










Novo Nordisk Diabetes Product Portfolio From January 2006

Novo Nordisk Analogue Insulin Range

Penfill® Cartridges 5 x 3ml <small>For use with NovoPen®3</small>		FlexPen® 5 x 3ml	Time Action Characteristics
NovoRapid® Insulin aspart			
NovoRapid® Penfill®		NovoRapid® FlexPen®	
Levemir® Insulin detemir			
Levemir® Penfill®		Levemir® FlexPen®	
NovoMix® 30 Biphasic insulin aspart			
NovoMix® 30 Penfill®		NovoMix® 30 FlexPen®	

Disposable pen, 1–60 Units • NovoFine® 6mm/8mm needles • Dials up in one unit increments
Available on prescription

The graphical representations above are for educational and illustrative purposes only

Novo Nordisk Human Insulin Range

Actrapid® Human insulin, rDNA	Only available in 10ml vial	100%
Penfill® Cartridges 5 x 3ml		
Insulatard® Human insulin, rDNA		100%
Insulatard® Penfill®		
<small>Also available as Insulatard® InnoLet®</small>		
Mixtard® 10 Human insulin, rDNA		90%
Mixtard® 10 Penfill®		
Mixtard® 20 Human insulin, rDNA		80%
Mixtard® 20 Penfill®		
Mixtard® 30 Human insulin, rDNA		70%
Mixtard® 30 Penfill®		
<small>Also available as Mixtard® 30 InnoLet®</small>		
Mixtard® 40 Human insulin, rDNA		60%
Mixtard® 40 Penfill®		
Mixtard® 50 Human insulin, rDNA		50%
Mixtard® 50 Penfill®		

NovoRapid®, Actrapid®, Insulatard®, Mixtard® 30, Velosulin® (Human insulin, rDNA), Pork Actrapid® (Porcine insulin)*, Pork Insulatard® (Porcine insulin)* and Pork Mixtard® 30 (Porcine insulin)* are available in 10ml vials.

***No longer available after December 2007**

Novo Nordisk Diabetes Care Products

NovoPen® 3* Insulin pen, 2–70 Units Penfill® 3ml NovoFine® 6mm/8mm needles Dials up in one unit increments Available as 'Classic' Silver, 'Fun' Red and 'Fun' Blue Available on prescription	NovoPen® Junior* Insulin pen, 1–35 Units Penfill® 3ml NovoFine® 6mm/8mm needles Dials up in half unit increments Also available as NovoPen® 3 Demi Available on prescription
InnoLet® Human insulin Disposable insulin doser 1–50 Units, prefilled 3ml NovoFine® 6mm/8mm needles Dials up in one unit increments Available on prescription as Insulatard® InnoLet® and Mixtard® 30 InnoLet®	GlucaGen® HypoKit 1mg Glucagon (rys) Available on prescription
NovoFine® Needles 6mm 31G (short cap) 8mm 30G (short cap) 12mm 28G Available on prescription	PenMate® Injection aid for users of NovoPen® 3, Demi or Junior. For further information call the Novo Nordisk Customer Care Centre.

*Can be used with the full range of Novo Nordisk 3ml cartridges.

Prescribing Information

NovoRapid® Insulin aspart
NovoRapid® 10ml
NovoRapid® Penfill® 3ml
NovoRapid® FlexPen® 3ml

All presentations contain insulin aspart 100 U/ml.

