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Public statement

Ionsys

Withdrawal of the marketing authorisation in the European Union

On 27 September 2018 the European Commission withdrew the marketing authorisation for Ionsys (fentanyl) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Incline Therapeutics Europe Ltd, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Ionsys was granted marketing authorisation in the EU on 19 November 2015 for treatment of acute moderate to severe post-operative pain.

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Assessment Report (EPAR) for Ionsys will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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