EMA/638722/2014
EMEA/H/C/001046

EPAR summary for the public

Tepadina

thiotepa

This is a summary of the European Public Assessment Report (EPAR) for Tepadina. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Tepadina.

What is Tepadina?

Tepadina is a powder that is made up into a solution for infusion (drip into a vein). It contains the active substance thiotepa.

What is Tepadina used for?

Tepadina is used in combination with chemotherapy (medicines to treat cancer) in two ways:

- as a 'conditioning' (preparative) treatment before transplantation of haematopoietic progenitor cells (the cells that make blood cells). This type of transplant is used in patients who need to replace their blood-making cells because they have a blood disease such as a cancer of the blood (including leukaemia) or diseases causing low red blood cell counts (including thalassaemia or sickle-cell anaemia);
- during the treatment of solid tumours when high-dose chemotherapy followed by transplantation of haematopoietic progenitor cells is needed.

Tepadina can be used for transplantation of cells from a donor and for transplantation of cells derived from the patient's own body.

Because the number of patients in the European Union (EU) that undergo this type of conditioning and transplant is low, Tepadina was designated an 'orphan medicine' (a medicine used in rare diseases) on 29 January 2007.

The medicine can only be obtained with a prescription.

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How is Tepadina used?

Tepadina treatment must be supervised by a doctor who has experience in treatments given before transplantation. It must be given as an infusion into a large vein lasting two to four hours.

The dose of Tepadina depends on the type of blood disease or solid tumour that the patient has and the type of transplantation to be carried out. The dose also depends on the patient's body surface area (calculated using the height and weight of the patient) or on the patient's weight. In adults, the daily dose ranges from 120 to 481 mg per square metre (m2) given for up to five days before transplantation. In children, the daily dose ranges from 125 to 350 mg/m2 given for up to three days before transplantation. For further information, see the summary of product characteristics (also part of the EPAR).

How does Tepadina work?

The active substance in Tepadina, thiotepa, belongs to a group of medicines called 'alkylating agents'. These substances are 'cytotoxic'. This means that they kill cells, especially cells that multiply rapidly, such as cancer or progenitor (or 'stem') cells (cells that can develop into different types of cell). Tepadina is used with other medicines before transplantation to destroy the abnormal cells and the patient's existing blood-making cells. This allows new cells to be transplanted, by creating space for the new cells and reducing the risk of rejection.

Thiotepa has been used to prepare patients for transplantation of blood-making cells in the European Union (EU) since the late 1980s.

How has Tepadina been studied?

Because thiotepa has been used for many years in the EU, the company presented data from the published literature. This included 109 studies involving around 6,000 adults and 900 children with blood diseases or solid tumours, who were having a transplant of blood-making cells. The studies looked at the number of patients with successful transplantations, how long it took for the diseases to come back and how long the patients survived.

What benefit has Tepadina shown during the studies?

The published studies showed that thiotepa used in combination with other chemotherapy medicines is beneficial to adults and children being treated for blood diseases and solid tumours. It helps to destroy the patient's existing blood-making cells, resulting in the successful transplantation of new cells, improved survival and a reduced risk of the diseases coming back.

What is the risk associated with Tepadina?

The most common side effects seen with Tepadina when used with other medicines are infections, cytopenia (low number of cells in the blood), graft-versus-host disease (when the transplanted cells attack the body), disorders of the gut, haemorrhagic cystitis (bleeding and inflammation in the bladder) and mucosal inflammation (inflammation of the moist body surfaces). For the full list of all side effects reported with Tepadina in adults and children, see the package leaflet.

Tepadina must not be used in women who are pregnant or breast-feeding. It must also not be used together with the vaccine against yellow fever or vaccines containing live viruses or bacteria. For the full list of restrictions, see the package leaflet.

Why has Tepadina been approved?

The CHMP noted that the active substance in Tepadina, thiotepa, has a well established used. This means that it has been used for many years and that there was sufficient information on its effectiveness and safety. The Committee decided that, based on available published information, Tepadina's benefits are greater than its risks and recommended that it be given marketing authorisation.

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

A risk management plan has been developed to ensure that Tepadina 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 for Tepadina, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Tepadina

The European Commission granted a marketing authorisation valid throughout the European Union for Tepadina on 15 March 2010.

The full EPAR for Tepadina can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Tepadina, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist..

The summary of the opinion of the Committee for Orphan Medicinal Products for Tepadina can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/Rare disease designation.

This summary was last updated in 11-2014.