AUSTRALIAN PRODUCT INFORMATION

HUMALOG® U200 KWIKPEN® [INSULIN LISPRO (RBE)]

1. NAME OF THE MEDICINE

Insulin lispro (rbe)

2 AND 3. QUALITATIVE AND QUANTITATIVE COMPOSITION AND PHARMACEUTICAL FORM

Insulin lispro solution [recombinant DNA origin] is an aqueous solution of insulin lispro ([Lys (B28), Pro (B29)] human insulin analogue, adjusted to pH 7.0 - 7.8. It also contains metacresol, glycerol, trometamol, zinc oxide and water for injection. Hydrochloric acid and sodium hydroxide may be used to adjust pH.

HUMALOG U200 is available as a clear, colourless solution for subcutaneous administration in a concentration of 200 units/mL in a 3 mL prefilled insulin delivery device (HUMALOG U200 KwikPen).

HUMALOG U200 is a Lilly human insulin analogue. It has a very quick onset of action and a short duration of activity.

HUMALOG U200 should be given immediately (up to 15 minutes) before a meal. When necessary, it can be given soon after meals (within 20 minutes of the start of a meal).

4. CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

For the treatment of patients with Type 1 (IDDM) and Type 2 (NIDDM) diabetes mellitus who require insulin for the maintenance of normal glucose homeostasis.

4.2 DOSE AND METHOD OF ADMINISTRATION

Adults

In adults, HUMALOG U200 can be given immediately (up to 15 minutes before a meal). When necessary, it can be given soon after meals (within 20 minutes of the start of the meal). It is anticipated the same dose of HUMALOG U200 to HUMALOG 100 units/mL will be required.

In patients with Type 2 diabetes HUMALOG U200 may be administered in combination therapy with oral sulfonylurea agents.

Children

In clinical studies involving children and adolescents (ages 3 –19 years), HUMALOG 100 units/mL has been shown to be safe, effective and well-tolerated.

There have been no studies of HUMALOG U200 in children (see **4.4 Special warnings and precautions for use**).

General

During changes to a patient's insulin regimen, increase the frequency of glucose monitoring.

HUMALOG U200 should be given by subcutaneous injection.

Subcutaneous administration should be in the abdomen or thighs. The injection sites should be rotated so that the same site is not used more than approximately once a month, in order to reduce the risk of lipodystrophy and localised cutaneous amyloidosis. Do not inject into areas of lipodystrophy or localised cutaneous amyloidosis.

The time course of action of any insulin may vary considerably in different individuals or at different times in the same individual. As with all insulin preparations, the duration of action of HUMALOG U200 is dependent on dose, site of injection, blood supply, temperature and physical activity.

As HUMALOG U200 is a rapid acting insulin and has a time activity profile that is different from other insulins, patients previously stabilised on other types-of-insulins should be titrated cautiously with HUMALOG U200, under medical supervision (see **4.4 Special warnings and precautions for use**).

HUMALOG U200 and HUMALOG (100 units/mL)

HUMALOG KwikPen is available in two strengths. For both, the needed dose is dialed in units. Both prefilled pens, the HUMALOG U200 KwikPen and the HUMALOG KwikPen deliver 1 – 60 units in steps of 1 unit in a single injection. The dose counter shows the number of units regardless of strength and no dose conversion should be done when transferring a patient to a new strength.

HUMALOG U200 should be reserved for the treatment of patients with diabetes requiring daily doses of more than 20 units of rapid-acting insulin. The HUMALOG U200 solution should not be withdrawn from the KwikPen, or mixed with any other insulin, or diluted (see **4.4 Special warnings and precautions for use**).

Do not use HUMALOG U200 solution for injection in an insulin infusion pump.

Do not use HUMALOG U200 solution for injection intravenously.

Only patients who have been trained in the correct administration technique, and were educated about the different posology of this product, should attempt self-administration.

4.3 CONTRAINDICATIONS

Hypoglycaemia.

