swissmedic

Summary report on authorisation dated 30 October 2025

Trecondi® (active substance: treosulfan)

Indication extension in Switzerland: 17 January 2025

Medicinal product (powder for solution for infusion) for the treatment of leukaemia and certain malignant and non-malignant diseases

About the medicinal product

The medicinal product Trecondi, containing the active substance treosulfan, is a powder for solution for infusion and is used in combination with fludaribine. It is administered as part of conditioning treatment prior to allogeneic haematopoietic stem cell transplantation (allo-HSCT) in adult patients and children and adolescents older than one month suffering from malignant and non-malignant diseases.

The medicinal product Trecondi was first authorised in Switzerland on 10 August 2020 as part of conditioning treatment prior to allo-HSCT in adult patients with malignant and non-malignant diseases, and in children and adolescents older than one month suffering from malignant diseases.

This indication extension means that the medicinal product Trecondi can now also be used in children and adolescents older than one month suffering from non-malignant diseases as part of conditioning treatment prior to allo-HSCT.

Allogeneic haematopoietic stem cell transplantations may be able to cure certain forms of cancer and blood diseases.

Information on authorisation

In deciding whether to authorise the medicinal product Trecondi, containing the active substance treosulfan, Swissmedic took into account the assessment of the European Medicines Agency (EMA). The clinical data were assessed on the basis of the assessment report issued by the EMA and the corresponding product information.
Swissmedic authorised the indication extension for the medicinal product Trecondi on 17 January 2025 for use in Switzerland.

Since the assessment of the clinical data was based on the EMA assessment report, the preconditions for a SwissPAR (Swiss Public Assessment Report) and a resulting Summary report on authorisation are not fully met. Swissmedic refers to the authorisation of the foreign comparator product: www.ema.europa.eu (Procedure No. EMEA/H/C/004751/II/0014).

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Trecondi®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.