Indication: Insulin requiring diabetes mellitus. **Dosage:** Individual by subcutaneous injection. NovoRapid® has a faster onset and shorter duration of action than soluble human insulin and should generally be given immediately before the meal. When necessary NovoRapid® can be given soon after the meal. May also be used in a suitable pump system for continuous subcutaneous insulin infusion. If necessary may be administered intravenously by health care professional. No studies in children under the age of 2 years. Can be used in children in preference to soluble insulin when a fast onset of action might be beneficial. **Contraindications:** Hypoglycaemia, hypersensitivity. **Special warnings and special precautions:** Patients whose blood glucose control is greatly improved may experience a change in their usual warning symptoms of hypoglycaemia. If hypoglycaemia occurs, it may occur earlier after an injection compared with soluble human insulin. Changes in early warning symptoms of hypoglycaemia may occur on transfer between different types of insulin products. The fast onset of action should be considered in patients where a delayed absorption of food might be expected. Transferring to a new type or brand of insulin should be done under strict medical supervision. Patients taking NovoRapid® may require an increased number of daily injections or a change in dosage. Too much insulin, omission of a meal or strenuous exercise may lead to hypoglycaemia. Hypoglycaemia may constitute a risk when driving or operating machinery. Too little insulin may lead to hyperglycaemia and ketoacidosis which are potentially lethal. Contains metacresol which may rarely cause allergic reactions.

Pregnancy and lactation: Limited clinical experience in pregnancy. No restrictions on use during lactation. **Undesirable effects:** Hypoglycaemia; oedema and refraction anomalies on instituting therapy; local hypersensitivity; generalised hypersensitivity reactions are rare but potentially life-threatening; lipodystrophy. Rapid improvement in glycaemic control may be associated with acute painful neuropathy (usually reversible) and worsening of diabetic retinopathy. **PL number:** NovoRapid®, 1 x 10ml EU/1/99/119/001. NovoRapid® Penfill®, 5 x 3ml EU/1/99/119/003. NovoRapid® FlexPen®, 5 x 3ml EU/1/99/119/009. **Legal category:** POM. **Basic NHS price:** 1 x 10ml vial £17.27, 5 x 3ml Penfill® £29.43, 5 x 3ml FlexPen® £32.00. **Date last revised:** April 2005.

NovoMix® 30 Biphasic Insulin Aspart.
NovoMix® 30 Penfill®
NovoMix® 30 FlexPen®

All presentations contain soluble insulin aspart/protamine-crystallised insulin aspart 100 U/ml in the ratio 30/70.

Indication: Treatment of diabetes mellitus. **Dosage:** Individual by subcutaneous injection. NovoMix® 30 has a faster onset of action than biphasic human insulin and should generally be given immediately before a meal. When necessary NovoMix® 30 can be given soon after a meal. In patients with type 2 diabetes, NovoMix® 30 can be given in monotherapy or in combination with metformin, when blood glucose is inadequately controlled with metformin alone. The recommended starting dose is 6 U at breakfast and 6 U at the evening meal. Titration is according to pre-meal blood glucose levels (pre-breakfast glucose for adjustment of evening dose and pre-evening meal glucose for adjustment of breakfast dose). NovoMix® 30 can also be initiated once daily with 12 U at the evening meal. When using NovoMix® 30 once daily it is generally recommended to split the dose in two when the daily dose reaches 30 U. In patients with type 1 diabetes the individual insulin requirement is usually between 0.5 and 1.0 U/kg/day and may be fully or partially supplied with NovoMix® 30. No studies in children and adolescents under the age of 18 years. **Contraindications:** Hypoglycaemia, hypersensitivity. **Warnings and precautions for use:** Use of dosages which are inadequate, or discontinuation of treatment may lead to hyperglycaemia and ketoacidosis which are potentially lethal. Too much insulin, omission of a meal or strenuous exercise may lead to hypoglycaemia. Compared with biphasic human insulin NovoMix® 30 may have a stronger hypoglycaemic effect up to 6 hours after injection. This may need to be compensated for through adjustment of dose and/or food intake. Reduction of early warning symptoms of hypoglycaemia may be seen upon tightening control. Tighter control of glucose levels can increase the potential for hypoglycaemic episodes and therefore require special attention during dose intensification. The fast onset of action should be considered in patients where a delayed absorption of food might be expected. Transferring to a new type or brand of insulin should be done under strict medical supervision. Hypoglycaemia may constitute a risk when driving or operating machinery. **Pregnancy and lactation:** Limited clinical experience in pregnancy. No restrictions on use during lactation. **Undesirable effects:** Hypoglycaemia, oedema and refraction anomalies on instituting therapy; local hypersensitivity; generalised hypersensitivity reactions are rare but potentially life-threatening; lipodystrophy. Rapid improvement in glycaemic control may be associated with acute painful neuropathy (usually reversible) and worsening of diabetic retinopathy. **MA numbers:** NovoMix® 30 Penfill EU/1/00/142/004 NovoMix® 30 FlexPen EU/1/00/142/009 **Legal category:** POM. **Basic NHS price:** 5 x 3 ml Penfill £29.43, 5 x 3 ml FlexPen £32.00 **Further prescribing information can be obtained from:** Novo Nordisk Limited, Broadfield Park, Brighton Road, Crawley, West Sussex, RH11 9RT. **Date last revised:** March 2006.