Hypersensitivity to insulin lispro or one of its excipients.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Change in Insulin

Patients using HUMALOG U200 should be educated about the safe use of insulin. HUMALOG U200 is a "rapid acting" type-of-insulin (see **5 Pharmacological properties, 4.2 Dose and method of administration, 4.9 Overdose)**

Changing types-of-insulin (i.e., rapid acting, short acting, intermediate acting, long acting) should be done cautiously and under medical supervision. More frequent monitoring of blood glucose levels is recommended.

Within the "rapid acting" type-of-insulin category, changes to the molecular form of the insulin analogue (e.g., lispro, aspart, glulisine) should be done cautiously and under medical supervision. More frequent monitoring of blood glucose levels is recommended.

Injection technique

Patients must be instructed to perform continuous rotation of the injection site to reduce the risk of developing lipodystrophy and cutaneous amyloidosis. There is a potential risk of delayed insulin absorption and worsened glycaemic control following insulin injections at sites with these reactions. A sudden change in the injection site to an unaffected area has been reported to result in hypoglycaemia. Blood glucose monitoring is recommended after the change in the injection site, and dose adjustment of antidiabetic medications may be considered.

Hypoglycaemia

All insulins, including HUMALOG U200, lower blood glucose levels and may cause hypoglycaemia (see OVERDOSAGE). Patients should be educated about the symptoms of hypoglycaemia (e.g., hunger, anxiety, sweating, tachycardia, confusion, etc.); and the risk factors for hypoglycaemia (e.g., reduced carbohydrate intake, exercise, oral hypoglycaemic agents, alcohol). Following an episode of hypoglycaemia, more frequent blood glucose monitoring and dose adjustment may be required.

The ability to concentrate and to react may be impaired as a result of hypoglycaemia, in particular recurrent hypoglycaemia. This may constitute a risk in situations where these abilities are of special importance (e.g., driving a car or operating machinery). Patients should be advised to take precautions to avoid hypoglycaemia while driving, this is particularly important in those who have reduced or absent awareness of the warning signs of hypoglycaemia or have frequent episodes of hypoglycaemia. The advisability of driving should be considered in these circumstances.

Conditions which may make the early warning symptoms of hypoglycaemia different or less pronounced include long duration of diabetes, intensified insulin therapy, diabetic nerve disease, or medical products such as beta blockers.

Hyperglycaemia

Use of dosages which are inadequate or discontinuation of treatment, especially in insulin-dependent diabetics, may lead to hyperglycaemia and diabetic ketoacidosis; conditions which are potentially lethal.

Insulin Requirements and Dosage Adjustment

Insulin requirements may be increased during illness or emotional disturbances.

Adjustment of dosage may also be necessary if patients undertake increased physical activity or change their usual diet.

Combination of HUMALOG U200 with Thiazolidinediones

Thiazolidinediones (TZDs) in combination with insulin are associated with an increased risk of oedema and heart failure; especially in patients with underlying cardiac disease

Medication Error

HUMALOG U200 solution for injection must not be transferred from the prefilled KwikPen to a syringe. The markings on the insulin syringe will not measure the dose correctly. Overdose can result causing severe hypoglycaemia. HUMALOG U200 solution for injection must not be transferred from the KwikPen to any other insulin delivery device, including insulin infusion pumps.

Renal or Hepatic Impairment

Some studies with human insulin have shown increased levels of circulating insulin in patients with renal and/or hepatic dysfunction. However, some patients with chronic hepatic impairment may have increased insulin requirements. Careful glucose monitoring and dose adjustments of HUMALOG U200 may be necessary (see **4.2 Dose and method of administration**).

Use in hepatic impairment

Insulin requirements may be reduced in patients with hepatic impairment due to reduced capacity for gluconeogenesis and reduced insulin breakdown; however, in patients with chronic hepatic impairment, an increase in insulin resistance may lead to increased insulin requirements.

Use in renal impairment

Insulin requirements may be reduced in the presence of renal impairment.

