

December 2006






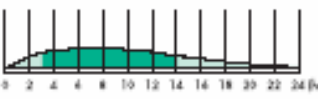


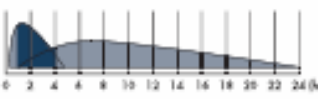


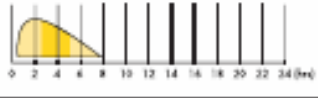




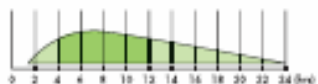



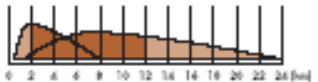

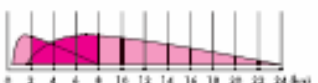


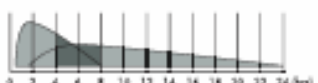
Novo Nordisk Insulin Range Chart

For the use of HCPs only
December 2006

changing diabetes



NOVO NORDISK - BALANCING INSULIN AND DELIVERY.

Brand	Cartridge†		Pre-filled delivery†		Vials	Schematic Time-Action Profile*	Insulin Profile**
	Penfill® 3mL	FlexPen® 3mL	InnoLet® 3mL	NovoLet® 3mL			
NovoRapid® <i>Rapid-acting insulin aspart (rys)</i>							Onset: 10-20 minutes Peak: 1-3 hours Duration: 3-5 hours
Levemir® <i>Long-acting insulin detemir (rys)</i>							Peak: 3-14 hours Duration: Up to 24 hours
NovoMix® 30 <i>30% Rapid-acting & 70% Intermediate-acting insulin aspart (rys)</i>							Onset: 10-20 minutes Peak: 1-4 hours Duration: 24 hours
Actrapid® <i>Short-acting human insulin (rys)</i>							Onset: 30 minutes Peak: 2.5-5 hours Duration: 8 hours
Protaphane® <i>Intermediate-acting human insulin (rys)</i>							Onset: 1.5 hours Peak: 4-12 hours Duration: 24 hours
Mixtard® 30/70 <i>30% Short-acting & 70% Intermediate-acting human insulin (rys)</i>							Onset: 30 minutes Peak: 2-1.2 hours Duration: 24 hours
Mixtard® 20/80 <i>20% Short-acting & 80% Intermediate-acting human insulin (rys)</i>		PRODUCT DISCONTINUATION 1 SEPTEMBER 2007					Onset: 30 minutes Peak: 2-8 hours Duration: 24 hours
Mixtard® 50/50 <i>50% Short-acting & 50% Intermediate-acting human insulin (rys)</i>							Onset: 30 minutes Peak: 4-8 hours Duration: 24 hours

NovoCare® Customer Care Centre 1800 668 626

www.novonordisk.com.au

Please review Product Information before prescribing. Product information is available from Novo Nordisk Customer Care Centre 1800 668 626. Novo Nordisk Pharmaceuticals Pty Ltd. ABN 40 002 879 996. Level 3, 21 Solent Circuit, Baulkham Hills, NSW 2153. © Registered trademark of Novo Nordisk A/S

*Requires NovoRapid® needles purchased separately from script. Free of charge at most Diabetes Australia branches. **In clinical practice, the duration of insulin action may be shorter or longer than the duration specified. Variations between and within patients may occur depending upon injection site and technique, insulin dosage, as well as diet and exercise. †Penfill® is available for use in NovoPen® 3, NovoPen® 3 Densit, 1.5x5x3mL, 1 repeat, 2.5x10mL, 2 repeats, 3. Approved Product Information. 08/2011 81200111



PBS Information: General benefit.
Refer to PBS schedule for full PBS
listing information for each product.

Levemir: Restricted benefit.

Type 1 diabetes.

ABRIDGED PRODUCT INFORMATION NovoMix® 30 (Insulin aspart (lys))

