

encapsulate

Welcome to 'encapsulate'

The eighth edition of **encapsulate** elaborates on a recent Medication Safety Alert regarding subcutaneous Insulin. We look at the potentially increased risk of recurrent myocardial infarction in patients who are co-prescribed clopidogrel and proton pump inhibitors. Also, we introduce the new once daily formulation of Tramadol and highlight the importance of clear prescriptions to ensure the correct formulation is dispensed, and errors are avoided.

You can obtain further copies of **encapsulate** via our website - www.slade.net.au. Please forward any comments or suggested topics for our next issue to marketing@slade.net.au.

Medication Safety Alert: Insulin

Insulin is used to regulate blood glucose levels in Type 1 and some Type 2 diabetic patients. The pharmacology of the drug, complexity of dosing, and wide variety of products available all contribute to the potential for error.

There have been critical incidents throughout Australia and overseas where errors in the administration of subcutaneous insulin have occurred. In some overseas cases, these errors have been fatal.

In December, the Victorian Medicines Advisory Committee (VMAC) released a high risk medicine alert regarding subcutaneous insulin. As such, Slade Pharmacy Services and Galen Health have released a Medication Safety Alert for Insulin.

The alert was distributed to all pharmacy, dispensary, nursing and medical staff to communicate the potential risks, contributing factors and recommendations to prevent future medication incidents with subcutaneous insulin. The recommendations are based on those published by VMAC.

For further information please refer to the Medication Safety Alert – Insulin.

Since Slade Pharmacy Services and Galen Health release the alert, insulin has received further medical media coverage. The F.D.A. in the U.S. has recently been made aware of instances, in at least two hospitals, where insulin pens have been used on multiple patients. It is suspected that some of these patients have contracted Hepatitis C as a result. Even when changing the disposable needle, there is still a significant risk for transmission of blood-borne pathogens. This further strengthens VMAC's recommendation not to share insulin pens.

Clopidogrel & Proton Pump Inhibitors – Increased Risk of Recurrent Myocardial Infarction?

The use of proton pump inhibitors (PPIs) in patients taking clopidogrel post myocardial infarction (MI) has been suspected to increase the risk of reinfarction.^{1,2}

A recent Canadian study has strengthened this hypothesis. The 5 year study investigated the use of PPIs in patients receiving clopidogrel post MI. More than 13,000 patients, over 66 years of age, were involved in the study.¹ Overall, PPIs were seen to be associated with a 40% increase in the risk of reinfarction within 90 days of hospital discharge post MI. However, pantoprazole (Somac®) was not associated with this increased risk.^{1,2}

Clopidogrel is an inactive prodrug that is converted to its active form in the liver by cytochrome P450 2C19. PPIs, with the exception of pantoprazole, are known to inhibit this isoenzyme, which may explain the findings of the Canadian study.

Interestingly, a French study investigated the effects of polymorphism in the cytochrome P450 2C19 producing gene in young patients treated with clopidogrel post MI. The 12 year study followed 259 patients under 45 years of age and concluded that the cytochrome P450 2C19 genetic variant was a major determinant in the prognosis of these patients. Patients who were cytochrome P450 2C19 deficient

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were more likely to reinfarct. This further concurs with the findings of the Canadian study.³

It is important to note that following publication of the Canadian trial, the Food and Drug Administration in America (FDA) has advised patients to continue taking their PPIs in combination with clopidogrel but has asked clinicians to re-evaluate and rationalise therapy.² This is a sensible approach that aims to ensure optimal health outcomes are achieved for patients.

Some clinicians routinely co-prescribe PPIs with aspirin/clopidogrel combinations, for their gastro protective effect. The appropriateness of this practice needs to be re-assessed. H₂-antagonists, such as ranitidine, should be considered as an alternative to PPI therapy in patients taking clopidogrel.¹ Where treatment with a PPI is considered essential, pantoprazole should be prescribed.^{1, 2}

References

1. PPIs with clopidogrel may increase recurrent MI risk, *The Pharmaceutical Journal*. 2009; 282.
2. Rouse, R., *New concerns raised over proton pump inhibitor interactions*, *Medical Observer*; 6th February 2009.
3. Collet J.P., et al. *Cytochrome P450 2C19 polymorphism in young patients treated with clopidogrel after myocardial infarction: a cohort study*, *Lancet*. 2009; 373(9660):309-17.