Use in the Elderly

No data available

Paediatric Use

There have been no studies of HUMALOG U200 in children. HUMALOG U200 was shown to be bioequivalent to HUMALOG 100 units/mL in healthy adults (n=73) (see **5 Pharmacological properties**).In clinical studies involving children and adolescents (ages 3 –19 years), HUMALOG 100 units/mL has been shown to be safe, effective and well-tolerated

Effects on Laboratory Tests

No data available

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

The medical practitioner should be consulted when using other medication in addition to insulin lispro (see **4.4 Special warnings and precautions for use**).

Insulin requirements may be increased by drugs with hyperglycaemic activity, such as oral contraceptives, corticosteroids, thyroid replacement therapy, isoniazid, phenothiazines, danazol or beta-2 stimulants (such as salbutamol, terbutaline).

Insulin requirements may be reduced in the presence of drugs with hypoglycaemic activity, such as oral hypoglycaemics, salicylates (for example, aspirin), sulphonamides, certain antidepressants (monoamine oxidase inhibitors), certain angiotensin converting enzyme inhibitors (captopril and enalapril), angiotensin II receptor blockers, beta blockers, octreotide and alcohol.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No effects on male or female fertility have been observed in rats dosed subcutaneously with insulin lispro at dose levels up to 20 U/kg/day.

Use in pregnancy

Pregnancy Category A

HUMALOG U200 can be used during pregnancy. There is a large body of data which suggests that the use of insulin lispro during pregnancy is beneficial, and as safe as other forms of insulin therapy.

In a retrospective cohort study, the medical records of 496 women with Type 1 or Type 2 diabetes treated with HUMALOG for at least 1 month before conception and during at least the first trimester of pregnancy were reviewed to determine the rate of major congenital anomalies in their offspring. Outcomes of 533 pregnancies (542 offspring) showed the incidence of major congenital anomalies in the offspring was 5.4% (95% CI: 3.45%, 7.44%), consistent with previously published results for the offspring of women with type 1 and type 2 pregestational diabetes.

It is essential to maintain good control of the insulin-treated patient (insulin-dependent or gestational diabetes) throughout pregnancy. Insulin requirements usually fall during the first trimester and increase during the second and third trimesters. Patients with diabetes should be advised to inform their doctor if they are pregnant or are contemplating pregnancy. Careful monitoring of the patient is required throughout pregnancy. During the perinatal period, careful monitoring of infants born to mothers with diabetes is warranted.

A reproductive study in rats showed no adverse effects on pregnancy or foetal development when insulin lispro was injected subcutaneously once daily at doses up to 20 U/kg. Teratogenic potential has not been adequately assessed in rabbits, although one study showed no embryotoxic or teratogenic activity at subcutaneous doses up to 0.75 U/kg/day.

Use in lactation

Patients with diabetes who are lactating may require adjustments in insulin dose, diet or both. It is not known if insulin lispro is excreted in significant amounts in human milk. Many drugs, including human insulin, are excreted in human breast milk.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The ability to concentrate to react may be impaired as a result of hypoglycaemia, in particular recurrent hypoglycaemia. This may constitute a risk in situations where these abilities are of special importance (e.g., driving a car or operating machinery). Patients should be advised to take precautions to avoid hypoglycaemia while driving, this is particularly important in those who have reduced or absent awareness of the warning signs of hypoglycaemia or have

frequent episodes of hypoglycaemia. The advisability of driving should be considered in these circumstances.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

The preclinical safety profile indicates that insulin lispro (the active ingredient in HUMALOG U200 and HUMALOG) is safe in the chronic treatment of diabetes in humans. The safety profile of insulin lispro has been assessed in a series of preclinical studies. In in vitro tests, including binding to insulin receptor sites and effects on growing cells, insulin lispro behaved in a manner that closely resembled human insulin. Toxicology studies produced no significant toxicity findings. Most importantly, and like human insulin, insulin lispro did not produce proliferative effects or tumours in organs and tissues when given at very high subcutaneous doses in chronic toxicity tests.

