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Public statement

Kepivance

Withdrawal of the marketing authorisation in the European Union

On 1 April 2016, the European Commission withdrew the marketing authorisation for Kepivance (palifermin) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Swedish Orphan Biovitrum AB (publ), which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Kepivance was granted marketing authorisation in the EU on 25 October 2005 to decrease the incidence, duration and severity of oral mucositis in adult patients with haematological malignancies receiving myeloablative radiochemotherapy associated with a high incidence of severe mucositis and requiring autologous haematopoietic stem cell support.

The marketing authorisation holder has committed to ensure that patients who need treatment with Kepivance continue to receive it until complete exhaustion of stock.

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Assessment Report (EPAR) for Kepivance will be updated accordingly to indicate that the marketing authorisation is no longer valid.

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