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Public statement

Glubrava

Withdrawal of the marketing authorisation in the European Union

On 24 May 2022 the European Commission withdrew the marketing authorisation for Glubrava (pioglitazone / metformin hydrochloride) 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.

Glubrava was granted marketing authorisation in the EU on 11 December 2007 for treatment of type 2 diabetes mellitus. The marketing authorisation was initially valid for a 5-year period. It was subsequently renewed for an additional 5-year period in 2012. It was then granted unlimited validity in 2017. The product had not been marketed in the EU since 2021.

Glubrava is identical to Competact, which is authorised in the EU to treat type 2 diabetes mellitus in adult patients.

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European Public Assessment Report (EPAR) for Glubrava will be updated to indicate that the marketing authorisation is no longer valid.

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