Hypoglycaemia

Hypoglycaemia is the most frequent undesirable effect of insulin therapy. Severe hypoglycaemia may lead to loss of consciousness and, in extreme cases, death. The clinical studies on HUMALOG 100 units/mL showed no difference between the frequency of symptomatic hypoglycaemia or the frequency of hypoglycaemic coma when compared to HUMULIN R; however, the studies did show a consistent, but not always significant, reduction of postprandial glycaemic excursion in patients using HUMALOG.

Allergic Reactions

Local allergy in patients occasionally occurs as redness, swelling and itching at the site of insulin injection. This condition usually resolves in a few days to a few weeks. In some instances, this condition may be related to factors other than insulin, such as irritants in the skin cleansing agent or poor injection technique. Systemic allergy, less common but potentially more serious, is a generalised allergy to insulin. It may cause rash over the whole body, shortness of breath, wheezing, reduction in blood pressure, fast pulse or sweating. Severe cases of generalised allergy may be life- threatening.

Lipodystrophy

Rarely, administration of insulin subcutaneously can result in lipoatrophy or lipohypertrophy. A change in injection technique may help alleviate the problem.

Spontaneous Data

Cases of oedema have been reported with insulin therapy, particularly if previous poor metabolic control is improved by intensified insulin therapy.

Lipodystrophy and localised cutaneous amyloidosis at the injection site have occurred. Hyperglycaemia has been reported with repeated insulin injections into areas of lipodystrophy or localised cutaneous amyloidosis; hypoglycaemia has been reported with a sudden change to an unaffected injection site (see section **4.4 Special warnings and precautions for use)**.

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at http://www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Insulins have no specific overdose definitions because serum glucose concentrations are a result of complex interactions between insulin levels, glucose availability and other metabolic processes. Hypoglycaemia may occur as a result of an excess of insulin or insulin analogue relative to food intake and energy expenditure.

Hypoglycaemia may be associated with listlessness, confusion, palpitations, headache, sweating and vomiting.

Mild hypoglycaemic episodes will respond to oral administration of glucose or other sugar or saccharated products.

Correction of moderately severe hypoglycaemia can be accomplished by intramuscular or subcutaneous administration of glucagon, followed by oral carbohydrate when the patient recovers sufficiently. Patients who fail to respond to glucagon must be given glucose solution intravenously.

If the patient is comatose, glucagon should be administered intramuscularly or subcutaneously. However, glucose solution must be given intravenously if glucagon is not available or if the patient fails to respond to glucagon. The patient should be given a meal as soon as consciousness is recovered.

For information on the management of overdose, contact the Poison Information Centre on 131126 (Australia).

5. PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

The unique structure of HUMALOG U200 results in a fast rate of absorption from subcutaneous sites of injection, a rapid effect and a short duration of action, more closely mimicking the normal physiological response.

HUMALOG U200 has a very rapid onset of action, allowing it to be given immediately before a meal, compared to regular insulin, which should be given 30 minutes before a meal. HUMALOG U200 solution for injection was bioequivalent to HUMALOG 100 units/mL solution for injection after subcutaneous administration of a single 20 unit dose in healthy adults (n=73). Time to maximum concentration was also similar between formulations. In initial clinical pharmacology studies, the onset of action of HUMALOG 100 units/mL was seen within 15 minutes of administration. Serum insulin levels peak earlier with insulin lispro (the active ingredient in HUMALOG U200 and HUMALOG) at 1 hour, corresponding to an earlier peak action of insulin lispro. Insulin lispro has a short duration of activity of 3.5 to 4.5 hours.

As with all insulin preparations, the time course of HUMALOG U200 action may vary in different individuals or at different times in the same individual and is dependent on site of injection, blood supply, body temperature and physical activity. The primary activity of HUMALOG U200 is the regulation of glucose metabolism.

In addition, insulins have several anabolic and anti-catabolic actions on a variety of different tissues. In muscle and other tissues (except the brain), insulin causes rapid transport of

glucose and amino acids intracellularly, promotes anabolism, and inhibits protein catabolism. In the liver, insulin promotes the uptake and storage of glucose in the form of glycogen, inhibits gluconeogenesis, and promotes the conversion of excess glucose into fat.