Levemir® Insulin detemir
Levemir® Penfill®
Levemir® FlexPen®

All presentations contain insulin detemir 100 U/ml.

Levemir® is a long-acting basal insulin used in combination with meal-related short- or rapid-acting insulin. **Indication:** Treatment of diabetes mellitus. **Dosage:** Individual by once or twice daily subcutaneous injection. When given twice daily, the evening dose may be administered in the evening or at bedtime. Transfer from other insulins may require adjustment of dosage and timing of administration; monitor glucose during transfer and in initial weeks thereafter. Concurrent short-acting insulin treatment may need to be adjusted. No studies in children below the age of 6 years. **Contraindications:** Hypersensitivity to insulin detemir or excipients. **Warnings and precautions for use:** Use of dosages which are inadequate, or discontinuation of treatment may lead to hyperglycaemia and ketoacidosis which are potentially lethal. 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. Careful monitoring is recommended in patients with severe hypoalbuminaemia. Levemir® should not be administered intravenously; avoid intramuscular administration; do not use in insulin infusion pumps. Avoid mixing of rapid-acting insulin with Levemir®. Contains metacresol, which may cause allergic reactions. Hypoglycaemia may constitute a risk when driving or operating machinery. **Pregnancy and lactation:** No clinical experience in pregnancy and lactation; exercise precaution when prescribing to pregnant or lactating women. **Undesirable effects:** Common: Hypoglycaemia, injection site reactions, usually transitory. Uncommon: Lipodystrophy; oedema and refraction anomalies on instituting therapy; allergic reactions; generalised hypersensitivity reactions are potentially life-threatening; abrupt improvement in glycaemic control may be associated with worsening of diabetic retinopathy. Rare: Acute painful neuropathy may be associated with rapid improvement in blood glucose control, usually reversible. **MA numbers:** Levemir® Penfill® EU/1/04/278/002. Levemir® FlexPen® EU/1/04/278/005. **Legal category:** POM. **Basic NHS price:** 5 x 3ml Penfill® £39.00, 5 x 3ml FlexPen® £39.00. **Date last revised:** April 2005.

Full prescribing information can be obtained from:

Novo Nordisk Limited, Broadfield Park, Brighton Road, Crawley, West Sussex, RH11 9RT. Tel: 01293 613555.

Date of literature preparation: April 2006.

Information about adverse event reporting can be found at www.yellowcard.gov.uk

Adverse events should be reported to Novo Nordisk Limited.

Tel. Novo Nordisk Customer Care: 0845 600 5055

Calls charged at local rate and may be recorded for training purposes.

INS/589/0406

Actrapid®, Insulatard®, Insulatard® Penfill®, Insulatard® InnoLet®; Mixtard® 10 Penfill®; Mixtard® 20 Penfill®; Mixtard® 30, Mixtard® 30 Penfill®, Mixtard® 30 InnoLet®; Mixtard® 40 Penfill®; Mixtard® 50 Penfill®; Velosulin®

Insulin human, rDNA.

