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Ituxredi (*rituximab*)

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

What is Ituxredi and what is it used for?

Ituxredi 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);
- two inflammatory conditions of blood vessels known as granulomatosis with polyangiitis (GPA or Wegener's granulomatosis) and microscopic polyangiitis (MPA);
- moderate to severe pemphigus vulgaris, an autoimmune disease characterised by widespread blistering and erosion of the skin and mucous membranes (the linings of internal organs). '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, Ituxredi may be given on its own, or with chemotherapy, methotrexate or a corticosteroid.

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

Ituxredi contains the active substance rituximab.

How is Ituxredi used?

Ituxredi can only be obtained with a prescription. It should be given under the close supervision of an experienced healthcare professional and in an environment where facilities for resuscitating patients are immediately available.

Ituxredi is given as an 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 for fever). Depending on the condition being treated, the patients can also be given other medicines.

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 Ituxredi, see the package leaflet or contact your doctor or pharmacist.

How does Ituxredi work?

The active substance in Ituxredi, rituximab, is a monoclonal antibody (a type of protein) designed to attach to a protein called CD20 present on B lymphocytes. 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 Ituxredi have been shown in studies?

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

In addition, a main study has shown that Ituxredi is as effective as MabThera in treating follicular lymphoma that has a low tumour burden (cancer with a low number of genetic changes) and is CD20-positive (when the cancer cells have a protein called CD20 on their surface). The study involved around 317 patients who were given either Ituxredi or MabThera. The main measure of effectiveness was a complete response (no signs of cancer) or a partial response (reduction in the extent of the cancer) at least once during the first 28 weeks of treatment. Around 80% (130 out of 162) of patients given Ituxredi had at least one complete or partial response, compared with 79% (123 out of 155) of patients given MabThera.

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

What are the risks associated with Ituxredi?

The safety of Ituxredi 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 MabThera.

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

The most common side effects with Ituxredi include reactions related to the infusion (such as fever, chills and shivering), while most common serious side effects are infusion reactions, infections and heart-related problems.

Ituxredi must not be used in patients with a severe infection or a severely weakened immune system. Patients with rheumatoid arthritis, GPA, MPA or pemphigus must not receive Ituxredi if they have severe heart problems.

Why is Ituxredi authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Ituxredi 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 in patients with follicular lymphoma has shown that Ituxredi and MabThera are equivalent in terms of effectiveness.

All these data were considered sufficient to conclude that Ituxredi will have the same effects as MabThera in its authorised uses. Therefore, the Agency's view was that, as for MabThera, the benefits of Ituxredi 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 Ituxredi?

The company marketing Ituxredi will provide doctors and patients using the medicine for rheumatoid arthritis, GPA, MPA or pemphigus with educational materials on the risk of infection, including a rare severe infection known as progressive multifocal leukoencephalopathy. These patients will also receive an alert card which they should always carry, instructing them to contact their doctor immediately if they experience symptoms of infection.

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

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

Other information about Ituxredi

Ituxredi received a marketing authorisation valid throughout the EU on 19 September 2024.

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

This overview was last updated in 09-2024.