The pharmacodynamics of a single 20 unit dose of HUMALOG U200 administered subcutaneously were compared to the pharmacodynamics of a single 20 unit dose of HUMALOG 100 units/mL administered subcutaneously in a euglycemic clamp study enrolling healthy subjects. In this study, the overall, maximum, and time to maximum glucose lowering effect were similar between HUMALOG U200 and HUMALOG 100 units/mL. The mean area under the glucose infusion rate curves (measure of overall pharmacodynamic effect) were 125 g and 126 g for HUMALOG U200 and HUMALOG 100 units/mL, respectively. The maximum glucose infusion rate was 534 mg/min and 559 mg/min and the corresponding median time (min, max) to maximum effect were 2.8 h (0.5 h – 6.3 h) and 2.4 h (0.5 h – 4.7 h) for HUMALOG U200 and HUMALOG 100 units/mL, respectively (see Figure 1).

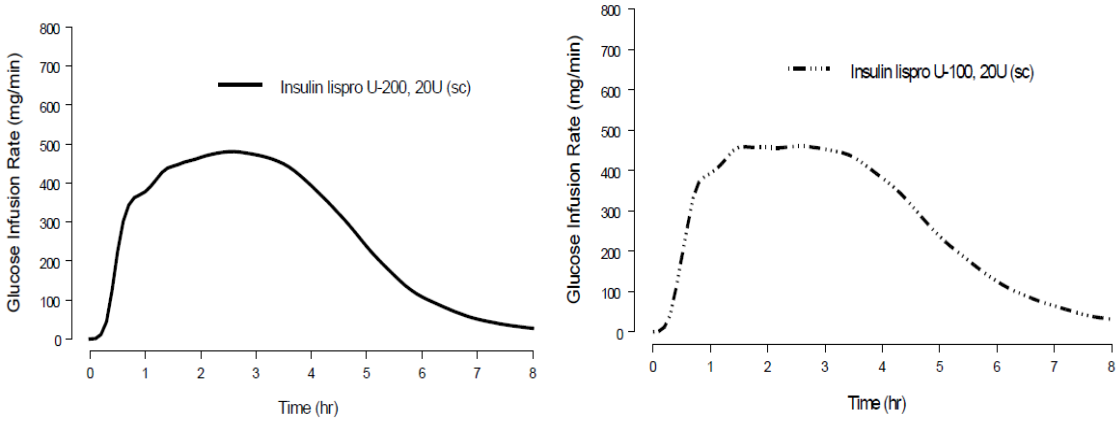


Figure 1: Pharmacodynamic Response of insulin lispro 100 and 200 IU/mL in Healthy Subjects.

Clinical trials

Eight pivotal studies were designed to evaluate the use of HUMALOG 100 units/mL as a mealtime insulin using postprandial glucose control as the primary efficacy objective. These studies were designed to incorporate men and women of many racial/ethnic heritages and cultural dietary patterns aged 12 to 85 with new or previously treated Type 1 or Type 2 diabetes mellitus. In these trials, 2,247 patients received HUMALOG 100 units/mL.

Four global, multicentre, clinical studies of HUMALOG 100 units/mL (studies IOAA - IOAD) were designed to incorporate Type 1 and Type 2 patients who were already receiving insulin therapy and who had been treated with human insulin for at least 2 months prior to study entry. All four were 1-year, open-label, randomised, parallel studies using HUMULIN R in a multiple daily injection, basal-bolus therapeutic regimen as the active comparator (see table).

Four global, multicentre, clinical studies of HUMALOG 100 units/mL (studies IOAE - IOAH) were conducted to incorporate Type 1 and Type 2 patients who had never received insulin, to evaluate antibody formation in patients not previously treated with insulin, and to have larger studies of both Type 1 and 2 patients previously treated with insulin (see table).

The studies in new Type 1 and Type 2 patients, IOAE and IOAF, were 1-year, open-label, randomised, parallel, studies using HUMULIN R as the active comparator. The choice of basal insulin was at the discretion of the investigator, either HUMULIN NPH or HUMULIN UL, and

once chosen was the basal insulin for the entire study. The study design was identical to the earlier studies, IOAA - IOAD.

