25 June 2015
EMA/CHMP/393290/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Levemir

insulin detemir

On 25 June 2015, 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 Levemir. The marketing authorisation holder for this medicinal product is Novo Nordisk A/S.

The CHMP adopted an extension to an existing indication as follows[2]:

"Levemir is indicated for treatment of diabetes mellitus in adults, adolescents and children aged ~~2 years~~ **1 year** and above."

For information, the full indication for Levemir will be as follows:

"Levemir is indicated for treatment of diabetes mellitus in adults, adolescents and children aged 1 year and above."

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, removed text as strikethrough

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