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EPAR summary for the public

Busulfan Fresenius Kabi

busulfan

This is a summary of the European public assessment report (EPAR) for Busulfan Fresenius Kabi. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Busulfan Fresenius Kabi.

For practical information about using Busulfan Fresenius Kabi, patients should read the package leaflet or contact their doctor or pharmacist.

What is Busulfan Fresenius Kabi and what is it used for?

Busulfan Fresenius Kabi is a medicine that contains the active substance busulfan. It is used in adults and children as part of 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 disorder (such as a rare type of anaemia) or a cancer of the blood.

For a conventional conditioning treatment, Busulfan Fresenius Kabi is given before treatment with a second medicine, cyclophosphamide in adults, and either cyclophosphamide or melphalan in children. In adult patients who are eligible for a 'reduced-intensity' conditioning regimen, Busulfan Fresenius Kabi is given right after treatment with another medicine, fludarabine.

Busulfan Fresenius Kabi is a 'generic medicine'. This means that Busulfan Fresenius Kabi is similar to a 'reference medicine' already authorised in the European Union (EU) called Busilvex. For more information on generic medicines, see the question-and-answer document here.

How is Busulfan Fresenius Kabi used?

Busulfan Fresenius Kabi can only be obtained with a prescription and should only be used by a doctor who has experience in treatments given before transplantation.

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The medicine is available as a concentrate to be made up into a solution for central intravenous infusion (drip into a central vein in the chest). When used in combination with cyclophosphamide or melphalan the recommended dose of Busulfan Fresenius Kabi in adults is 0.8 mg per kilogram body weight. In children up to 17 years of age, the recommended dose of Busulfan Fresenius Kabi varies between 0.8 and 1.2 mg per kilogram depending on the weight of the child. Each infusion lasts for two hours and it is given to the patient every six hours on four consecutive days before treatment with cyclophosphamide or melphalan and the transplant.

When used in combination with fludarabine, the recommended dose of Busulfan Fresenius Kabi is 3.2 mg per kilogram given once a day as a three-hour infusion immediately after fludarabine, for 2 or 3 consecutive days.

Before receiving Busulfan Fresenius Kabi, patients are given anticonvulsive medicines (to prevent seizures) and anti-emetic medicines (to prevent vomiting).

How does Busulfan Fresenius Kabi work?

The active substance in Busulfan Fresenius Kabi, busulfan, belongs to a group of medicines called 'alkylating agents'. These substances are 'cytotoxic'. This means that they kill cells, especially cells that develop rapidly, such as cancer or progenitor ('stem') cells (cells that make other types of cell).

Busulfan is used before transplantation to destroy abnormal cells and the patient's existing blood-making cells. This is called 'myeloablation'. Cyclophosphamide, melphalan or fludarabine are used to suppress the immune system, so that the body's natural defences are decreased. This helps the transplanted cells to 'engraft' (when they start to grow and produce normal blood cells).

How has Busulfan Fresenius Kabi been studied?

The company provided data from the published literature on busulfan. No additional studies were needed as Busulfan Fresenius Kabi is a generic medicine that is given by infusion and contains the same active substance as the reference medicine, Busilvex.

What are the benefits and risks of Busulfan Fresenius Kabi?

Because Busulfan Fresenius Kabi is given by infusion and contains the same active substance as the reference medicine, its benefits and risks are taken as being the same as the reference medicine's.

Why is Busulfan Fresenius Kabi approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that, in accordance with EU requirements, Busulfan Fresenius Kabi has been shown to be comparable to Busilvex. Therefore, the CHMP's view was that, as for Busilvex, the benefit outweighs the identified risk. The Committee recommended that Busulfan Fresenius Kabi be approved for use in the EU.

What measures are being taken to ensure the safe and effective use of Busulfan Fresenius Kabi?

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

Further information can be found in the summary of the risk management plan.

Other information about Busulfan Fresenius Kabi

The European Commission granted a marketing authorisation valid throughout the European Union for Busulfan Fresenius Kabi on 22 September 2014.

The full EPAR and risk management plan summary for Busulfan Fresenius Kabi 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 Busulfan Fresenius Kabi, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The full EPAR for the reference medicine can also be found on the Agency's website.

This summary was last updated in 03-2015.