**Levemir®** Insulin detemir.

**Levemir® Penfill®**

**Levemir® FlexPen®**

**Levemir® InnoLet®**

All presentations contain insulin detemir. 1ml of the solution contains 100 U insulin detemir (equivalent to 14.2 mg). 1 cartridge contains 3 ml equivalent to 300 U. 1 pre-filled pen contains 3 ml equivalent to 300 U.

**Indication:** Treatment of diabetes mellitus in adults and adolescents and children aged 6 - 17 years. **Posology and administration:** Levemir® is a long-acting insulin analogue used as a basal insulin. Levemir® is for subcutaneous administration only. In combination with oral antidiabetic medicinal products use Levemir® once daily initially at a dose of 10 U or 0.1 to 0.2 U/kg. The injection can be given at any time during the day, but at the same time each day. The dose should be titrated based on individual patients’ needs. When used as part of a basal-bolus insulin regimen administer once or twice daily depending on the patients’ needs. Dose should be adjusted individually. When given twice daily, the evening dose may be administered in the evening or at bedtime. Adjustment of dose may be necessary if patients undertake increased physical activity, change their usual diet or during concomitant illness. In elderly patients, patients with renal or hepatic impairment, and in children and adolescents, glucose monitoring should be intensified and insulin detemir dose adjusted on an individual basis. Efficacy and safety of Levemir® has not been studied in children below the age of 6 years. Levemir® should only be used in this age group under careful medical supervision. When transferring from other insulins, adjustment of dose and timing of administration may be necessary; monitor glucose during transfer and in initial weeks thereafter. Adjustment of dose and timing of administration may be necessary; careful medical supervision. When transferring from other insulins, Levemir® is a long-acting insulin analogue equivalent to 300 U.

**Treatment of diabetes mellitus in adults and adolescents and children aged 6 - 17 years.**

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**Precautions for use:** Use of doses which are inadequate or discontinuation of treatment may lead to hyperglycaemia and ketoadiposis which are potentially lethal. Travelling between time zones may require change in the applied 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 within an area may help reduce or prevent these reactions. Rarely injection site reactions may require discontinuation of Levemir®. Careful monitoring is recommended in patients with severe hypoaalbuminaemia. Hypoglycaemia may constitute a risk when driving or operating machinery. Substances added to Levemir® may cause degradation; Levemir® must not be mixed with other medicinal products. Cases of cardiac failure were reported when pioglitazone was used in combination with insulin, especially in patients with risk factors for development of cardiac heart failure. If the combination of pioglitazone and Levemir® 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 function occurs. Fertility, pregnancy and lactation: No clinical experience in pregnancy and breast-feeding; exercise precaution when prescribing to pregnant or breast-feeding women. Animal studies have not revealed any adverse 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:** Levemir® Penfill® EU/1/042/78/002 Levemir® FlexPen® EU/1/042/78/005 Levemir® InnoLet® EU/1/042/78/008 **Legal category:** POM. **Basic NHS price:** 5 x 3 ml Penfill® £42.00 5 x 3 ml FlexPen® £42.00 5 x 3 ml InnoLet® £44.85 Full prescribing information can be obtained from: Novo Nordisk Limited, Broadfield Park, Brighton Road, Crawley, West Sussex, RH11 9RT.

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