Prescribing Information

Actrapid®; Insulatard®
Insulin human, rDNA.

Actrapid® 10 ml vial
Insulatard® 10 ml vial
Insulatard® Penfill®
Insulatard® InnoLet®
10 ml vials (Actrapid®, Insulatard®); 3 ml Penfill® cartridges (Insulatard® Penfill®); 3 ml compact, disposable, dial-a-dose delivery device able to deliver 1-50 units in increments of 1 unit (Insulatard® InnoLet®). All are available in a strength of 100 iu/ml. Actrapid® is a soluble insulin and Insulatard® is an isophane insulin.
Indication: The treatment of diabetes mellitus.
Posology and administration: Dosing is individual, usually between 0.3-1.0 iu/kg/day and given by subcutaneous injection; Actrapid® may be given intravenously but must not be used in insulin infusion pumps. Injection of Actrapid® should be followed by a meal or snack within 30 minutes of administration. Resuspend Insulatard® before use by gently agitating it. Insulatard® (vials only) may be mixed in the syringe with fast-acting insulin. Insulatard® must not be administered intravenously or used in insulin infusion pumps. In elderly patients, in patients with renal or hepatic impairment, glucose monitoring should be intensified and the dose adjusted on an individual basis. Actrapid® and Insulatard® can be used in children. Penfill® cartridges are designed to be used with Novo Nordisk insulin delivery systems and NovoFine® and NovoTwist® needles. NovoFine® and NovoTwist® needles are designed to be used with the InnoLet® device. Penfill® cartridges and InnoLet® devices are for single-patient use only.
Contraindications: Hypersensitivity to human insulin or any of the excipients.
Special warnings and precautions for use: Inadequate dosing or discontinuation of treatment may lead to hyperglycaemia and ketoacidosis which are potentially lethal. Hypoglycaemia may occur if the insulin dose is too high in relation to requirements, in which case insulin must not be injected. Change in early warning symptoms of hypoglycaemia may be seen upon tightening control and when transferring between different types of insulin. Transfer to another type or brand of insulin should be under medical supervision. Injection site reactions, usually transitory, may occur; rotation of injection sites within an area may help reduce the risk of developing these reactions, rarely they may require discontinuation of Actrapid® or Insulatard®. 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 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: No adverse effects on fertility revealed during animal reproduction studies. There are no restrictions on the treatment of diabetes with insulin during pregnancy or lactation. Intensified blood glucose control during pregnancy and when contemplating pregnancy is recommended. Insulin requirements usually fall during the first trimester and increase during the second and third trimesters. Insulin treatment of the nursing mother presents no risk to the baby.
Undesirable effects: Very common: Hypoglycaemia; Uncommon: Refraction disorders, oedema, injection site reactions (may occur at insulin initiation but are usually transient in nature), urticaria, rash, peripheral neuropathy, lipodystrophy; Very rare: Anaphylactic reactions, diabetic retinopathy. Generalised hypersensitivity reactions are very rare but can be potentially life-threatening. Continuous rotation of injection site may help to reduce the risk of lipodystrophy. Rapid improvement in glycaemic control may be associated with acute painful neuropathy (usually reversible) and worsening of diabetic retinopathy. The Summary of Product Characteristics should be consulted for a full list of side effects.
MA Numbers and Basic NHS Price:
Actrapid® 10 ml vial EU/1/02/230/003 £7.48;
Insulatard® 10 ml vial EU/1/02/233/003 £7.48;
Insulatard® Penfill® EU/1/02/233/006 £22.90;
Insulatard® InnoLet® EU/1/02/233/011 £20.40.
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.
Date last revised: February 2013.

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.