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Truxima (*rituximab*)

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

What is Truxima and what is it used for?

Truxima is a medicine used 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
- moderate to severe pemphigus vulgaris, an autoimmune disease characterised by widespread blistering and erosion of the skin and mucous membranes (moist body surfaces, such as the lining of the mouth). 'Autoimmune' means that the disease is caused by the immune system (the body's natural defences) attacking the body's own cells.

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 another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Truxima is MabThera. For more information on biosimilar medicines, see here.

How is Truxima used?

Truxima can only be obtained with a prescription. It is 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). Depending on the condition being treated, patients may receive other medicines as well. 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.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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

How does Truxima work?

The active substance in Truxima, rituximab, is a monoclonal antibody (a type of protein) designed to attach to a protein called CD20 present on the surface of B cells (types of white blood cells). When rituximab attaches to CD20, it causes the death of B cells, which helps in lymphoma and CLL (where B cells have become cancerous) and in rheumatoid arthritis (where B cells are involved in joint inflammation). In pemphigus vulgaris, GPA and MPA, destroying the B cells reduces 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 structure, purity and biological activity.

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.

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

What are the risks associated with Truxima?

The safety of Truxima has been evaluated and, on the basis of all the studies, its side effects are considered comparable to those of the reference medicine MabThera.

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 with 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 of 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, MPA or pemphigus vulgaris must also not receive Truxima if they have severe heart problems.

Why is Truxima authorised in the EU?

The European Medicines Agency 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.

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

The company marketing Truxima will provide doctors and patients using the medicine for non-cancer conditions 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.

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

Other information about Truxima

Truxima received a marketing authorisation valid throughout the EU on 17 February 2017.

The full EPAR for Truxima can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/truxima.

This overview was last updated in 10-2020.