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EPAR summary for the public

Truxima

rituximab

This is a summary of the European public assessment report (EPAR) for Truxima. 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 Truxima.

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

What is Truxima and what is it used for?

Truxima is a medicine used in adults to treat the following blood cancers and inflammatory conditions:

- follicular lymphoma and diffuse large B cell non-Hodgkin's lymphoma (two types of non-Hodgkin's lymphoma, a blood cancer)
- chronic lymphocytic leukaemia (CLL, another blood cancer affecting white blood cells)
- severe rheumatoid arthritis (an inflammatory condition of the joints)
- granulomatosis with polyangiitis (GPA or Wegener's granulomatosis) and microscopic polyangiitis (MPA), which are inflammatory conditions of the blood vessels.

Depending on the condition it is used to treat, Truxima may be given on its own, or with chemotherapy (other cancer medicines) or medicines used for inflammatory disorders (methotrexate or a corticosteroid). Truxima contains the active substance rituximab.

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

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How is Truxima used?

Truxima can only be obtained with a prescription. It is available as a concentrate for making a solution that must be given by infusion (drip) into a vein. Before each infusion, the patient should be given an antihistamine (to prevent allergic reactions) and an anti-pyretic (a medicine to prevent fever). In addition, the medicine should be given under the close supervision of an experienced healthcare professional and in a place where facilities for resuscitating patients are immediately available.

For further information, see the package leaflet.

How does Truxima work?

The active substance in Truxima, rituximab, is a monoclonal antibody (a type of protein) designed to recognise and attach to a protein called CD20 present on the surface of B lymphocytes (types of white blood cells). When rituximab attaches to CD20, it causes the death of B lymphocytes, which helps in lymphoma and CLL (where B-lymphocytes have become cancerous) and in rheumatoid arthritis (where B lymphocytes are involved in joint inflammation). In GPA and MPA, destroying the B lymphocytes lowers the production of antibodies thought to play an important role in attacking the blood vessels and causing inflammation.

What benefits of Truxima have been shown in studies?

Extensive laboratory studies comparing Truxima with MabThera have shown that rituximab in Truxima is highly similar to rituximab in MabThera in terms of chemical structure, purity and biological activity.

Because Truxima is a biosimilar medicine, the studies on effectiveness and safety carried out for MabThera do not need to be repeated for Truxima. Truxima has been compared with MabThera given into a vein in a study involving 372 patients with active rheumatoid arthritis. The study showed that Truxima and MabThera led to similar levels of rituximab in the blood. In addition, the two medicines had comparable effects on arthritis symptoms: after 24 weeks, the proportion of patients with a 20% improvement in symptom score (called ACR20) was 74% (114 of 155 patients) with Truxima and 73% (43 of 59 patients) with MabThera. Supportive studies in patients with rheumatoid arthritis and in patients with advanced follicular lymphoma also indicated that the medicines produced similar responses.

What are the risks associated with Truxima?

The most common side effects with rituximab are reactions related to the infusion (such as fever, chills and shivering) which occur in the majority of patients after the first infusion. The risk of such reactions decreases in subsequent infusions. The most common serious side effects are infusion reactions, infections (which may affect more than half of all patients) and heart-related problems. Other serious side effects include hepatitis B reactivation (return of previous active liver infection with hepatitis B virus) and a rare severe infection known as progressive multifocal leukoencephalopathy (PML). For the full list of side effects reported with Truxima, see the package leaflet.

Truxima must not be used in people who are hypersensitive (allergic) to rituximab, mouse proteins or any of the other ingredients. It must also not be used in patients with a severe infection or a severely weakened immune system. Patients with rheumatoid arthritis, GPA or MPA must also not receive Truxima if they have severe heart problems.

Why is Truxima approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that, in accordance with EU requirements for biosimilar medicines, Truxima has a highly similar structure, purity and biological activity to MabThera and is distributed in the body in the same way. In addition, a study comparing Truxima to MabThera in rheumatoid arthritis adult patients showed that both medicines are similarly effective. Thus, all these data were considered sufficient to conclude that Truxima will behave in the same way in terms of effectiveness as MabThera in its approved indications. Therefore, the CHMP's view was that, as for MabThera, the benefit outweighs the identified risk. The Committee recommended that Truxima be given marketing authorisation.

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

The company marketing Truxima will provide doctors and patients using the medicine for rheumatoid arthritis with educational material on the need to give the medicine where facilities for resuscitation are available and on the risk of infection, including PML. Patients are also to receive an alert card, which they are to carry at all times, instructing them to contact their doctor immediately if they have any of the listed symptoms of infection.

Doctors prescribing Truxima for cancer will be provided with educational material reminding them of the need to use the medicine only by infusion into a vein.

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

Other information about Truxima

The European Commission granted a marketing authorisation valid throughout the European Union for Truxima on 17 February 2017.

The full EPAR for Truxima 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 Truxima, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 02-2017.