NovoMix® 30 contains 100 units/mL biphasic insulin aspart (lys) suspension for injection s.c. (30% soluble insulin aspart (lys), 70% protamine-crystallised insulin aspart (lys)). **Indications:** Treatment of diabetes mellitus. **Contra-Indications:** Hypoglycaemia, hypersensitivity to insulin aspart or any of the excipients. **Warnings and precautions for use:** Inadequate dosing or discontinuation of treatment may lead to hyperglycaemia and diabetic ketoacidosis, which are potentially life threatening. Where blood glucose control is greatly improved, e.g. by intensified insulin therapy, patients may experience a change in usual warning symptoms of hypoglycaemia, and should be advised accordingly. The impact of the rapid onset of action should be considered in patients where a delayed absorption of food might be expected. NovoMix 30 is not to be used in insulin infusion pumps. Transferring to a new type or brand of insulin should be performed under strict medical supervision. Insulin requirements may increase during illness. Too much insulin, omission of a meal, or strenuous exercise may lead to hypoglycaemia. No studies have been performed in children. **Pregnancy and lactation:** Pregnancy category B3. No clinical experience in pregnancy. No restrictions on use during lactation. Insulin requirements vary during pregnancy and lactation and dose adjustments may be necessary. **Adverse effects:** Hypoglycaemia; oedema and refraction anomalies on instituting therapy; local hypersensitivity; generalised hypersensitivity reactions are rare but potentially life-threatening; lipodystrophy. **Interactions:** Alcohol, oral hypoglycaemic agents, octreotide, MAOIs, α -blockers, β -blockers, ACE inhibitors, salicylates, anabolic steroids, quinine, quinidine, sulphonamides, oral contraceptives, thiazides, glucocorticoids, thyroid hormones, sympathomimetics, growth hormone, diazoxide, asparaginase, nicotinic acid. **Dosage and administration:** Dosage as determined by physician. NovoMix 30 has a faster onset of action than soluble human insulin and should generally be given immediately before a meal. When necessary, NovoMix 30 can be given soon after the start of a meal. NovoMix 30 is administered by subcutaneous injection in the abdominal wall, the thigh, the deltoid region, the gluteal region, or by subcutaneous infusion in the abdominal wall. Injection sites should be rotated within the same region. When injected subcutaneously into the abdominal wall, the onset of action will occur within 10-20 minutes of injection. The maximum effect is exerted between 1 and 3 hours after the injection. The duration of action is 3 to 5 hours. As with all insulins the duration of action will vary according to the dose, injection site, blood flow, temperature and level of physical activity. The faster onset of action of NovoMix 30 compared to soluble human insulin is maintained regardless of injection site. Formal studies on the bioavailability of NovoMix 30 administered by subcutaneous injection in the gluteal region have not been conducted. NovoMix 30 may also be used intravenously under medical supervision. For emergency use with Penfil® FlexPen®, the insulin aspart must first be withdrawn into a syringe. Discard Penfil® FlexPen cartridge/pen after emergency use. NovoMix 30 has been used intravenously (see 'Clinical Trials' in full PI). No studies have been conducted in critically ill people with diabetes who are likely to require intravenous administration. There is no pharmacokinetic or pharmacodynamic advantage in using NovoMix 30 over soluble human insulin when these insulins are given intravenously. **Presentations:** NovoMix 30 70mL vial for use with U100 insulin syringes and for continuous subcutaneous insulin infusion (CSII) in suitable pump systems. NovoMix 30 Penfil® 3mL cartridge for use with Novo Nordisk insulin delivery systems and NovoFine® needles. NovoMix 30 FlexPen®: pre-filled, disposable, multidose syringe for use with NovoFine needles. Refer to full PI before prescribing.

Approved by TGA 21 May 2002. Abridged 3 April 2008.
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ABRIDGED PRODUCT INFORMATION NovoRapid® (Insulin aspart (lys))

NovoRapid® contains 100 units/mL insulin aspart (lys) solution for injection. **Indications:** Treatment of diabetes mellitus. **Contra-Indications:** Hypoglycaemia, hypersensitivity to insulin aspart or any of the excipients. **Warnings and precautions for use:** Inadequate dosing or discontinuation of treatment may lead to hyperglycaemia and diabetic ketoacidosis, which are potentially life threatening. Where blood glucose control is greatly improved, e.g. by intensified insulin therapy, patients may experience a change in usual warning symptoms of hypoglycaemia, and should be advised accordingly. The impact of the rapid 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

