Prescribing Information

Levemir®
Insulin detemir.

Levemir® Penfill®
Levemir® FlexPen®
Levemir® InnoLet®
All presentations contain insulin detemir. 1 ml of solution contains 100 U insulin detemir (equivalent to 14.2 mg). 1 cartridge and 1 pre-filled device contains 3 ml equivalent to 300 U.

Indication: Treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above.
Posology and administration: Levemir® is a long-acting insulin analogue used alone as basal insulin or in combination with bolus insulin. It can be used in combination with oral antidiabetic medicinal products or as add-on therapy to liraglutide; use Levemir® once daily initially at a dose of 10 U or 0.1 to 0.2 U/kg. Levemir® is for subcutaneous administration only. It can be given at any time during the day, but at the same time. When used as part of a basal-bolus regimen administer once/twice daily depending on patients' needs. Doses should be adjusted based on individual patients' needs. When given twice daily, the evening dose may be administered in the evening/bedtime. Adjustment of dose may be necessary if patients undertake increased physical activity, change their diet or during concomitant illness. In elderly patients, patients with renal/hepatic impairment, and in children/adolescents, glucose monitoring should be intensified and the dose adjusted on an individual basis. Levemir® has not been studied in children below the age of 2 yrs. When transferring from other insulins, adjustment of dose/timing of administration may be necessary; glucose levels should be monitored. Concomitant antidiabetic treatment may need to be adjusted. Levemir® must not be administered intravenously or in insulin infusion pumps; avoid intramuscular administration. Penfill® designed to be used with Novo Nordisk insulin delivery systems. Penfill®, FlexPen® and InnoLet® designed to be used with NovoFine® and NovoTwist® needles.
Contraindications: Hypersensitivity to insulin detemir or excipients.
Special warnings and precautions for use: Use of inadequate doses or discontinuation of treatment may lead to hyperglycaemia and ketoacidosis which are potentially lethal. Travelling between time zones may require change in the insulin regimen. Too much insulin, omission of a meal or strenuous exercise may lead to hypoglycaemia. Reduction of warning symptoms of hypoglycaemia may be seen upon tightening control and also in patients with long-standing diabetes. Transferring to a new type or brand of insulin should be done under strict medical supervision. Injection site reactions, usually transitory, may occur; rotation of injection sites may help reduce or prevent these reactions, rarely they may require discontinuation of Levemir®. Careful monitoring is recommended in patients with severe hypoalbuminaemia. Hypoglycaemia may constitute a risk when driving or operating machinery. Levemir® must not be mixed with other medicinal products**.** Cases of cardiac failure reported when pioglitazone was used in combination with insulin, especially in patients with risk factors for development of cardiac heart failure; if the combination is used, patients should be observed for signs and symptoms of heart failure, weight gain and oedema. Pioglitazone should be discontinued if any deterioration in cardiac symptoms occurs**.**
Fertility, pregnancy and lactation: Levemir® can be considered during pregnancy; potential benefit must be weighed against possibly increased risk of adverse pregnancy outcome. Unknown whether insulin detemir is excreted in human milk. No metabolic effects of ingested insulin detemir on the breast-fed newborn/infant are anticipated. Animal studies have not revealed any harmful effects on fertility.
Undesirable effects: Very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1,000 to < 1/100); rare (≥ 1/10,000 to < 1/1,000); very rare (< 1/10,000); not known (cannot be estimated from the available data). Very common: Hypoglycaemia. Common: Injection site reactions; Allergic and potentially allergic reactions reported in three studies of Levemir® in combination with oral antidiabetic agents. Uncommon: Lipodystrophy; oedema and refraction disorders; allergic and potentially allergic reactions, urticaria, rash and eruptions in basal-bolus regimens, generalised hypersensitivity reactions are very rare but can potentially be life threatening; abrupt improvement in glycaemic control may be associated with temporary worsening of diabetic retinopathy. Rare: Acute painful neuropathy may be associated with rapid improvement in blood glucose control, usually reversible. The Summary of Product Characteristics should be consulted for a full list of side effects.
MA numbers and Basic NHS Price:
5 x 3 ml Penfill® EU/1/04/278/002 £42.00;
5 x 3 ml FlexPen® EU/1/04/278/005 £42.00;
5 x 3 ml InnoLet® EU/1/04/278/008 £44.85.
Legal category: POM.
Full prescribing information can be obtained from:
Novo Nordisk Limited, Broadfield Park, Brighton Road, Crawley, West Sussex, RH11 9RT.
Marketing Authorisation Holder: Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd, Denmark.
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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Novo Nordisk Limited (Telephone Novo Nordisk Customer Care Centre 0845 6005055). Calls may be monitored for training purposes.