23 July 2020
EMA/CHMP/112785/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Fortacin

lidocaine / prilocaine

On 23 July 2020, 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 Fortacin. The marketing authorisation holder for this medicinal product is Recordati Ireland Ltd.

The variation concerns a change in the classification of Fortacin from "medicinal product subject to medical prescription" to "medicinal product not subject to medical prescription".

This change is based on the fact that CHMP agreed that the criteria for classifying a medicine as subject to medical prescription as laid down in the European Commission Guideline do not apply to Fortacin. Therefore, the Committee recommended that the change in the supply classification is approvable.

For information, the full indication for Fortacin is as follows:

"Fortacin is indicated for the treatment of primary premature ejaculation in adult men."

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

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