26 January 2023
EMA/CHMP/31201/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Trecondi

treosulfan

On 26 January 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Trecondi. The marketing authorisation holder for this medicinal product is medac Gesellschaft für klinische Spezialpräparate mbH.

The CHMP adopted an extension to an existing indication to include treatment of non-malignant diseases in paediatric patients undergoing allogeneic haematopoietic stem cell transplantation. For information, the full indication for Trecondi will therefore be as follows:[2]

> 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 **and non-malignant** diseases.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[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
[2] New text in bold, removed text as strikethrough

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