Tramadol: ONCE Daily Formulation

A new, once daily, tramadol formulation has recently been launched in Australia. The new extended release tablet, Durotram-XR, which is available on the PBS, is constructed in two parts: the outer layer of the tablet releases 25% of the dose within 2 hours, and then the remaining 75% is gradually released from the inner-core of the tablet over 24 hours. This once daily formulation has similar efficacy to that of twice-daily tramadol.

The three oral tramadol formulations now available in Australia are:

- **immediate-release**, taken every **4–8 hours**, 50mg
E.g. GenRx® Tramadol, Zydol®, Tramal®
- **sustained-release**, taken **twice** daily, 50mg, 100mg, 150mg & 200mg

E.g. TramaHexal® SR, Zydol® SR, Tramal® SR

- **extended-release**, taken **once** daily, 100mg, 200mg & 300mg

E.g. Durotram-XR®

Introduction of a new preparation of any drug inevitably increases the potential for medication errors to occur.

Care must be taken to ensure that patients are adequately counselled on 'how and when' to take their medicines. This is especially important when a patient has previously received an immediate or sustained-release tramadol product. Patients must be aware not to take any other product containing tramadol, while taking the extended-release preparation, without first speaking to a doctor or pharmacist.

Prescribers are encouraged to make their medication orders clear to avoid any confusion. Instead of writing 'SR' or 'XR', which could easily be confused or misinterpreted, prescribers should write 'sustained-release twice daily' or 'extended-release once daily', as appropriate, and specify an administration time.

Ambiguous or unclear prescribing must always be queried by nursing staff and pharmacists. The outcome should be documented, to avoid any further confusion.

For more information on the new or existing tramadol formulations speak to a pharmacist or consult an approved drug reference.

References

1. *Australian Medicines Handbook 2008*
2. RADAR - *National Prescribing Service, Once-daily tramadol extended-release (Durotram XR) for pain*, December 2008

This publication is intended to provide a general outline and is not intended to be and is not a complete or definitive statement of the information on the subject matter. Further professional advice should be sought before any action is taken in relation to the matters described in this publication. To obtain further copies of all documents referred to in this publication please see your pharmacist.

Medication Safety Alert - Insulin

Safe Practice Recommendation No. 09

Subcutaneous insulin can be fatal or cause serious harm if administered inappropriately.

Insulin is used to regulate blood glucose levels in Type 1 and some Type 2 diabetic patients. The pharmacology of the drug, complexity of dosing, and wide variety of products available all contribute to the potential for error.

Critical incidents have been reported in Australia and overseas involving errors in prescribing and administration of subcutaneous insulin.

The types of errors that have been reported include:

- Prescribing incorrect dose;
- Prescribing incorrect formulation;
- Selecting and administering incorrect formulation;
- Administering incorrect dose;
- Misinterpreting prescribed dose and administering incorrect dose.

Contributing factors in these errors include:

- Use of 'U' to indicate the number of units of insulin prescribed. This has been misinterpreted by nursing staff as the number zero. For example, a dose of 4U (i.e. 4 units) misinterpreted as 40 (i.e. 40 units).
- Confusing insulin product names particularly when a number is included in the brand name. For example, NovoMix 30® misinterpreted as a dose of 30 units.
- Similar looking insulin packaging and sound alike product names resulting in incorrect selection of insulin and subsequent administration to a patient. For example, Humalog® and Humalog Mix 25®.
- Large and variable dose ranges used, making errors less easily detected. For example, a large dose which is safe in one patient may be harmful in another.
- Confusing prescriptions or unusually large doses not queried prior to administration.

Slade Pharmacy recommends the following action to reduce the risk of error with subcutaneous insulin. They are based on recommendations by the Victorian Medicines Advisory Committee (VMAC), released in December 2008.


