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EPAR summary for the public

Levemir

insulin detemir

This document is a summary of the European public assessment report (EPAR) for Levemir. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Levemir.

What is Levemir?

Levemir is a solution for injection that contains the active substance insulin detemir. It is available in cartridges and in pre-filled pens.

What is Levemir used for?

Levemir is used to treat diabetes in adults, adolescents and children from the age of one year.

The medicine can only be obtained with a prescription.

How is Levemir used?

Levemir is given as an injection under the skin in the abdominal (tummy) wall, the thigh, the upper arm, the shoulder or the buttock. Levemir is a long-acting insulin. It can be used in the following ways:

- alone as basal insulin
- in combination with injections of a short- or rapid-acting insulin at mealtimes
- in combination with diabetes medicines taken by mouth
- in combination with a type of diabetes medicines called GLP-1 receptor agonists that are given by injection. When a GLP-1 receptor agonist is added to Levemir, the Levemir dose should be reduced, and subsequently adjusted according to the individual patient's blood glucose levels.

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Levemir can be given at any time of day, provided that it is the same time each day. The dose of Levemir should be adjusted according to the individual patient's blood glucose (sugar) levels, which should be regularly tested to find the lowest effective dose.

How does Levemir work?

Diabetes is a disease in which the body does not produce enough insulin to control the level of blood glucose. Levemir is a replacement insulin that is very similar to the insulin made by the body.

Insulin detemir is very slightly different from human insulin. The change means that it is absorbed more slowly by the body, and takes longer to reach its target in the body. This means that Levemir has a long duration of action. The replacement insulin acts in same way as naturally produced insulin and helps glucose enter cells from the blood. By controlling the level of blood glucose, the symptoms and complications of diabetes are reduced.

How has Levemir been studied?

Levemir has been studied in 1,575 adult patients with type 1 diabetes (when the pancreas cannot produce insulin) and over 2,500 adult patients with type 2 diabetes (when the body is unable to use insulin effectively). The studies compared Levemir with human insulin NPH (an intermediate-acting insulin) or insulin glargine (a long-acting insulin) given once or twice a day. Injections of fast-acting insulin were also used at mealtimes. In four of the six studies in type 2 diabetes, patients also received one or two antidiabetes medicines taken by mouth.

Levemir has also been studied in two main studies involving 695 children and adolescents with diabetes aged 2-17 years in combination with insulin aspart and comparing it to insulin NPH.

The effects of Levemir have also been studied in combination with metformin and liraglutide (a GLP-1 receptor agonist). In one study, 323 patients with type 2 diabetes whose blood glucose levels were not well controlled with metformin and liraglutide either received Levemir in addition to their treatment or continued on metformin and liraglutide alone.

All of the studies measured the level of a substance in the blood called glycosylated haemoglobin (HbA1c), which gives an indication of how well the blood glucose is controlled. Levemir has not been studied in children below one year of age.

What benefit has Levemir shown during the studies?

The studies showed that Levemir controls blood glucose levels in a similar manner to insulin NPH, with less risk of low blood glucose levels during the night and no associated weight gain. In combination with diabetes medicines taken by mouth, Levemir also controlled blood glucose levels in a similar manner to insulin glargine. Patients using Levemir in combination with liraglutide and metformin achieved a decrease of 0.5% in Hb1Ac compared with no decrease in patients using liraglutide and metformin alone. Additionally the weight benefit from liraglutide was sustained when adding Levemir.

What is the risk associated with Levemir?

The most common side effect with Levemir (seen in more than 1 patient in 10) is hypoglycaemia (low blood glucose levels). For the full list of all side effects and restrictions with Levemir, see the package leaflet.

Levemir doses might need to be adjusted when given with some other medicines that may have an effect on blood glucose levels. The full list is available in the package leaflet.

Why has Levemir been approved?

The CHMP decided that Levemir's benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Levemir?

A risk management plan has been developed to ensure that Levemir is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Levemir, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Levemir:

The European Commission granted a marketing authorisation valid throughout the European Union for Levemir on 1 June 2004.

The full EPAR for Levemir can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Levemir, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 07-2015.