28 January 2021
EMA/CHMP/60776/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Thiotepa Riemser

thiotepa

On 28 January 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Thiotepa Riemser, intended for use as a conditioning treatment before haematopoietic progenitor cell transplantation. The applicant for this medicinal product is Riemser Pharma GmbH.

Thiotepa Riemser will be available as 15 mg and 100 mg powder for concentrate for solution for infusion. The active substance of Thiotepa Riemser is thiotepa, a cell cycle-phase independent, non-specific alkylating antineoplastic agent (ATC code: L01AC01.

Thiotepa Riemser is a generic of Tepadina, which has been authorised in the EU since 15 March 2010. Studies have demonstrated the satisfactory quality of Thiotepa Riemser. Since Thiotepa Riemser is administered intravenously and is 100% bioavailable, a bioequivalence study versus the reference product Tepadina was not required. A question and answer document on generic medicines can be found here.

The full indication is:

Thiotepa Riemser is indicated, in combination with other chemotherapy medicinal products:

- with or without total body irradiation (TBI), as conditioning treatment prior to allogeneic or autologous haematopoietic progenitor cell transplantation (HPCT) in haematological diseases in adult and paediatric patients;
- when high dose chemotherapy with HPCT support is appropriate for the treatment of solid tumours in adult and paediatric patients.

Thiotepa Riemser administration should be supervised by physicians experienced in conditioning treatment.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.