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EPAR summary for the public

Rituzena[1]

rituximab

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

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

What is Rituzena and what is it used for?

Rituzena 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);
- 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, Rituzena may be given with chemotherapy (other cancer medicines) or medicines used for inflammatory disorders (corticosteroids). Rituzena contains the active substance rituximab.

Rituzena is a 'biosimilar medicine'. This means that Rituzena 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 Rituzena is MabThera. For more information on biosimilar medicines, see here.

[1] Previously known as Tuxella.

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How is Rituzena used?

Rituzena 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 reduce fever). Rituzena 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 Rituzena work?

The active substance in Rituzena, 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 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. In GPA and MPA, destroying the B cells lowers the production of antibodies thought to play an important role in attacking the blood vessels and causing inflammation.

What benefits of Rituzena have been shown in studies?

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

In addition, Rituzena has been compared with MabThera given into a vein in a main study involving 372 patients with active rheumatoid arthritis (an inflammatory disease). The study showed that Rituzena and MabThera 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 Rituzena and 73% (43 of 59 patients) with MabThera.

Further evidence came from supportive studies, including one involving 121 patients with advanced follicular lymphoma, where adding Rituzena to chemotherapy medicines was at least as effective as adding Rituxan, the US version of MabThera. In this study improvement was seen in 96% of cases (67 of 70 patients) with Rituzena and 90% (63 of 70 patients) with Rituxan.

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

What are the risks associated with Rituzena?

The most common side effects with rituximab are reactions related to the infusion (such as fever, chills and shivering) which occur in most cancer patients and in more than 1 in 10 GPA or MPA patients at the time of the first infusion. The risk of such reactions decreases in subsequent infusions. The most common serious side effects are infusion reactions, infections and, in cancer patients, heart-related problems. Other serious side effects include hepatitis B reactivation (return of previous active liver infection with hepatitis B virus) and a rare and severe brain infection known as progressive multifocal leukoencephalopathy (PML). For the full list of side effects reported with Rituzena, see the package leaflet.

Rituzena 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 GPA or MPA must also not receive Rituzena if they have severe heart problems.

Why is Rituzena approved?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Rituzena 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 Rituzena to MabThera in patients with rheumatoid arthritis (which can support its use in other inflammatory disorders such as GPA and MPA) showed that both medicines are similarly effective, and a supportive study in follicular lymphoma showed effectiveness in cancer. Thus, all these data were considered sufficient to conclude that Rituzena will behave in the same way in terms of effectiveness as MabThera in its approved indications. Therefore, the Agency's view was that, as for MabThera, the benefit outweighs the identified risk and it recommended that Rituzena be given marketing authorisation.

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

The company that markets Rituzena will provide doctors and patients using the medicine for non-cancer conditions with educational material including information 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 Rituzena 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 Rituzena have also been included in the summary of product characteristics and the package leaflet.

Other information about Rituzena

The European Commission granted a marketing aithorisation valid throughout the European Union for Tuxella on 13 July 2017. The name of the product was changed to Rituzena on 4 August 2017.

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

This summary was last updated in 08-2017.