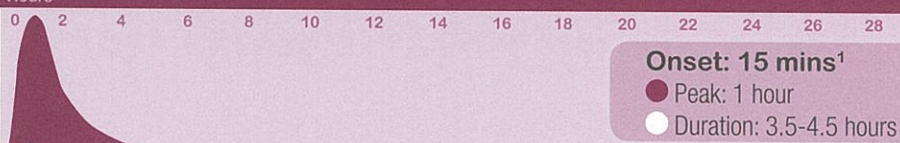

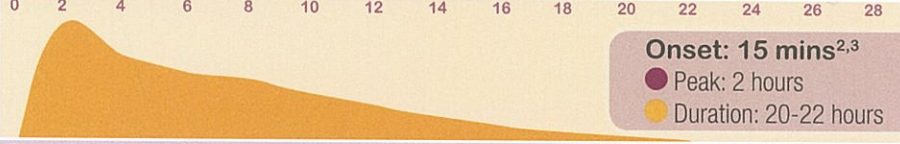

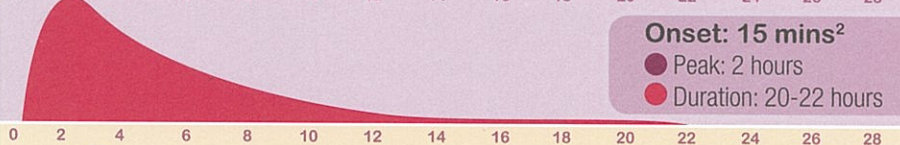

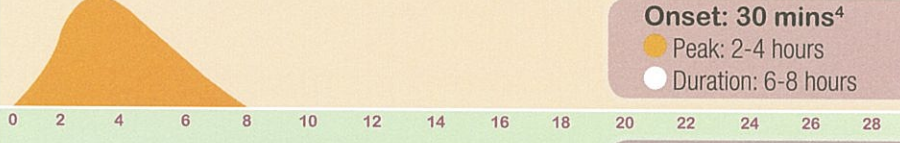

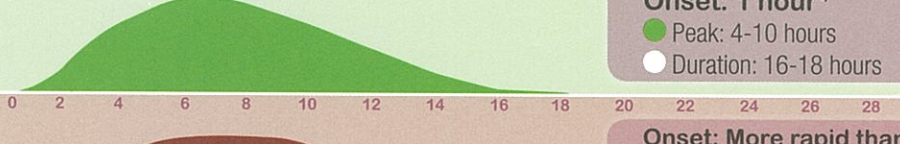


1. Undertake an immediate awareness campaign regarding the potential risks with subcutaneous insulin.

The awareness campaign should include educational posters on the range and names of insulin products available. Some posters are provided for your convenience. Attachments 1, 2 & 3 outline Lilly, NovoNordisk and Sanofi-Aventis products respectively.

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2. When prescribing subcutaneous insulin, the dose measure 'Units' must be written in full. Error prone abbreviations must never be used.
3. Always clarify unclear or potentially hazardous medication orders with the prescriber.
4. When labelling insulin packaging or containers never obscure important information. The following must always be clearly visible:
 - Brand name;
 - Name (generic) of the active ingredient(s);
 - Strength;
 - Form;
 - Expiry date;
 - Batch number; and
 - Directions for storage.
5. Use insulin syringes, with units of insulin equivalents clearly marked, or insulin pen devices for measuring insulin doses.
6. Use the correct insulin delivery device for specific insulin formulations.
 - For example, never withdraw insulin from a pen cartridge with a syringe and needle.
7. Review and rationalise the range of insulin formulations stocked in clinical areas:
 - Remove formulations which are not routinely used from clinical areas;
 - Store different formulations in separate clearly identified containers;
 - Consider placing colour photographs of the product on containers to aid identification; and
 - Dispense and supply insulin labelled for individual patients, whenever possible.
8. Develop an insulin protocol or review the existing protocol to ensure safe storage, prescribing, administration and management of insulin. The protocol should include blood glucose monitoring guidelines and management of hypoglycaemia/insulin overdose.

Lilly Insulin Range For Your Patient's Treatment Needs

Brand Name	Product Description	Presentation	Schematic Action Profile*
	insulin lispro Rbe RAPID-ACTING	10mL vials and 3mL cartridges	
	25% insulin lispro, 75% insulin lispro protamine suspension Rbe PREMIXED INSULIN LISPRO	3mL cartridges	
	50% insulin lispro, 50% insulin lispro protamine suspension Rbe PREMIXED INSULIN LISPRO	3mL cartridges	
	insulin neutral (Soluble) SHORT-ACTING	10mL vials and 3mL cartridges	
	isophane (NPH) INTERMEDIATE ACTING	10mL vials and 3mL cartridges	
	30% insulin neutral, 70% isophane (NPH) PREMIXED INSULIN	10mL vials and 3mL cartridges	

*Duration of action may vary from patient to patient.

