PROFESSIONAL INFORMATION

SCHEDULING STATUS S3

1. NAME OF THE MEDICINE

HUMALOG MIX 25 (Suspension for injection)

HUMALOG MIX 50 (Suspension for injection)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains 100 units insulin lispro*.

HUMALOG MIX 25

HUMALOG MIX 25 consists of 25 % insulin lispro solution and 75 % insulin lispro protamine suspension.

Vial

Each vial contains 1 000 units of insulin lispro in 10 ml suspension.

Cartridge

Each cartridge contains 300 units of insulin lispro in 3 ml suspension.

KwikPen

Each pre-filled pen contains 300 units of insulin lispro in 3 ml suspension.

Each KwikPen delivers 1-60 units in steps of 1 unit.

HUMALOG MIX 50

HUMALOG MIX 50 consists of 50 % insulin lispro solution and 50 % insulin lispro protamine suspension.

Cartridge

Each cartridge contains 300 units of insulin lispro in 3 ml suspension.

KwikPen

Each pre-filled pen contains 300 units of insulin lispro in 3 ml suspension.

Each KwikPen delivers 1-60 units in steps of 1 unit.

*Produced in *E.coli* by recombinant DNA technology.

For a full list of excipients, please see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for Injection.

Sterile, white suspension.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

HUMALOG MIX 25 and HUMALOG MIX 50 are indicated for the treatment of patients with diabetes mellitus who require insulin for the maintenance of normal glucose homeostasis.

4.2. Posology and method of administration

Posology

The dosage should be determined by the healthcare professional, according to the requirements of the patient.

Both HUMALOG MIX 25 and HUMALOG MIX 50 may be given shortly before meals. When necessary, HUMALOG MIX 25 and HUMALOG MIX 50 can be given soon after meals. HUMALOG MIX 25 and HUMALOG MIX 50 should only be given by subcutaneous injection. Under no circumstances should HUMALOG MIX 25 or HUMALOG MIX 50 be given intravenously.

The rapid onset and early peak of activity of Humalog itself is observed following the subcutaneous administration of HUMALOG MIX 25 and HUMALOG MIX 50. This allows HUMALOG MIX 25 and HUMALOG MIX 50 to be given very close to mealtime.

The duration of action of the insulin lispro protamine suspension component of HUMALOG MIX 25 and HUMALOG MIX 50 are similar to that of a basal insulin (NPH).

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 MIX 25 and HUMALOG MIX 50 is dependent on dose, site of injection, blood supply, temperature, and physical activity.

Special populations

Renal impairment:

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

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.

Paediatric population:

The safety and effectiveness of HUMALOG MIX 25 and HUMALOG MIX 50 in patients less than 18 years of age have not been established.

Method of administration

Subcutaneous administration should be in the upper arms, thighs, buttocks, or abdomen. Use of 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 cutaneous amyloidosis (see section 4.4 and 4.8).

When administered subcutaneously care should be taken when injecting HUMALOG MIX 25 or HUMALOG MIX 50 to ensure that a blood vessel has not been entered. After injection, the site of injection should not be massaged.

Patients must be educated to use the proper injection techniques.

HUMALOG MIX 25 and HUMALOG MIX 50 KWIKPEN: The KWIKPEN delivers 1 – 60 units in steps of 1 unit in a single injection. The needed dose is dialled in units. **The number of units is shown in the dose window of the pen**.

For instructions on the handling and preparation of HUMALOG MIX 25 and HUMALOG MIX 50 refer to section 6.6.

4.3. Contraindications

Hypersensitivity to insulin lispro or to any of the excipients listed in section 6.1.

Hypoglycaemia.

4.4. Special warnings and precautions for use

Transferring of a patient to another type or brand of insulin

Transferring a patient to another type or brand of insulin should be done under strict medical supervision. Changes in strength, brand (manufacturer), type (regular/soluble, NPH/isophane, etc.), species (animal, human, human insulin analogue) and/or method of

manufacture (recombinant DNA versus animal-source insulin) may result in the need for a change in dosage.

Hypoglycaemia and hyperglycaemia

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 medications such as beta-blockers.

A few patients who have experienced hypoglycaemic reactions after transfer from animal-source insulin to human insulin have reported that the early warning symptoms of hypoglycaemia were less pronounced or different from those experienced with their previous insulin. Uncorrected hypoglycaemic or hyperglycaemic reactions can cause loss of consciousness, coma, or death.

