



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Rixathon (*rituximab*)

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

What is Rixathon and what is it used for?

Rixathon 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;
- pemphigus vulgaris, a serious condition involving widespread blistering of the skin and lining of the mouth, nose, throat and genitals.

Depending on the condition it is used to treat, Rixathon may be given on its own, or with chemotherapy (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 another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Rixathon is MabThera. For more information on biosimilar medicines, see [here](#).

How is Rixathon used?

Rixathon can only be obtained with a prescription. It should be given under the close supervision of an experienced healthcare professional and in a place where facilities for resuscitating patients are immediately available. The medicine is available for infusion (drip) into a vein.

Before each infusion, the patient should be given an antihistamine (to prevent allergic reactions) and an antipyretic (a medicine to reduce fever). Depending on the condition being treated, the patients are also given other medicines to manage side effects.

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

How does Rixathon work?

The active substance in Rixathon, rituximab, is a monoclonal antibody designed to attach to a protein called CD20, which is present on B cells. When rituximab attaches to CD20, it causes the B cells to die, which helps in lymphoma and CLL (where B cells have become cancerous) and in rheumatoid arthritis and pemphigus (where B cells are involved in inflammation). In GPA and MPA, destroying 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 the reference medicine MabThera have shown that the active substance in Rixathon is highly similar to that in MabThera in terms of structure, purity and biological activity. Studies have also shown that giving Rixathon produces similar levels of the active substance in the body to giving MabThera.

In addition, Rixathon was 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 improved 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.

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.

What are the risks associated with Rixathon?

The safety of Rixathon 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.

The most common side effects with Rixathon are 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.

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

For the full list of side effects and restrictions of Rixathon, see the package leaflet.

Why is Rixathon authorised in the EU?

The European Medicines Agency 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 in patients with follicular lymphoma has shown that the safety and effectiveness of Rixathon are equivalent to those of MabThera.

All these data were considered sufficient to conclude that Rixathon 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 Rixathon 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 Rixathon?

The company marketing Rixathon will provide doctors with additional information about giving the medicine correctly. It will also provide doctors and patients using the medicine for rheumatoid arthritis, GPA, MPA or pemphigus with educational material on the risk of infection including that of a rare severe infection, progressive multifocal leukoencephalopathy (PML). These 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 symptoms of infection.

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.

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

Other information about Rixathon

Rixathon received a marketing authorisation valid throughout the EU on 15 June 2017.

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

This overview was last updated in 10-2020.