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EPAR summary for the public

Rixathon

rituximab

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

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

What is Rixathon and what is it used for?

Rixathon 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, Rixathon may be given on its own, or with chemotherapy (other cancer medicines) or medicines used for inflammatory disorders (methotrexate or a corticosteroid). Rixathon contains the active substance rituximab.

Rixathon is a 'biosimilar medicine'. This means that Rixathon 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 Rixathon is MabThera. For more information on biosimilar medicines, see the question-and-answer document here.

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How is Rixathon used?

Rixathon 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). 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 Rixathon work?

The active substance in Rixathon, 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) and in rheumatoid arthritis (where B cells are involved in joint inflammation). 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 Rixathon have been shown in studies?

Laboratory studies comparing Rixathon with MabThera have shown that the active substance in Rixathon is highly similar to that in MabThera in terms of structure, purity and biological activity.

Because Rixathon is a biosimilar medicine, the studies on effectiveness and safety of rituximab carried out with MabThera do not all need to be repeated for Rixathon. Studies were carried out to show that giving Rixathon produces similar levels of the active substance in the body to giving MabThera.

Rixathon was also shown to be as effective as MabThera in one main study involving 629 patients with advanced, untreated follicular lymphoma, where Rixathon or MabThera were added to other chemotherapy for part of the treatment. The cancer responded to treatment in just over 87% of those given Rixathon (271 of 311 patients), and in similar numbers of those given MabThera (274 of 313 patients). A supportive study in patients with rheumatoid arthritis also indicated similar effectiveness between MabThera and Rixathon.

What are the risks associated with Rixathon?

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 cancer patients and about a quarter of rheumatoid arthritis 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 Rixathon, see the package leaflet.

Rixathon 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 Rixathon if they have severe heart problems.

Why is Rixathon approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that, in accordance with EU requirements for biosimilar medicines, Rixathon 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 Rixathon to MabThera in patients with follicular lymphoma showed that both medicines are similarly effective. Thus, all these data were considered sufficient to conclude that Rixathon 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 Rixathon be given marketing authorisation.

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

The company that markets Rixathon 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 Rixathon 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 Rixathon have also been included in the summary of product characteristics and the package leaflet.

Other information about Rixathon

The European Commission granted a marketing authorisation valid throughout the European Union for Rixathon on 15 June 2017.

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

This summary was last updated in 06-2017.