that collect and pass out urine the structures that carry urine).

Tyenne 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 Tyenne 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 Tyenne authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Tyenne 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 involving patients with rheumatoid arthritis has shown that the safety and effectiveness of Tyenne is equivalent to that of RoActemra in the treatment of this disease.

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

The company that markets Tyenne must supply all doctors expected to prescribe the medicine for rheumatoid arthritis, systemic juvenile idiopathic arthritis, juvenile idiopathic polyarthritis and giant cell arteritis with an educational pack containing important information on the safety and correct use of Tyenne. 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 Tyenne have also been included in the summary of product characteristics and the package leaflet.

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

Other information about Tyenne

Tyenne received a marketing authorisation valid throughout the EU on 15 September 2023.

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

This overview was last updated in 09-2023.