performed under strict medical supervision. Insulin requirements may increase during illness. Renal or hepatic impairment may reduce the patient's insulin requirements. Too much insulin, omission of a meal, or strenuous exercise may lead to hypoglycaemia. No studies have been performed in children under the age of 6 years. **Pregnancy and lactation:** Pregnancy category B3. Limited clinical experience in pregnancy. No restrictions on use during lactation. Insulin requirements vary during pregnancy and lactation and dose adjustments may be necessary. **Adverse effects:** Hypoglycaemia; oedema and refraction anomalies on instituting therapy; local hypersensitivity; generalised hypersensitivity reactions are rare but potentially life-threatening; lipodystrophy. **Interactions:** Alcohol, oral hypoglycaemic agents, octreotide, MAOIs, α -blockers, β -blockers, ACE inhibitors, salicylates, anabolic steroids, quinine, quinidine, sulphonamides, oral contraceptives, thiazides, glucocorticoids, thyroid hormones, sympathomimetics, growth hormone, diazoxide, asparaginase, nicotinic acid. **Dosage and administration:** Dosage as determined by physician. NovoRapid has a faster onset of action than soluble human insulin and should generally be given immediately before a meal. When necessary, NovoRapid can be given soon after the start of a meal. NovoRapid is administered by subcutaneous injection in the abdominal wall, the thigh, the deltoid region, the gluteal region, or by subcutaneous infusion in the abdominal wall. Injection sites should be rotated within the same region. When injected subcutaneously into the abdominal wall, the onset of action will occur within 10-20 minutes of injection. The maximum effect is exerted between 1 and 3 hours after the injection. The duration of action is 3 to 5 hours. As with all insulins the duration of action will vary according to the dose, injection site, blood flow, temperature and level of physical activity. The faster onset of action of NovoRapid compared to soluble human insulin is maintained regardless of injection site. Formal studies on the bioavailability of NovoRapid administered by subcutaneous injection in the gluteal region have not been conducted. NovoRapid may also be used intravenously under medical supervision. For emergency use with Penfil® FlexPen®, the insulin aspart must first be withdrawn into a syringe. Discard Penfil® FlexPen cartridge/pen after emergency use. NovoRapid has been used intravenously (see 'Clinical Trials' in full PI). No studies have been conducted in critically ill people with diabetes who are likely to require intravenous administration. There is no pharmacokinetic or pharmacodynamic advantage in using NovoRapid over soluble human insulin when these insulins are given intravenously. **Presentations:** NovoRapid® 70mL vial for use with U100 insulin syringes and for continuous subcutaneous insulin infusion (CSII) in suitable pump systems. NovoRapid® Penfil® 3mL cartridge for use with Novo Nordisk insulin delivery systems and NovoFine® needles. NovoRapid® FlexPen®: pre-filled, disposable, multidose syringe for use with NovoFine 'S' short-cap needles. Refer to full PI before prescribing.

Approved by TGA 2 June 2003.
Abridged 13 August 2004.
Novo Nordisk Pharmaceuticals Pty Ltd
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Baulkham Hills NSW 2153

ABRIDGED PRODUCT INFORMATION

Human Insulin

Actrapid® (Neutral Insulin Injection, short-acting solution)

Protaphane® (biphasic insulin injection, intermediate-acting suspension)

Mixtard® 20/80, Mixtard® 30/70, Mixtard® 50/50 (Biphasic isophane insulin injection, intermediate-acting suspension)

Composition: Human Insulin (lys). **Indications:** Treatment of insulin-requiring diabetes. **Contra-Indications:** Hypoglycaemia. Hypersensitivity to human insulin or excipients. Insulin suspensions should not be administered intravenously or for treatment of diabetic ketoacidotic coma. **Precautions:** Inadequate dosing or discontinuation of treatment may lead to hyperglycaemia and diabetic ketoacidosis. Insulin requirements may increase during illness and decrease with renal or hepatic impairment, insufficient food intake or increased physical activity. Avoid hypoglycaemia whilst driving or operating machinery. Transfer of patients between insulin types should be done under strict medical supervision and may require a change in dose. On transfer from animal-source insulin to human insulin, a few patients have reported the early warning symptoms for hypoglycaemia were less pronounced than with animal-source insulins. Patients whose blood glucose control is greatly improved may experience a change in their usual warning symptoms of hypoglycaemia. **Pregnancy and Lactation:** Intensified treatment is recommended throughout pregnancy and when contemplating pregnancy. Insulin requirements vary during pregnancy and in nursing mothers and dose adjustments may be necessary. **Interactions:** Oral hypoglycaemic agents, octreotide, ACE inhibitors, salicylates, anabolic steroids, quinine, quinidine, sulphonamides, glucocorticoids, diuretics, oral contraceptives, thyroid hormones, sympathomimetics, growth hormone, diazoxide, asparaginase, nicotinic acid, monoamine oxidase inhibitors, alpha and beta-blockers, alcohol. In general, insulin should only be added to compounds with which it has known compatibility. **Adverse Reactions:** Hypoglycaemia, lipodystrophy, insulin resistance, hypersensitivity, oedema, refraction abnormalities. **Dosage and Administration:** Dosage as determined by physician. Rotate injection sites. Insulin suspensions should not be used in infusion pumps or given intravenously. Eat within 30 minutes after injection of Actrapid® or Mixtard®, Actrapid®. Subcutaneous. In an emergency, Actrapid is suitable for intramuscular administration under medical guidance, or for intravenous administration if administered by a physician. For emergency use with Penfil® InnoLet®, the insulin must first be withdrawn into a syringe. Discard Penfil® InnoLet cartridge/syringe after emergency use. Suitable for treatment of diabetic ketoacidosis, hyperosmolar non-ketotic syndrome, initial stabilisation of diabetes, severe infection, major trauma and/or surgery in people with diabetes. Not suitable for CSI pumps. **Protaphane®, Mixtard® 20/80, Mixtard® 30/70, Mixtard® 50/50:** Subcutaneous injection. Intramuscular injection in emergency under medical supervision. For such use with Penfil® NovoLat/InnoLet the insulin must first be withdrawn into a syringe. Discard Penfil® NovoLat/InnoLet cartridge/syringe after emergency use. **Presentation:** 100 IU/mL. Penfil® 3mL cartridge - Actrapid, Protaphane, Mixtard 20/80, Mixtard 30/70, Mixtard 50/50. For use with Novo Nordisk insulin delivery systems and NovoFine® needles. NovoLat® 3mL - Protaphane. Innolet® 3mL - Protaphane, Mixtard 30/70, 70mL vial - Actrapid, Protaphane, Mixtard 30/70, Mixtard 50/50.

