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Thiotepa Riemser (*thiotepa*)

An overview of Thiotepa Riemser and why it is authorised in the EU

What is Thiotepa Riemser and what is it used for?

Thiotepa Riemser is used in combination with chemotherapy in two ways:

- as a 'conditioning' (preparative) treatment before transplantation of haematopoietic progenitor cells (the cells that make blood cells). This type of transplant is used in patients who need replacement blood-making cells because they have a blood disease such as a cancer of the blood (e.g. leukaemia) or diseases causing low red-blood cell counts (including thalassaemia or sickle-cell anaemia);
- during the treatment of solid tumours when high-dose chemotherapy followed by transplantation of haematopoietic progenitor cells is needed.

Thiotepa Riemser can be used for transplantation of progenitor cells from a donor or for transplantation of progenitor cells from the patient's own body.

Thiotepa Riemser contains the active substance thiotepa and is a 'generic medicine'. This means that Thiotepa Riemser contains the same active substance and works in the same way as a 'reference medicine' already authorised in the EU called Tepadina. For more information on generic medicines, see the question-and-answer document here.

How is Thiotepa Riemser used?

Thiotepa Riemser can only be obtained with a prescription. The medicine must be given under the supervision of a doctor who has experience in conditioning treatments given before transplantation.

Thiotepa Riemser is given by infusion (drip) into a large vein over 2 to 4 hours. The dose depends on the type of blood disease or tumour that the patient has and the type of transplantation to be carried out as well as the patient's weight or weight and height.

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

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How does Thiotepa Riemser work?

The active substance in Thiotepa Riemser, thiotepa, belongs to a group of medicines called 'alkylating agents'. These substances are 'cytotoxic'. This means that they kill cells, especially cells that multiply rapidly, such as cancer of progenitor (or 'stem') cells (cells that can develop into different types of cell).

Thiotepa Riemser is used with other medicines before transplantation to destroy the abnormal cells and the patient's existing blood-making cells. This allows new cells to be transplanted, by creating space for the new cells and reducing the risk of rejection. Thiotepa has been used to prepare patients for transplantation of blood-making cells in the European Union (EU) since the late 1980s.

How has Thiotepa Riemser been studied?

The company provided data from the published literature on thiotepa. Studies on the benefits and risks of the active substance in the authorised uses have already been carried out with the reference medicine, Tepadina, and do not need to be repeated for Thiotepa Riemser.

As for every medicine, the company provided studies on the quality of Thiotepa Riemser. There was no need for 'bioequivalence' studies to investigate whether Thiotepa Riemser is absorbed similarly to the reference medicine to produce the same level of the active substance in the blood. This is because Thiotepa Riemser is given by infusion into a vein, so the active substance is delivered straight into the bloodstream.

What are the benefits and risks of Thiotepa Riemser?

Because Thiotepa Riemser is a generic medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Thiotepa Riemser authorised in the EU?

The European Medicines Agency concluded that, in accordance with EU requirements, Thiotepa Riemser has been shown to be comparable to Tepadina. Therefore, the Agency's view was that, as for Tepadina, the benefits of Thiotepa Riemser 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 Thiotepa Riemser?

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

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

Other information about Thiotepa Riemser

Thiotepa Riemser received a marketing authorisation valid throughout the EU on 26 March 2021.

Further information on Thiotepa Riemser can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/thiotepa-riemser. Information on the reference medicine can also be found on the Agency's website.

This overview was last updated in 03-2021.