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Ruxience (*rituximab*)

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

What is Ruxience and what is it used for?

Ruxience 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, Ruxience may be given on its own, or with chemotherapy (cancer medicines) or medicines used for inflammatory disorders (methotrexate or a corticosteroid).

Ruxience contains the active substance rituximab.

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

How is Ruxience used?

Ruxience 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 given by infusion (drip) into a vein.

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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.

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

How does Ruxience work?

The active substance in Ruxience, 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 Ruxience have been shown in studies?

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

In addition, Ruxience was as effective as MabThera in a study in 394 patients with follicular lymphoma, who were given an infusion of Ruxience or MabThera once a week for 4 weeks; after 26 weeks, the disease had responded partially or completely (disappearance of all signs of disease) in 148 of 196 given Ruxience (76%) and in a comparable proportion of those given MabThera (140 of 198; 71%).

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

What are the risks associated with Ruxience?

The safety of Ruxience 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 Ruxience 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.

Ruxience 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 Ruxience if they have severe heart problems.

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

Why is Ruxience authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Ruxience 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 follicular lymphoma has shown that the safety and effectiveness of Ruxience are equivalent to those of MabThera.

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

The company marketing Ruxience 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 Ruxience have also been included in the summary of product characteristics and the package leaflet.

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

Other information about Ruxience

Ruxience received a marketing authorisation valid throughout the EU on 01 April 2020.

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

This overview was last updated in 08-2020.