HumaPen Luxura can be used with any Lilly 3mL Cartridge⁵

- Robust and reliable⁶
- Simple to use⁷
- Stylish⁶


simply stylish



For more information please call our Customer Information Line 1800 023 764.

Need a snack in between your meals?

It is OK for people with diabetes to have snacks, especially if they are taking certain diabetes tablets or insulin.⁸ The best snacks for them are those that are low in saturated fat, high in fibre and contain some carbohydrates (up to 20 grams for most people).⁹ If the person with diabetes is aiming to achieve a healthy weight, remind them that large snacks will contribute to weight gain, so keep the snacks small.⁸

Here are some ideas to get started:⁸

✓ Breads and cereals

- English muffin or crumpet topped with 100% fruit spreads or tomato or low fat cheese (such as cottage)
- Fruit or raisin toast with a thin scrape of margarine
- Small bowl of a high fibre breakfast cereal with low fat milk

✓ Fruit and vegetables options

- Fresh fruit – look out for those in season!
- Tinned fruit in natural juice such as apricots, peaches, fruit salad
- Small handful of dried fruit such as apples, apricots or sultanas
- Frozen cubes of fruit (eg cut up some pineapple and stick in the freezer!)
- Vegetable sticks with some favourite low fat dip

✓ Dairy choices

- Low fat or diet yoghurts – there are hundreds of flavours
- Other low fat dairy desserts – check out the dairy case in the supermarket
- Low fat custard – mix it with some fruit!

✓ Other options

- A high fibre, low fat sweet biscuit (look for those made with wholemeal flour, bran, oats and dried fruit)
- Rice crackers or rice cakes
- Toasted pita bread triangles with cottage cheese or low fat dip
- Handful of plain popcorn
- Small handful of nuts (no added salt)
- Small can of baked beans
- Unsalted, oven baked pretzels
- Sushi rolls
- Fruit smoothie made with low fat milk/yoghurt and fresh fruit

For advice that is specific to one's needs, it is best to speak to an Accredited Practising Dietitian (APD). You can find one at www.daa.asn.au

PBS INFORMATION: General Benefit. Refer to PBS Schedule for full PBS listing information for each product.

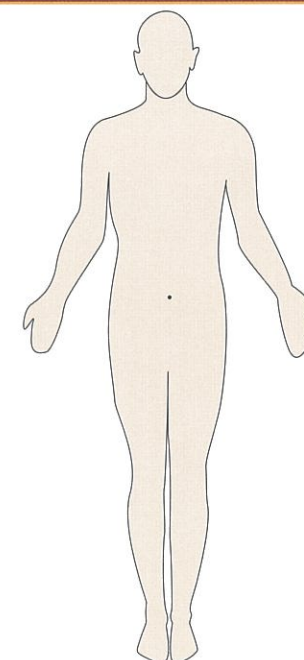
HUMALOG®, HUMALOG® MIX25, HUMALOG® MIX50 MINIMUM PRODUCT INFORMATION

APPROVED INDICATION: Treatment of diabetes mellitus. **CONTRAINDICATIONS:** Hypoglycaemia; hypersensitivity to insulin lispro or one of its excipients; intravenous administration. **PRECAUTIONS:** Any change of insulin or human insulin analogue should be made under medical supervision; loss of warning symptoms of hypoglycaemia; adjust dose for changes in exercise, diet and illness; should not be mixed with other insulins. **ADVERSE REACTIONS:** Hypoglycaemia, allergic reactions and lipodystrophy. **DOSAGE:** As determined by physician; subcutaneous injection; before meals (15 minutes). Refer to full PI for complete dosage information. Please review Full PI before Prescribing. Full PI is available on request from Eli Lilly. Based on PI last amended 30 January 2007. Eli Lilly Australia Pty. Limited. ABN 39 000 233 992. 112 Wharf Rd, West Ryde, NSW 2114. ®Registered trademark and ™Trademark of Eli Lilly.