The 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.

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.

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. Exercise taken immediately after a meal may increase the risk of hypoglycaemia.

Combination of HUMALOG MIX 25 and HUMALOG MIX 50 with pioglitazone

Cases of cardiac failure have been reported when pioglitazone was used in combination with insulin, especially in patients with risk factors for development of cardiac failure. This should be kept in mind, if treatment with the combination of pioglitazone and HUMALOG MIX 25 or HUMALOG MIX 50 is considered. If the combination is used, patients should be observed for signs and symptoms of heart failure, weight gain and oedema. Pioglitazone should be discontinued if any deterioration in cardiac symptoms occurs.

Avoidance of medication errors

Patients must be instructed to always check the insulin label before each injection to avoid accidental mix-ups between the two different strengths of HUMALOG KwikPen as well as other insulin products.

Patients must visually verify the dialled units on the dose counter of the pen. Therefore, the requirement for patients to self-inject is that they can read the dose counter on the pen. Patients who are blind or have poor vision must be instructed to always get help/assistance from another person who has good vision and is trained in using the insulin device.

HUMALOG MIX 25 and HUMALOG MIX 50 contain sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e., essentially "sodium-free".

4.5. Interaction with other medicines and other forms of interaction

Insulin requirements may be increased by medicines with hyperglycaemic activity, such as oral contraceptives, corticosteroids, or thyroid replacement therapy, danazol, beta$_2$ stimulants (such as ritodrine, salbutamol, terbutaline).

Insulin requirements may be decreased in the presence of medicines with hypoglycaemic activity, such as oral hypoglycaemics, salicylates (for example, acetylsalicylic acid), sulpha antibiotics, certain anti-depressants (monoamine oxidase inhibitors, selective serotonin reuptake inhibitors), certain angiotensin converting enzyme inhibitors (captopril, enalapril), angiotensin II receptor blockers, beta-blockers, octreotide, or alcohol.

Mixing HUMALOG MIX 25 or HUMALOG MIX 50 with other insulins has not been studied.

The healthcare professional should be consulted when using other medication in addition to HUMALOG MIX 25 or HUMALOG MIX 50 (see section 4.4).

4.6. Fertility, pregnancy and lactation

Pregnancy

Data on a large number of exposed pregnancies do not indicate any adverse effect of insulin lispro on pregnancy or on the health of the foetus/newborn.

It is essential to maintain good control of the insulin-treated (insulin-dependent or gestational diabetes) patient 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 glucose control, as well as general health, is essential in pregnant patients with diabetes.

Breastfeeding

Patients with diabetes who are breastfeeding may require adjustments in insulin dose, diet, or both.

Fertility

Insulin lispro did not induce fertility impairment in animal studies (see section 5.3).

4.7. Effects on ability to drive and use machines

The patient's ability to concentrate and react may be impaired as a result of 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 whilst 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. Undesirable effects

Summary of safety profile

Hypoglycaemia is the most frequent undesirable effect of insulin therapy that a patient with diabetes may suffer. Severe hypoglycaemia may lead to loss of consciousness, and in extreme cases, death. No specific frequency for hypoglycaemia is presented, since

hypoglycaemia is a result of both the insulin dose and other factors e.g., a patient's level of diet and exercise.

Tabulated list of adverse reactions

The following related adverse reactions from clinical trials are listed below as MedDRA preferred term by system organ class and in order of decreasing incidence (very common: ≥ 1/10; common: ≥ 1 /100 to < 1/10; uncommon: ≥ 1/1 000 to < 1/100; rare: ≥ 1/10 000 to < 1/1 000; very rare: < 1/10 000); not known (cannot be estimated form the available data).

Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

MedDRA system organ class	**Very common**	**Common**	**Uncommon**	**Rare**	**Very rare**	**Not known**
Immune system disorder						
Local allergy		X				
Systemic allergy				X		
Skin and subcutaneous tissue disorders						
Lipodystrophy			X			
Cutaneous amyloidosis						X

Description of selected adverse reactions

Local allergy

Local allergy in patients is common. Redness, swelling, and itching can occur 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

Systemic allergy, which is rare but potentially more serious, is a generalised allergy to insulin. It may cause a 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.

Skin and subcutaneous tissue disorders

Lipodystrophy and cutaneous amyloidosis may occur at the injection site and delay local insulin absorption. Continuous rotation of the injection site within the given injection area may help to reduce or prevent these reactions (see section 4.4).

