EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 September 2015
EMA/CHMP/588247/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ionsys

fentanyl

On 24 September 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ionsys, intended for the treatment of post-operative pain. The applicant for this medicinal product is Incline Therapeutics Europe Ltd.

Ionsys will be available as a transdermal system (3.2 mg/24h). The active substance of Ionsys is fentanyl, an opioid (ATC code: N02AB03) which produces analgesia via activation of μ-opioid receptors primarily within the central nervous system.

The benefits with Ionsys are its ability to reduce post-operative pain. The most common side effects are nausea, vomiting and erythema at the application site.

The full indication is: "Ionsys is indicated for the management of acute moderate to severe post-operative pain in adult patients." It is proposed that Ionsys be prescribed by physicians experienced in the management of opioid therapy. Ionsys is to be administered in a hospital setting only.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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