HAUTE AUTORITÉ DE SANTÉ

DIABETOLOGY
New indication
September 2016

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

LEVEMIR (insulin detemir), long-acting human insulin analogue

No actual benefit demonstrated relative to TRESIBA in the management of type 1 diabetes in children aged 1 to 2 years.

Main points

- LEVEMIR has Marketing Authorisation in type 1 diabetes in children aged 1 year.
- The available clinical efficacy data in children between age 1 and 2 years are limited to a non-inferiority study versus insulin degludec conducted on 350 children with type 1 diabetes aged between 1 and 17 years, of which only 4 were aged 1 to 2 years.

Pre-existing indications*

- LEVEMIR also has Marketing Authorisation in the treatment of diabetes in adults, adolescents and children aged 2 years and older.

Therapeutic use

- Several insulin therapy regimens are possible in children with type 1 diabetes. In most of them, glycaemic control is achieved by means of a basal-bolus regimen which includes an intermediate-acting NPH insulin as basal insulin. In children who are not controlled by intermediate-acting NPH insulin and/or have worrying nocturnal hypoglycaemic episodes, long-acting insulin analogues may be treatment alternatives to intermediate-acting NPH insulin. The choice of insulin treatment regimen depends on the blood glucose objectives for each child, its preferences, its lifestyle and those of its family. The acceptability of treatment (particularly the daily number of injections required) is an important factor to be taken into account, particularly in infants.
- **Role of the medicinal product in the therapeutic strategy**
  LEVEMIR is a first-line treatment in children with type 1 diabetes aged 1 year and older in combination with a fast-acting insulin or fast-acting analogue.

Clinical data

- A randomised, parallel-group, open-label study of 350 children with type 1 diabetes aged 1 to 17 years compared LEVEMIR to insulin degludec in combination with basal-bolus fast-acting insulin aspart for a duration of 26 weeks. This study only included 4 children aged 1 to 2 years (2 in each group). This small study population does not provide a convincing demonstration of the therapeutic benefit of LEVEMIR in children with type 1 diabetes aged 1 to less than 2 years. In the overall study population of children aged 1 to 17 years, after 26 weeks of treatment, sensitivity analysis in the per-protocol population showed a difference in HbA1c variation of 0.19, 95% CI [0.01; 0.37] and in the intention-to-treat population, a difference in HbA1c variation estimated between the 2 groups of 0.15, 95% CI [-0.03; -0.32], p = 0.003, confirming that treatment with insulin degludec is not inferior to treatment with LEVEMIR.
- An extension phase of 26 weeks evaluated long-term safety. The percentage of patients who reported an adverse event (AE) was comparable in the insulin degludec (92.5%) and LEVEMIR (89.7%) groups.

* This summary does not cover this indication.

Benefit of the medicinal product

- The actual benefit* of LEVEMIR is substantial.
- LEVEMIR provides no clinical added value** (CAV V) relative to TRESIBA (insulin degludec) in the management of type 1 diabetes in children aged 1 to 2 years.
- Recommends inclusion on the list of reimbursable products for supply by pharmacists and for hospital use.

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This document was created on the basis of the Transparency Committee Opinion of 21 September 2016 (CT-15145) and is available at **www.has-sante.fr**

* The actual benefit (AB) of a proprietary medicinal product describes its benefit primarily in terms of its clinical efficacy and the seriousness of the condition being treated. The HAS Transparency Committee assesses the AB, which can be substantial, moderate, low or insufficient for reimbursement for hospital use.

** The clinical added value (CAV) describes the improvement in treatment provided by a medicinal product compared with existing treatments. The HAS Transparency Committee assesses the degree of CAV on a scale from I (major) to IV (minor). A level V CAV means “no clinical added value”.