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: Dosage is individual, given by subcutaneous injection; Actrapid® may be given intravenously. Injection of Actrapid® should be followed by a meal 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. Penfill® cartridges are designed to be used with Novo Nordisk insulin delivery systems and NovoFine® and NovoTwist® needles; instructions for use are included with the devices. Instructions for use of InnoLet® delivery device is given in the package leaflet. 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: Hypoglycaemia; hypersensitivity to human insulin or any of the 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. Hypoglycaemia may occur if the insulin dose is too high in relation to requirements. Reduction of early warning symptoms for hypoglycaemia may be seen upon tightening control and has been reported by a few patients on transfer from animal source to human 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 or prevent these reactions, rarely they may require discontinuation of Actrapid® or Insulatard®. Actrapid® should not be used in insulin pumps for continuous subcutaneous infusion. Actrapid® and Insulatard® contain metacresol which may cause allergic reactions. 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: There are no restrictions on the treatment of diabetes with insulin during pregnancy or lactation. Intensified control during 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: Hypoglycaemia. Oedema, refraction anomalies and local hypersensitivity reactions may occur at initiation of insulin therapy, but usually disappear during continued treatment. Generalised hypersensitivity reactions may occasionally occur and are potentially life-threatening. Lipodystrophy may result from failure to rotate injection sites. 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:

Actrapid® 10 ml vial	EU/1/02/230/003
Insulatard® 10 ml vial	EU/1/02/233/003
Insulatard® Penfill®	EU/1/02/233/006
Insulatard® InnoLet®	EU/1/02/233/011

Legal Category: POM
Basic NHS Price:

1 x 10 ml vial	£ 7.48
5 x 3 ml Penfill® cartridges	£22.90
5 x 3 ml InnoLet®	£20.40

Full prescribing information can be obtained from:
Novo Nordisk Limited, Broadfield Park, Brighton Road, Crawley, West Sussex, RH11 9RT.
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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.