Oedema

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

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications –

https://www.sahpra.org.za/Publications/Index/8. Alternatively, report suspected adverse events to the company at ade_za@lilly.com.

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 activity 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.

Sustained carbohydrate intake and observation may be necessary because hypoglycaemia may recur after apparent clinical recovery.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Drugs used in diabetes, insulins, and analogues for injection, intermediate or long acting combined with fast-acting.

ATC code: A10AD04

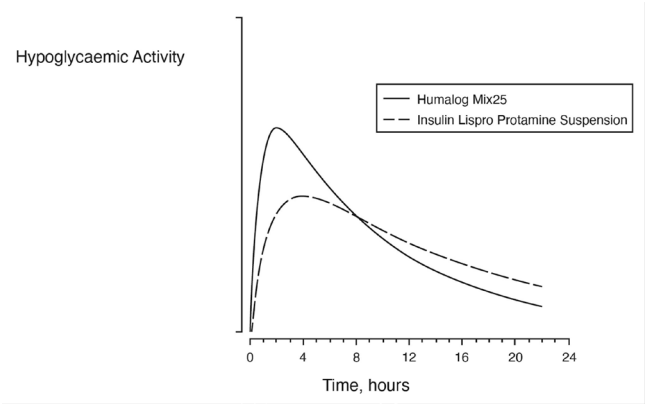
The primary activity of insulin lispro is the regulation of glucose metabolism.

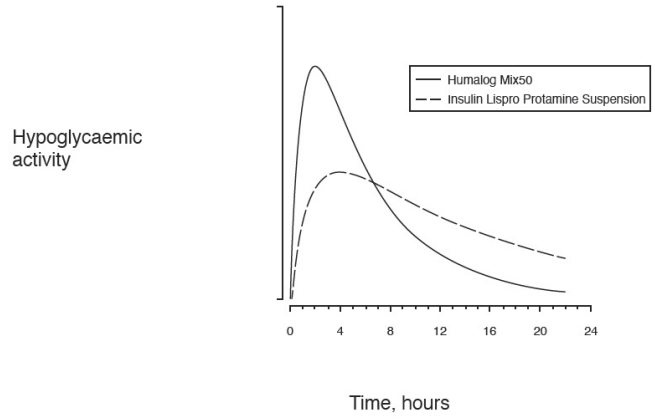
In addition, insulins have several anabolic and anti-catabolic actions on a variety of different tissues. Within muscle tissue this includes increasing glycogen, fatty acid, glycerol and protein synthesis and amino acid uptake, while decreasing glycogenolysis, gluconeogenesis, ketogenesis, lipolysis, protein catabolism and amino acid output.

Insulin lispro has a rapid onset of action (approximately 15 minutes), thus allowing it to be given closer to a meal (within zero to 15 minutes of the meal) when compared to soluble insulin (30 to 45 minutes before). The rapid onset and early peak of activity of insulin lispro is observed following the subcutaneous administration of HUMALOG MIX 25 and HUMALOG MIX 50. Insulin lispro protamine suspension has an activity profile that is very similar to that of a basal insulin (NPH) over a period of approximately 15 hours.

Clinical trials in patients with type 1 and type 2 diabetes have demonstrated reduced postprandial hyperglycaemia with HUMALOG MIX 25 compared to human insulin mixture 30/70. In one clinical study there was a small (0,38 mmol/l) increase in blood glucose levels at night (3 a.m.).

In the figure below the pharmacodynamics of HUMALOG MIX 25 and HUMALOG MIX 50 and insulin lispro protamine suspension are illustrated.





The above representation reflects the relative amount of glucose over time required to maintain whole blood glucose concentrations near fasting levels and is an indicator of the effect of these insulins on glucose metabolism over time.

The glucodynamic response to insulin lispro is not affected by renal or hepatic function impairment. Glucodynamic differences between insulin lispro and soluble human insulin, as measured during a glucose clamp procedure, were maintained over a wide range of renal function.

Insulin lispro has been shown to be equipotent to human insulin on a molar basis but its effect is more rapid and of a shorter duration.

In two 8-month open label crossover studies, type 2 diabetes patients who were either new to insulin therapy or already using one or two injections of insulin, received 4 months of treatment

with HUMALOG MIX 25 (used twice daily with metformin) and insulin glargine (used once daily with metformin) in a randomised sequence. Detailed information can be found in the following table.