HUMULIN RANGE INDICATIONS: For the treatment of insulin-dependent diabetic patients. **CONTRAINDICATIONS:** Hypoglycaemia, Hypersensitivity to human insulin and its excipients (unless as part of a desensitisation program). HUMULIN NPH and 30/70 vials: intravenous administration, HUMULIN R, NPH and 30/70 cartridges: intramuscular or intravenous administration. **PRECAUTIONS:** Changing insulin or human insulin analogue, number and size of daily doses, time of administration, diet and exercise requires medical supervision. For circumstances that may affect dose requirements, refer to full PI. **ADVERSE REACTIONS:** Hypoglycaemia, allergic reactions, insulin resistance and lipodystrophy. **DOSAGE:** As determined by physician. HUMULIN R vials: subcutaneous, intramuscular or intravenous administration; HUMULIN NPH and 30/70 vials: subcutaneous or intramuscular administration; HUMULIN R, NPH and 30/70 cartridges: subcutaneous administration. Please review the Product Information before prescribing. Full PI available on request from Eli Lilly.

References: 1. Humalog Prescribing Information, 2007. 2. Heise T *et al.* Time-action profiles of novel premixed preparations of insulin lispro and NPL insulin. *Diabetes Care* 1998; 21: 800-3. 3. Couper JJ & Prins JB. Recent advances in therapy of diabetes. *Med J Aust* 2003; 179: 441-7. 4. Humulin Consumer Medicine Information, 2006. 5. Humapen Luxura Instruction Leaflet. 6. Canadian Diabetes Association. 2007 Consumer's guide to diabetes products. Ontario: Canadian Diabetes Association, 2007. 7. Toshinari A *et al.* Usability comparison for two types of insulin delivery device (HumaPen Luxura® and NovoPen®300) using a clinical questionnaire and basic test for patients with diabetes mellitus. *Pharma Health Care Sci* 2005; 31: 993-1003. 8. Diabetes Australia - NSW. Healthy snacks and diabetes. Talking diabetes No. 21. Available from www.diabetesnsw.com.au/PDFs/About_Diabetes_PDFs/HealthySnacksFactsheet.pdf accessed on 19.02.08. 9. Diabetes Australia - Victoria. Introduction to healthy eating. Available from <http://www.dav.org.au/content.asp?rid=509> accessed on 19.02.08.

Injection Site Map



Treatment Targets

HbA1c (%) _____

Fasting BG* (mmol/L) _____

Post meal BG* (mmol/L) _____

Weight (kgs) _____

Waist circumference (cm) _____

*Blood Glucose

NOVO NORDISK - BALANCING INSULIN AND DELIVERY

Brand	Cartridge†	Pre-filled delivery†			Vials	Schematic Time-Action Profile*	Insulin Profile* ³
	Penfill® ² 3mL	FlexPen® 3mL	InnoLet® 3mL	NovoLet® 3mL	10mL Vial ²		
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: 2-12 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 NovoFine® 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 durations 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 Demi. 1. 5x5x3mL 1 repeat. 2. 5x10mL 2 repeats. 3. Approved Product Information. Dec 07 943830 HJ07727



PBS Information: General benefit.
Refer to PBS schedule for full PBS listing information for each product.
Levemir: Restricted benefit.
Type 1 diabetes.

MINIMUM PRODUCT INFORMATION* NovoMix® 30 (insulin aspart (rys))

Indications: Treatment of diabetes mellitus.
Contraindications: Hypoglycaemia. Hypersensitivity to insulin aspart or excipients.
Precautions: Inadequate dosing or discontinuation of treatment, especially in type 1 diabetes, may lead to hyperglycaemia and diabetic ketoacidosis. Where blood glucose 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. Do not use in insulin infusion pumps. No studies in children and adolescents under the age of 18. No clinical experience in pregnancy. **Adverse Effects:** hypoglycaemia.
Dosage and Administration: Dosage as determined by physician. NovoMix®30 should be administered immediately before a meal, or when necessary after the start of a meal. Resuspend immediately before use. Discard the needle after each injection. Subcutaneous injection only. NovoMix®30 must not be administered intravenously. Refer to full PI before prescribing, available on request (June 2007).

