24 July 2014
EMA/CHMP/388260/2014
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Busulfan Fresenius Kabi

busulfan

On 24 July 2014 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Busulfan Fresenius Kabi intended for conditioning treatment prior to conventional haematopoietic progenitor cell transplantation.

The applicant for this medicinal product is Fresenius Kabi Oncology PLC. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Busulfan Fresenius Kabi is busulfan an alkyl sulfonate (L01AB0) and a potent cytotoxic agent and a bifunctional alkylating agent. In aqueous media, release of the methanesulphonate groups produces carbonium ions which can alkylate DNA, thought to be an important biological mechanism for its cytotoxic effect.

Busulfan Fresenius Kabi is a generic of Busilvex, which has been authorised in the EU since 09 July 2003. Studies have demonstrated the satisfactory quality of Busulfan Fresenius Kabi. Busulfan Fresenius Kabi is administered intravenously and is 100% bioavailable; therefore, a bioequivalence study versus the reference product Bulsivex was not required. A question and answer document on generic medicines can be found here.

A pharmacovigilance plan for Busulfan Fresenius Kabi will be implemented as part of the marketing authorisation.

The approved indication is:

Busulfan followed by cyclophosphamide (BuCy2) is indicated as conditioning treatment prior to conventional haematopoietic progenitor cell transplantation (HPCT) in adult patients when the combination is considered the best available option.

[1] Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued 67 days from adoption of the opinion.

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Busulfan followed by cyclophosphamide (BuCy4) or melphalan (BuMel) is indicated as conditioning treatment prior to conventional haematopoietic progenitor cell transplantation in paediatric patients.

Busulfan administration should be supervised by a physician experienced in conditioning treatment prior to haematopoietic progenitor cell transplantation

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR), and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Busulfan Fresenius Kabi and therefore recommends the granting of the marketing authorisation.