	Insulin-Naive Patients n = 78	**Not Insulin-Naive Patients** n = 97
Mean total daily insulin dose at endpoint	0,63 units/kg	0,42 units/kg
Haemoglobin A1c –Reduction[1]	1,30 % (Mean at baseline = 8,7 %)	1,00 % (Mean at baseline = 8,5 %)
Reduction of the mean of combined morning / evening two-hour postprandial blood glucose[1]	3,46 mM	2,48 mM
Reduction of the mean fasting blood glucose[1]	0,55 mM	0,65 mM
Incidence of hypoglycaemia at endpoint	25 %	25 %
Bodyweight gain[2]	2,33 kg	0,96 kg

[1] from baseline to end of HUMALOG MIX 25 treatment.

[2] in patients randomised to HUMALOG MIX 25 during the first crossover period.

5.2. Pharmacokinetic properties

The pharmacokinetics of insulin lispro reflect a compound that is rapidly absorbed and achieves peak blood levels 30 to 70 minutes following subcutaneous injection. The

pharmacokinetics of insulin lispro protamine suspension are consistent with those of an intermediate acting insulin such as NPH. The pharmacokinetics of HUMALOG MIX 25 and HUMALOG MIX 50 are representative of the individual pharmacokinetic properties of the two components. When considering the clinical relevance of these kinetics, it is more appropriate to examine the glucose utilisation curves (as discussed in 5.1).

Insulin lispro maintains more rapid absorption when compared to soluble human insulin in patients with renal impairment. In patients with type 2 diabetes over a wide range of renal function the pharmacokinetic differences between insulin lispro and soluble human insulin were generally maintained and shown to be independent of renal function. Insulin lispro maintains more rapid absorption and elimination when compared to soluble human insulin in patients with hepatic impairment.

5.3 Preclinical safety data

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. Studies also demonstrate that the dissociation of binding to the insulin receptor of insulin lispro is equivalent to human insulin. Acute, one-month and twelve-month toxicology studies produced no significant toxicity findings.

Insulin lispro did not induce fertility impairment, embryotoxicity or teratogenicity in animal studies.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

HUMALOG MIX 25 and HUMALOG MIX 50 (Suspension for injection) contain:

Protamine sulphate

Metacresol

Phenol

Glycerol

Dibasic sodium phosphate (heptahydrate)

Zinc oxide

Water for injections

Hydrochloric acid and sodium hydroxide may be used to adjust pH.

6.2. Incompatibilities

Mixing HUMALOG MIX 25 or HUMALOG MIX 50 with other insulins has not been studied.

In the absence of compatibility studies, this medicine must not be mixed with any other medicines.

6.3. Shelf-life

The expiration date of this medicine is printed on the carton.

After first use/ after cartridge insertion

28 days.

6.4 Special precautions for storage

Do not freeze. Do not expose to excessive heat or direct sunlight.

HUMALOG MIX 25

Before use:

Store in a refrigerator at 2 to 8 ºC until time of use.

After first use/after cartridge insertion:

Vial

Store in use vial (after the stopper has been punctured) refrigerated for up to 28 days.

If refrigeration is not possible, the vial in use can be stored unrefrigerated at or below 30 °C for up to 28 days.

Cartridge

Store in use cartridge (after the disc seal has been punctured) unrefrigerated at or below 30 °C for up to 28 days. The pen with the inserted cartridge should not be stored with the needle attached.

KwikPen

Store in use pen (after the disc seal has been punctured) unrefrigerated at or below 30 °C for up to 28 days. The pre-filled pen should not be stored with the needle attached.

HUMALOG MIX 50

Before use:

Store in a refrigerator at 2 to 8 ºC until time of use.

After first use/after cartridge insertion:

Cartridge

Store in use cartridge (after the disc seal has been punctured) unrefrigerated at or below 30 °C for up to 28 days. The pen with the inserted cartridge should not be stored with the needle attached.

KwikPen

Store in use pen (after the disc seal has been punctured) unrefrigerated at or below 30 °C for up to 28 days. The pre-filled pen should not be stored with the needle attached.

6.5 Nature and contents of container

HUMALOG MIX 25

Vials: A 10 ml, clear, transparent, colourless flint-glass vial, sealed with a rubber stopper with a red aluminium seal, packed into an outer cardboard carton. Available in packs of 1.