Presentation: 10ml vials (Actrapid®, Insulatard®, Mixtard® 30, Velosulin®); 3ml Penfill® cartridges (Insulatard®, Mixtard® range); 3ml compact, disposable, dial-a-dose delivery device able to deliver 1–50 units in increments of 1 unit (Insulatard® InnoLet®, Mixtard® 30 InnoLet®). All are available in a strength of 100 iu/ml. Actrapid® is a soluble insulin, Insulatard® is an isophane insulin and Mixtard® is a mixture of soluble and isophane insulin, the ratio being indicated by the number in the name: 10 – 10/90, 20 – 20/80, 30 – 30/70, 40 – 40/60, 50 – 50/50. Velosulin® is a buffered soluble insulin. **Uses:** The treatment of diabetes mellitus. **Dosage and administration:** Dosage is individual, usually given by subcutaneous injection; Actrapid® and Velosulin® may be given intravenously. Velosulin® may also be given by continuous subcutaneous infusion (CSI) using a suitable pump, catheter and needle. Injection of Actrapid®, Velosulin® or Mixtard® should be followed by a meal within 30 minutes of administration. Resuspend suspensions before use by gently agitating. The suspensions (vials only) may be mixed in the syringe with fast-acting insulin. Insulin suspensions must not be administered intravenously or used in insulin infusion pumps. Actrapid® is not suitable for use in insulin pumps for CSI. Penfill® cartridges are designed to be used with Novo Nordisk insulin delivery systems and NovoFine® needles; instructions for use are included with the devices and must be carefully followed. Instructions for use of the InnoLet® delivery device is given in the package leaflet. NovoFine® needles are designed to be used with the InnoLet® device. Penfill® cartridges and InnoLet® devices are for single-patient use only. Actrapid®, Velosulin®, Insulatard® and Mixtard® contain metacresol which may cause allergic reactions. Patients using CSI may be more prone to infection at the injection site. **Contraindications:** Hypoglycaemia; hypersensitivity to human insulin or any of the excipients. **Precautions:** Use of dosages which are inadequate, or discontinuation of treatment may lead to hyperglycaemia and, in type 1 diabetes to ketoacidosis which is 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. When administered by CSI, Velosulin® should never be mixed with any other insulin. Transfer to another type or brand of insulin should be under medical supervision. **Pregnancy:** 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. **Side 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. **PL Numbers:** Actrapid® EU/1/02/230/003. Insulatard® EU/1/02/233/003. Mixtard® 30 EU/1/02/231/003. Velosulin® EU/1/02/232/001. Insulatard® Penfill® EU/1/02/233/006. Mixtard® 10 Penfill® EU/1/02/231/006. Mixtard® 20 Penfill® EU/1/02/231/009. Mixtard® 30 Penfill® EU/1/02/231/012. Mixtard® 40 Penfill® EU/1/02/231/015. Mixtard® 50 Penfill® EU/1/02/231/018. Insulatard® InnoLet® EU/1/02/233/011. Mixtard® 30 InnoLet® EU/1/02/231/031. **Legal category:** POM. **Basic NHS Price:** 1 x 10ml vial £7.48, 5 x 3ml Penfill® cartridges £20.08, 5 x 3ml InnoLet® £20.40. **Date last revised:** May 2005.

