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.

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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.

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NovoFine® and NovoTwist® are registered
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