22 September 2011
EMA/CHMP/775779/2011
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Levemir

insulin detemir

On 22 September 2011, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation 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. They may request a re examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a change to an indication as follows:

“Treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above.”

Original indication was as follows:

“Treatment of diabetes mellitus in adults, adolescents and children aged 6-17 years.”

Furthermore, the CHMP adopted a change to a posology[2] as follows:

"Levemir can be used alone as the basal insulin or in combination with bolus insulin. It can also be used in combination with oral antidiabetic medicinal products or as add-on therapy to liraglutide treatment".

Detailed conditions 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 the variation 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 within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.
[2] According to Annex V of Commission Regulation (EC) No 1234/2008 this variation was classified as an extension of indication.

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