Refer to full Product Information before prescribing.
Available on request.

Approved by TGA 9 October 2002. Abridged 19 Dec 2005.
Novo Nordisk Pharmaceuticals Pty Ltd
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Baulkham Hills NSW 2153

ABRIDGED PRODUCT INFORMATION: Leverim® FlexPen® (Insulin detemir (lys))

Indications: Treatment of diabetes mellitus where used as basal insulin in combination with meal-related short- or rapid-acting insulin. Not recommended for diabetes mellitus type 2 patients who still respond to oral hypoglycaemic agents. (See 'Clinical Trials' in full PI/datasheet.) **Contra-Indications:** Hypersensitivity to insulin detemir or excipients. **Precautions:** Inadequate dosing may lead to hyperglycaemia and DKA. Hypoglycaemia may occur if dose too high in relation to requirements - see full PI/datasheet. Avoid i.m. administration. I.v. administration may result in severe hypoglycaemia. Mixed with other insulins the action profile of either or both may change. Do not use in infusion pumps. No studies in children under 6 years. Studies do not suggest clinically relevant albumin binding interactions between insulin detemir and fatty acids or other protein-bound drugs. Do not add to infusion fluids. **Pregnancy category:** B3. No clinical experience during pregnancy or lactation. **Interactions:** OHA's, octreotide, lanreotide, MAOIs, alpha- and beta-blockers, ACE inhibitors, salicylates, alcohol, anabolic steroids, quinine, quinidine, sulphonamides, oral contraceptives, thiazides, glucocorticoids, thyroid hormones, sympathomimetics, growth hormone, diazoxide, asparaginase, nicotinic acid. Omission of a meal or unplanned, strenuous physical exercise may lead to hypoglycaemia. **Adverse Effects:** hypoglycaemia. **Dosage and Administration:** For subcutaneous injection. Leverim is a long-acting insulin analogue used as basal insulin in combination with meal-related short- or rapid-acting insulin. Adjust dosage individually. Administer once- or twice-daily according to patients' needs. For b.i.d. the evening dose can be administered either with the evening meal, at bedtime, or 12 hours after the morning dose. Intensity glucose monitoring and adjust dosage individually in elderly patients and patients with renal/hepatic impairment. If required, adjust dosage per increased physical activity/change of usual diet/during concomitant illness. Rotate injection sites within the same region. Diabetes mellitus type 2: the role of Leverim has not been established. Outside a basal bolus regimen, non-inferiority of HbA_{1c} compared to NPH has not been demonstrated. Not recommended for diabetes mellitus type 2 patients who still respond to oral hypoglycaemic agents (see 'Clinical Trials' in full PI/datasheet). Paediatric use: no evaluated data are available. Transfer from other insulins: transfer from intermediate or long-acting insulins may require adjustment of dose and timing of administration. Monitor glucose closely. Concomitant antidiabetic treatment may need to be adjusted (dose and timing of concurrent short-acting insulins of the dose of oral antidiabetic agents). Increases in soluble insulin requirements have been demonstrated in some individuals who have been transferred from human insulin to Leverim. **Presentation:** Leverim® FlexPen® (insulin detemir (lys) solution for injection). Refer to full PI/datasheet before prescribing, available on request. Approved by TGA 8 June 2004 and by Medsafe 11 April 2005. Abridged 18 August 2006. Novo Nordisk Pharmaceuticals Pty Ltd., Level 3, 21 Solent Circuit, Baulkham Hills, NSW 2153, Australia. Novo Nordisk Pharmaceuticals Ltd., PO Box 51-268, Pakuranga, Auckland, New Zealand.

