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Public statement

Pioglitazone Krka

Withdrawal of the marketing authorisation in the European Union

On 16 September 2014, the European Commission withdrew the marketing authorisation for Pioglitazone Krka (pioglitazone) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Krka d.d. Novo mesto, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Pioglitazone Krka was granted marketing authorisation in the EU on 21 March 2012 for treatment of type 2 diabetes mellitus. The marketing authorisation was initially valid for a 5-year period.

Pioglitazone Krka is a generic medicine of Actos. There are other generic medicinal products of Actos authorised and marketed in the EU.

The European Public Assessment Report (EPAR) for Pioglitazone Krka will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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