EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 December 2018
EMA/CHMP/848829/2018 Corr[1]
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[2] (initial authorisation)

Trecondi

treosulfan

On 13 December 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Trecondi, intended for the conditioning treatment prior to allogeneic haematopoietic stem cell transplantation (alloHSCT). Trecondi was designated as an orphan medicinal product on 23 February 2004. The applicant for this medicinal product is medac Gesellschaft fur klinische Spezialpraparate mbH.

Trecondi will be available as a 50 mg/ml powder for solution for infusion. The active substance of Trecondi is treosulfan, a prodrug of an alkylating agent with cytotoxic activity against haematopoietic precursor cells (ATC code: L01AB02).

The benefit with Trecondi is the increase of the rate of event-free survival after 2 years. The most common side effects are infections (bacterial, viral, fungal), stomatitis/mucositis, diarrhoea, nausea, vomiting and abdominal pain.

The full indication is: “Treosulfan in combination with fludarabine is indicated as part of conditioning treatment prior to allogeneic haematopoietic stem cell transplantation (alloHSCT) in adult patients with malignant and non-malignant diseases, and in paediatric patients older than one month with malignant diseases.”

It is proposed that Trecondi be prescribed by physicians experienced in conditioning treatment followed by alloHSCT.

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 made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] The word “injection” has been deleted
[2] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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