17 September 2020
EMA/CHMP/476199/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Exparel

bupivacaine

On 17 September 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Exparel, intended for the treatment of post-operative pain. The applicant for this medicinal product is Pacira Ireland Limited.

Exparel will be available as 133 mg/10 mL and 266 mg/20 mL dispersion for injection. The active substance of Exparel is bupivacaine, a local anaesthetic (ATC code: N01BB01) that blocks the generation and conduction of nerve impulses.

The benefits with Exparel are its ability to reduce post-operative pain. The most common side effects are dysgeusia and oral hypoaesthesia.

The full indication is:

> Exparel is indicated as a brachial plexus block or femoral nerve block for treatment of post-operative pain in adults, and as a field block for treatment of somatic post-operative pain from small- to medium-sized surgical wounds in adults (see section 5.1).
>
> Exparel should be administered in a setting where trained personnel and appropriate equipment are available.

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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