*Note changes in Product Information

Novo Nordisk Pharmaceuticals Pty Ltd
A.B.N. 40 002 879 996
Level 3, 21 Solent Circuit
Baulkham Hills NSW 2153

MINIMUM PRODUCT INFORMATION* NovoRapid® (insulin aspart (rys))

Indication: Treatment of diabetes mellitus.
Contraindications: Hypoglycaemia. Hypersensitivity to insulin aspart or excipients.
Precautions: Inadequate dosing or discontinuation of treatment may lead to hyperglycaemia and diabetic ketoacidosis. Where blood glucose 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. ***Pregnancy Category:** A. NovoRapid (insulin aspart) can be used in pregnancy. Data from two

randomised controlled clinical trials (157 + 14 insulin aspart-exposed pregnancies, respectively) did not indicate any adverse effect of insulin aspart on pregnancy or on the health of the foetus/newborn when compared to human insulin (see 'Clinical Trials' in full PI). Intensified blood glucose control and monitoring treatment of pregnant women with diabetes (type 1 diabetes, type 2 diabetes or gestational diabetes) are recommended throughout pregnancy and when contemplating pregnancy. **Adverse Effects:** hypoglycaemia. **Dosage and Administration:** Dosage as determined by physician. NovoRapid® should be administered immediately before a meal, or when necessary after the start of a meal. Discard the needle after each injection. *NovoRapid can be used in children. Clinical experience is available in children aged 2 years and over (see 'Clinical Trials' in full PI). NovoRapid can be used during pregnancy (see 'Use in Pregnancy' and 'Clinical Trials' in full PI). NovoRapid® can be used subcutaneously, intravenously or (10mL vial only) via continuous subcutaneous insulin infusion ('CSII'). Refer to full PI before prescribing, available on request (December 2007).

*Note changes in Product Information

Novo Nordisk Pharmaceuticals Pty Ltd
A.B.N. 40 002 879 996
Level 3, 21 Solent Circuit
Baulkham Hills NSW 2153

ABRIDGED PRODUCT INFORMATION

Human Insulin

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

Protaphane® (Isophane Insulin Injection, intermediate-acting suspension)

Mixtard® 30/70, Mixtard® 50/50 (Biphasic Isophane Insulin Injection, intermediate-acting suspension)

Composition: Human insulin (rys). **Indications:** Treatment of insulin-requiring diabetes.

Contraindications: 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 betablockers, alcohol. In general, insulin should only be added to compounds with which it has known compatibility.

Adverse Effects: 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 Penfill®/InnoLet®, the insulin must first be withdrawn into a syringe. Discard Penfill/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 CSII pumps. **Protaphane®, Mixtard® 30/70, Mixtard® 50/50:** Subcutaneous injection. Intramuscular injection in emergency under medical supervision. For such use with Penfill/NovoLet/InnoLet the insulin must first be withdrawn into a syringe. Discard Penfill/NovoLet/InnoLet cartridge/syringe after emergency use. **Presentation:** 100 IU/mL.

Penfill® 3mL cartridge - Actrapid, Protaphane, Mixtard 30/70, Mixtard 50/50. For use with Novo Nordisk insulin delivery systems and NovoFine® needles. **NovoLet® 3mL** - Protaphane. **InnoLet® 3mL** - Protaphane, Mixtard 30/70. **10mL vial** - Actrapid, Protaphane.

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

Approved by TGA 9 October 2002.

Abridged 02 October 2007.

Novo Nordisk Pharmaceuticals Pty Ltd
A.B.N. 40 002 879 996
Level 3, 21 Solent Circuit
Baulkham Hills NSW 2153

MINIMUM PRODUCT INFORMATION* Levemir® (insulin detemir (rys))

Levemir® (100U/ml) is a clear, colourless solution for injection. **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.) **Contraindications:** 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 a severe hypo. 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. No clinical experience during lactation. 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. **Adverse Effects:** hypoglycaemia. **Dosage and Administration:** Adjust dose individually. Administer once or twice daily depending on needs.

* Note changes in Product Information

Nordisk Pharmaceuticals Pty Ltd., Level 3, 21 Solent Circuit, Baulkham Hills, NSW 2153, Australia.



