LÄKEMEDELSVERKET
SWEDISH MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Thiotepa Abcur
(thiotepa)

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thiotepa

Powder for concentrate for solution for infusion, 15 mg, 100 mg

This is a summary of the public assessment report (PAR) for Thiotepa Abcur. It explains how the assessment was made and why the authorisation was recommended as well as the conditions of use. It is not intended to provide practical advice on how to use the product.

For practical information about the use of the product, patients should read the package leaflet or contact their doctor or pharmacist.

What is Thiotepa Abcur and what is it used for?
The product is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called TEPADINA.

The product is used to prepare patients for bone marrow transplantation.

How does Thiotepa Abcur work?
Thiotepa Abcur contains the active substance thiotepa, which belongs to a group of medicines called alkylating agents.
It works by destroying bone marrow cells. This enables the transplantation of new bone marrow cells (haematopoietic progenitor cells), which in turn enable the body to produce healthy blood cells.

How is Thiotepa Abcur used?

The pharmaceutical form is powder for concentrate for solution for infusion.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Thiotepa Abcur have been shown in studies?

No additional studies were needed as the product is a generic medicine that is given by infusion and contains the same active substance as the reference medicine, TEPADINA.

What are the possible side effects from Thiotepa Abcur?

Because the product is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

Why is Thiotepa Abcur approved?

It was concluded that, in accordance with EU requirements, the product has been shown to have comparable quality and is considered to be therapeutically equivalen to the reference medicine.

Therefore, the Swedish Medical Products Agency decided that, as for TEPADINA, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Thiotepa Abcur?

A risk management plan has been developed to ensure that the product is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Thiotepa Abcur

The full PAR for Thiotepa Abcur can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Thiotepa Abcur , please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in YYYY-MM.