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Public statement

Inpremzia (insulin human (rDNA))

Withdrawal of the marketing authorisation in the European Union

On 4 April 2023, the European Commission withdrew the marketing authorisation for Inpremzia (insulin human (rDNA)) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Baxter Holding B.V., which notified the European Commission of its decision not to market the product in the European Union for commercial reasons.

Inpremzia was granted marketing authorisation in the EU on 25 April 2022 for treatment of patients with diabetes mellitus who require intravenous insulin.

Inpremzia is a biosimilar medicinal product. It is highly similar to the reference product Actrapid (human insulin), which is authorised in the EU to treat diabetes mellitus.

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European Public Assessment Report (EPAR) for Inpremzia will be updated to indicate that the marketing authorisation is no longer valid.

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