Pork Actrapid®, Pork Insulatard®, Pork Mixtard® 30

Porcine Insulin

Presentation: 10ml vials containing: Pork Actrapid® – soluble porcine insulin; Pork Insulatard® – isophane porcine insulin; Pork Mixtard® 30 – a mixture of soluble and isophane porcine insulin in the ratio 30/70. All are available in a strength of 100 iu/ml. **Uses:** The treatment of diabetes mellitus. **Dosage and administration:** The dosage is determined by the physician according to the needs of the patient. Usually given by subcutaneous injection, Pork Actrapid® may also be given intravenously. Suspensions must be resuspended before use by gently agitating. Pork Actrapid® may be mixed in the syringe with Pork Insulatard® or Pork Mixtard® 30; the soluble insulin should be drawn into the syringe first and the injection given immediately after mixing. Insulin suspensions must not be used in insulin infusion pumps. Pork Actrapid® should not be used in ambulatory infusion pumps. **Contraindications:** Hypoglycaemia. Hypersensitivity to porcine insulin or any of the excipients. **Precautions:** Injection of Pork Actrapid® or Pork Mixtard® 30 should be followed by a meal within 30 minutes of administration. Use of dosages which are inadequate or discontinuation of treatment may lead to hyperglycaemia and ketoacidosis which are potentially lethal. A dosage reduction may be required on transfer from insulins which are less pure. Reduction of early warning symptoms for hypoglycaemia may be seen upon tightening of control. Beta-blockers, MAOs, ACE inhibitors, salicylate, anabolic steroids and alcohol may enhance hypoglycaemic effect of insulin. Oral contraceptives, thyroid hormones, corticosteroids, thiazides and sympathomimetics may increase insulin requirements. Beta-blockers may blur symptoms of hypoglycaemia. **Pregnancy:** Intensified control is recommended. Insulin requirements usually fall during the first trimester and increase during the second and third trimester. **Side Effects:** Oedema, refraction anomalies and local hypersensitivity reactions may occur at initiation of insulin therapy, but usually disappear during continued treatment. Persistent allergies to insulin and lipodystrophy are rarely reported. Lipodystrophy may result from failure to rotate injection sites. **PL Numbers:** Pork Actrapid® PL 3132/0121. Pork Insulatard® PL 3132/0018. Pork Mixtard® 30 PL 3132/0021. **Legal Category:** POM. **Basic NHS price:** 1 x 10ml vial: £4.00. **Date last revised:** November 2004.

GlucaGen® HypoKit 1mg

Glucagon (rys)

Presentation: A vial containing 1mg (1IU) glucagon (rys), as the hydrochloride, and lactose 107mg, together with a pre-filled syringe containing 1.1ml Water for Injections. **Uses:** The treatment of severe hypoglycaemic reactions which may occur in the management of diabetic patients receiving insulin. As a motility inhibitor in examinations of the gastrointestinal tract. As a motility inhibitor in CT, NMR and DSA. **Dosage:** The glucagon is dissolved in the accompanying diluent before use. **Treatment of severe hypoglycaemic reactions:** 1mg (adults, children above 25kg or 6–8 years) or 0.5mg (children below 25kg or 6–8 years) by subcutaneous, intramuscular, or intravenous injection. When the patient responds, administer oral carbohydrate. If no response within 10 minutes, give intravenous glucose. **Diagnostic indications:** Doses range from 0.1–2mg depending on the diagnostic technique used and the route of administration. Usual dose for relaxation of stomach, duodenal bulb, duodenum and small bowel is 0.2–0.5mg i.v. or 1mg i.m. To relax the colon 0.5–0.75mg i.v. or 2mg i.m. In CT, NMR and DSA doses up to 1mg i.v. are used. **Contra-indications:** Phaeochromocytoma. Hypersensitivity to glucagon or excipients. **Precautions:** Administer oral carbohydrate after use to prevent secondary hypoglycaemia. In case of severe hypoglycaemia i.v. glucose may be required. Glucagon reacts antagonistically towards insulin. Observe caution in patients with insulinoma or glucagonoma, and in diabetics or elderly patients with known cardiovascular disease. Do not use solution if it has viscous appearance or solid particles present. **Use in pregnancy:** Glucagon does not cross the placenta. Glucagon has been used in pregnant diabetics; no harmful effects known with respect to course of pregnancy or health of foetus and neonate. **Side effects:** Isolated cases of hypersensitivity. Rarely abdominal pain, nausea and vomiting, especially with dosages greater than 1 mg or with rapid injection. Hypertension has been reported up to 2 hours after use of GlucaGen in upper GI endoscopy procedures. Secondary hypoglycaemia, sometimes severe; may be more pronounced in patients having fasted before a diagnostic procedure. Positive inotropic and chronotropic effects (tachycardia). **PL numbers:** GlucaGen 1mg PL 4668/0027. Diluent for GlucaGen 1mg (syringe) PL 4668/0028. **Legal category:** POM. **Basic NHS price:** GlucaGen HypoKit 1mg £11.52. **Date last revised:** November 2004.