Studies IOAG and IOAH were 6-month, open-label, randomised, crossover studies in Type 1 and Type 2 patients who were currently being treated with insulin and had been using human insulin for at least the previous 2 months. HUMULIN R was the active comparator. The choice of basal insulin was at the discretion of the investigator, either HUMULIN NPH or HUMULIN UL, and once chosen was the basal insulin for the entire study. The power of the crossover design, with each patient serving as his or her own control, and the large patient numbers allowed these two studies to provide the major conclusions (consistent with the conclusions of the first six studies) regarding the efficacy of HUMALOG 100 units/mL on reduction of the postprandial glucose excursion in patients with diabetes. In addition, study IOAG demonstrated a significant reduction in the rate of hypoglycaemia overall as well as demonstrating significant reduction in nocturnal hypoglycaemia in patients receiving HUMALOG 100 units/mL.

In all of the studies there were no clinically significant safety issues with HUMALOG 100 units/mL. There was no evidence of increased immunogenicity of HUMALOG 100 units/mL compared to HUMULIN R.

In the clinical trials of HUMALOG 100 units/mL, approximately one-half to two-thirds of Type 1 patients and approximately one-third of Type 2 patients had their basal insulin in the morning. More than 90% of the patients having a morning dose of basal insulin had it mixed with their breakfast dose of HUMALOG 100 units/mL.

Table 1.

Study	Number of Patients[a]	2-Hour Excursion[b]		HbA_1c[c]	
		HUMALOG	HUMULIN R	HUMALOG	HUMULIN R
IOAA	167	0.07 ± 4.87 **	2.92 ± 4.28	8.14 ± 1.30 +	8.38 ± 1.37
IOAB	145	1.04 ± 3.66 *	2.49 ± 3.94	8.00 ± 1.21	8.20 ± 1.64
IOAC	169	1.99 ± 5.08	2.75 ± 4.64	8.08 ± 1.43	8.22 ± 1.44
IOAD	150	1.74 ± 3.76 *	2.84 ± 3.25	8.38 ± 1.52	8.50 ± 1.73
IOAE	98	1.31 ± 4.29	2.78 ± 4.37	7.77 ± 2.24	7.84 ± 2.35
IOAF	375	2.38 ± 3.64	2.83 ± 2.94	8.32 ± 1.57	8.08 ± 1.54
IOAG	1008	-0.51 ± 4.88 **	1.52 ± 5.05	8.24 ± 1.49	8.17 ± 1.46
IOAH	722	1.40 ± 3.67 **	2.97 ± 3.73	8.18 ± 1.30	8.18 ± 1.38

Abbreviations: HbA_1c = haemoglobin A_1c.

[a] Number of patients enrolled.

[b] Blood Glucose Excursion (mmol/L), Endpoint values, means ± standard deviation.

[c] Haemoglobin A_1c (%), Endpoint values, means ± standard deviation.

* $p < 0.025$ ** $p < 0.001$ + $p = 0.031$

Clinical studies have demonstrated significant improvement in postprandial glucose excursions without producing delayed postprandial hyperglycaemia and without an adverse effect on overall control as measured by haemoglobin A1c. Therapy with HUMALOG 100 units/mL was also associated with no adverse impact on hypoglycaemia, and, in fact, in the large studies with Type 1 patients (those most at risk of hypoglycaemia) there was a reduction in the rate of hypoglycaemia overall and a reduction in nocturnal hypoglycaemia. Across all of the studies there were no significant safety issues.

HUMALOG 100 units/mL is superior to regular human insulin in those measures that reflect rapid onset and shorter duration of action. Early studies showed no significant difference in overall glycaemic control, as measured by haemoglobin A1c, between HUMALOG 100 units/mL and regular human insulin, either in patients established on insulin or in newly diagnosed patients. Haemoglobin A1c is improved with HUMALOG 100 units/mL by varying the basal regimen, to compensate for preprandial hyperglycaemia and to make use of the reduced postprandial blood glucose levels provided by HUMALOG 100 units/mL.

