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Public statement

Glustin

Withdrawal of the marketing authorisation in the European Union

On 30 November 2021, the European Commission withdrew the marketing authorisation for Glustin (pioglitazone) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Takeda Pharma A/S, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Glustin was granted marketing authorisation in the EU on 11 October 2000 for the treatment of type 2 diabetes. The marketing authorisation was initially valid for a 5-year period. It was subsequently renewed for an additional 5-year period in 2005. It was then granted unlimited validity in 2010. The product had not been marketed in the EU since 2019.

Glustin was a duplicate application to Actos, which is marketed in several EU countries.

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European Public Assessment Report (EPAR) for Glustin will be updated to indicate that the marketing authorisation is no longer valid.

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