



23 April 2015
EMA/CHMP/272298/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Levemir

insulin detemir

On 23 April 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 a change in the way the medicine can be used, as reflected in the updated section 4.2 of the SmPC as follows:²

"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 **and/or GLP-1 receptor agonists** ~~or as add-on therapy to liraglutide.~~

~~In combination with oral antidiabetic medicinal products and as add-on to liraglutide~~ **When Levemir is used in combination with oral antidiabetic medicinal products or when added to GLP-1 receptor agonists** it is recommended to use Levemir once daily, initially at a dose of 10 units or 0.1-0.2 units/kg. The dose of Levemir should be titrated based on the individual patient's needs.

When a GLP-1 receptor agonist is added to Levemir, it is recommended to reduce the dose of Levemir by 20% to minimise the risk of hypoglycaemia. Subsequently, dosage should be adjusted individually."

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**

