CBG MEB

Summary Public Assessment Report

Generics

Cyclofosfamide Sandoz 500 mg, 1000 mg and 2000 mg, powder for solution for injection/infusion

cyclophosphamide

NL/H/2977/001-003/DC

Date: 29 December 2014

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Active substance: cyclophosphamide

This is a summary of the public assessment report (PAR) for Cyclofosfamide Sandoz 500 mg, 1000 mg and 2000 mg, powder for solution for injection/infusion. It explains how this medicine was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use this medicine.

For practical information about using Cyclofosfamide Sandoz patients should read the package leaflet or contact their doctor or pharmacist.

What is Cyclofosfamide Sandoz and what is it used for?
Cyclofosfamide Sandoz is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Endoxan I.V.

This medicine is often used alone or together with other anti-cancer drugs or radiotherapy in the treatment of various cancers. These include:

- certain types of cancer of the white blood cells (acute lymphoblastic leukemia, chronic lymphocytic leukemia);
- different forms of lymphomas that affect the immune system (Hodgkin's disease, non-Hodgkin's lymphoma and multiple myeloma);
- ovarian cancer and breast cancer
- Ewing's sarcoma (a form of bone cancer)
- small cell lung cancer;
- in the treatment of advanced or metastatic tumor of the central nervous system. (neuroblastoma);

Furthermore, cyclophosphamide is used in preparation for bone marrow transplantation to treat certain types of cancer of the white blood cells (acute lymphoblastic leukemia, chronic myeloid leukemia and acute myeloid leukemia)

Occasionally, some doctors may prescribe cyclophosphamide for other conditions not related to cancer:

- life threatening autoimmune diseases: severe progressive forms of lupus nephritis (inflammation of the kidney caused by a disease of the immune system) and Wegener's granulomatosis (a rare form of vasculitis).

How does this medicine work?
This medicine contains an active substance called cyclophosphamide. Cyclophosphamide is a cytotoxic medicine or anti-cancer medicine. It works by killing cancer cells, this is sometimes called 'chemotherapy'.

How is this medicine used?
The pharmaceutical form of Cyclofosfamide Sandoz is a powder for solution for injection/infusion and the route of administration is intravenous. This medicine is given as an injection and is normally added to a large bag of fluid and is slowly injected (infused) directly into a vein. The medicine can only be obtained with a prescription.

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

How has this medicine been studied?
No additional studies were needed as Cyclofosfamide Sandoz is a generic medicine that is given by intravenous injection as an aqueous solution and contains the same active substance in the same concentration as the reference medicine, Endoxan I.V.

What are the possible side effects of this medicine?
Because Cyclofosfamide Sandoz is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.
For the full list of all side effects reported with this medicine, see section 4 of the package leaflet.

Why is this medicine approved?
It was concluded that, in accordance with EU requirements, this medicine has been shown to have comparable quality and to be comparable to the reference medicine. Therefore, the Medicines Evaluation Board of the Netherlands decided that, as for Endoxan I.V., the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of this medicine?
A risk management plan has been developed to ensure that this medicine 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 Cyclofosfamide Sandoz, 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 this medicine
In the Netherlands, the marketing authorisation for Cyclofosfamide Sandoz 500 mg, 1000 mg and 2000 mg, powder for solution for injection/infusion was granted on 1 September 2014.

The full PAR for this medicine can be found on the website http://mri.medagencies.org/Human.
For more information about treatment with Cyclofosfamide Sandoz, read the package leaflet (http://mri.medagencies.org/download/NL_H_2977_001_FinalPL.pdf) or contact your doctor or pharmacist.

This summary was last updated in December 2014.