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Public statement

Busilvex (busulfan)

Withdrawal of the marketing authorisation in the European Union

On 9 January 2023, the European Commission withdrew the marketing authorisation for Busilvex (busulfan) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Pierre Fabre Medicament, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Busilvex was granted marketing authorisation in the EU on 9 July 2003 for use as a conditioning treatment prior to haematopoietic progenitor cell transplantation. The marketing authorisation was initially valid for a 5-year period. It was then granted unlimited validity in 2008.

There are generic medicinal products of Busilvex authorised and marketed in the EU.

The European Public Assessment Report (EPAR) for Busilvex will be updated to indicate that the marketing authorisation is no longer valid.

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