In patients with Type 2 diabetes on maximum doses of sulfonylurea agents, the addition of HUMALOG 100 units/mL resulted in an improvement in haemoglobin A1c compared to patients continuing on sulfonylurea therapy alone. Study IOCE was a 2-month randomised, open-label comparative study of HUMALOG 100 units/mL, sulfonylurea and insulin NPH combinations. In this study, haemoglobin A1c levels were reduced by 1.6% with the combination of HUMALOG 100 units/mL and sulfonylurea, when compared to baseline, in patients with fasting hyperglycaemia despite maximal doses of sulfonylurea.

5.2 PHARMACOKINETIC PROPERTIES

Refer to **5.1 Pharmacodynamic Properties.**

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

There was no evidence of any genotoxic activity in a range of assays for gene mutations, chromosomal effects and DNA damage.

Carcinogenicity

Carcinogenicity studies of insulin lispro have not been conducted.

6. PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Refer to **2 and 3 Qualitative and quantitative composition and Pharmaceutical form.**

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine**.**

6.3 SHELF-LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

HUMALOG U200 should be stored in a refrigerator between 2°C and 8°C. It should not be frozen or exposed to excessive heat or sunlight.

HUMALOG U200 KwikPen can be kept at ambient temperature below 30°C and away from direct heat and light for 28 days while in use.

6.5 NATURE AND CONTENTS OF CONTAINER

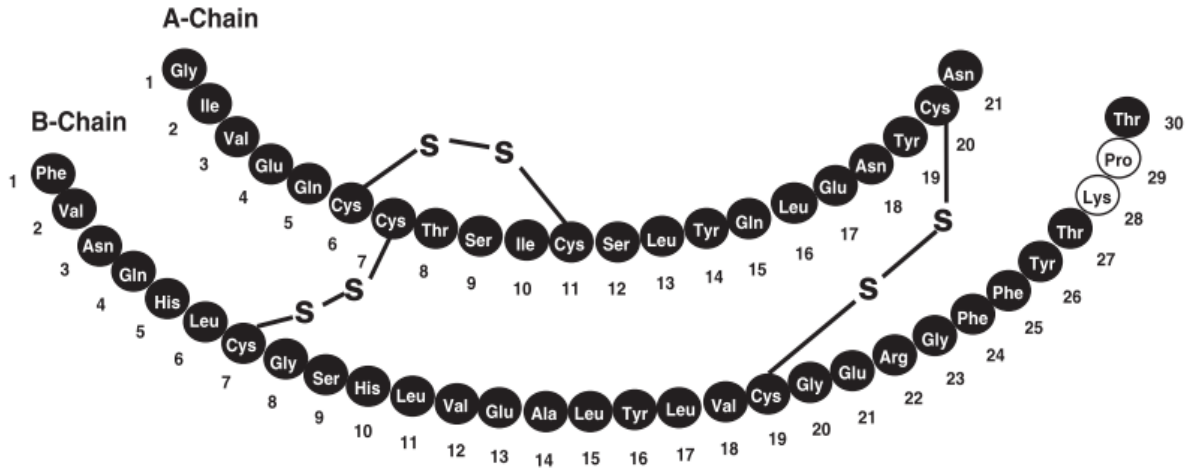
HUMALOG U200 [200 units/mL of insulin lispro (rbe)] is supplied in a KwikPen prefilled insulin delivery device containing a 3 mL cartridge (in packs of 2 and 5).

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

6.7 PHYSICOCHEMICAL PROPERTIES

Chemical structure



CAS number

133107-64-9

7. MEDICINE SCHEDULE (POISONS STANDARD)

S4 – Prescription only medicine

8. SPONSOR

Eli Lilly Australia Pty. Ltd
Level 9, 60 Margaret Street, Sydney, NSW 2000
AUSTRALIA
1800 454 559

9. DATE OF FIRST APPROVAL

9 November 2015.

10. DATE OF REVISION

21 September 2023

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
8	Sponsor address update

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