swissmedic

Public Summary SwissPAR dated 10.02.2021

Trecondi® (active substance: treosulfan)

First authorisation in Switzerland: 10 August 2020

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 was authorised in Switzerland on 10 August 2020.

Trecondi is used in combination with fludarabine as part of conditioning treatment prior to allogeneic haematopoietic stem cell transplantation (alloHSCT) in adult patients with malignant and non-malignant diseases, and in children and adolescents older than one month suffering from malignant diseases.

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 considered the assessment of the European Medicines Agency (EMA), which authorised Trecondi on 21 June 2019 for the same indication as requested for Switzerland.

The assessment of the clinical data was based on the assessment report issued by the EMA and the corresponding product information.

Swissmedic authorised Trecondi in Switzerland on 10 August 2020.

For further information on this authorisation application, Swissmedic refers to the authorisation of the foreign comparator medicinal product.

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 Public Summary SwissPAR are not fully met. Swissmedic refers to the authorisation of the foreign comparator product:

www.ema.europa.eu

Further information on the medicinal product

Information for healthcare professionals:
Information for healthcare professionals Trecondi®

Healthcare professionals (doctors, pharmacists) can answer any further questions.

This information is correct as at the date above. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

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.