15 September 2022
EMA/CHMP/762558/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Exparel liposomal

bupivacaine

On 15 September 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Exparel liposomal. The marketing authorisation holder for this medicinal product is Pacira Ireland Limited.

The CHMP adopted an extension to the existing indication for the treatment of somatic post-operative pain in children aged 6 years or older.

For information, the full indication for Exparel liposomal will be as follows[2]:

Exparel liposomal is indicated (see section 5.1):

- in adults as a brachial plexus block or femoral nerve block for treatment of post-operative pain.
- in adults **and children aged 6 years or older** as a field block for treatment of somatic post-operative pain from small- to medium-sized surgical wounds.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to 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
[2] New text in bold

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