Cartridges: A 3,0 ml, clear, transparent, colourless flint-glass cartridge sealed with a red rubber plunger head at the bottom of the cartridge and a rubber disc with an outer red aluminium seal at the top of the cartridge. The cartridges should be used in reusable pen injectors. Cartridges are packed into plastic blisters. Blisters are packed into an outer cardboard carton. Available in packs of 5.

Disposable pens: Prefilled, disposable pen injectors containing 3,0 ml cartridges are packed into an outer cardboard carton. The disposable pen injector consists of a glass cartridge, permanently sealed inside the pen's clear protective housing. The pen components consist of a pen cap, cartridge holder, pen body and dose knob. Available in packs of 5.

HUMALOG MIX 50

Cartridges: A 3,0 ml, clear, transparent, colourless flint-glass cartridge sealed with a red rubber plunger head at the bottom of the cartridge and a rubber disc with an outer red aluminium seal at the top of the cartridge. The cartridges should be used in reusable pen injectors. Cartridges are packed into plastic blisters. Blisters are packed into an outer cardboard carton. Available in packs of 5.

Disposable pens: Prefilled, disposable pen injectors containing 3,0 ml cartridges are packed into an outer cardboard carton. The disposable pen injector consists of a glass cartridge, permanently sealed inside the pen's clear protective housing. The pen components consist of a pen cap, cartridge holder, pen body and dose knob. Available in packs of 5.

6.6 Special precautions for disposal and other handling

Instructions for use and handling

To prevent the possible transmission of disease, each cartridge or pen must be used by one patient only, even if the needle on the delivery device is changed. Patients using vials must never share needles or syringes. The patient should discard the needle after every injection.

HUMALOG MIX 25 and HUMALOG MIX 50 should be examined frequently and should not be used if clumps of material are present or if solid white particles stick to the bottom or wall of the container, giving it a frosted appearance.

Preparing a dose

Vials containing HUMALOG MIX 25 should be rotated in the palms of the hands before use to resuspend the insulin until it appears uniformly cloudy or milky.

Cartridges and KwikPens containing HUMALOG MIX 25 or HUMALOG MIX 50 should be rotated in the palms of the hands ten times and inverted 180° ten times immediately before use to resuspend the insulin until it appears uniformly cloudy or milky. If not, repeat the above procedure until contents are mixed. Cartridges contain a small glass bead to assist mixing.

Do not shake vigorously as this may cause frothing which may interfere with the correct measurement of the dose.

Vial

The vial is to be used in conjunction with an appropriate syringe (100-unit markings).

1. Wash your hands.
2. If using a new vial, flip off the plastic protective cap, but **do not** remove the stopper.
3. Draw air into the syringe equal to the prescribed HUMALOG MIX 25 dose.

Wipe the top of the vial with a swab. Put the needle through rubber top of the HUMALOG MIX 25 vial and inject the air into the vial.

4. Turn the vial and syringe upside down. Hold the vial and syringe firmly in one hand.
5. Making sure the tip of the needle is in the HUMALOG MIX 25, withdraw the correct dose into the syringe.
6. Before removing the needle from the vial, check the syringe for air bubbles that reduce the amount of HUMALOG MIX 25 in it. If bubbles are present, hold the syringe straight up and tap its side until the bubbles float to the top. Push them out with the plunger and withdraw the correct dose.

Remove the needle from the vial and lay the syringe down so that the needle does not touch anything.

Cartridge

HUMALOG MIX 25 and HUMALOG MIX 50 cartridges are to be used with a Lilly reusable insulin pen and should not be used with any other reusable pen as the dosing accuracy has not been established with other pens.

The instructions with each individual pen must be followed for loading the cartridge, attaching the needle, and administering the insulin injection.

KwikPen

Before using the KwikPen the user manual included in the pack must be read carefully. The KwikPen has to be used as recommended in the user manual.

Pens should not be used if any part looks broken or damaged.

Injecting a dose

If using a pre-filled or reusable pen refer to the detailed instructions for preparing the pen and injecting the dose, the following is a general description.

1. Wash your hands.
2. Choose a site for injection.
3. Clean the skin as instructed.
4. Stabilise the skin by spreading it or pinching up a large area. Insert the needle and inject as instructed.
5. Pull the needle out and apply gentle pressure over the injection site for several seconds. Do not rub the area.
6. Using the outer needle cap, unscrew the needle and dispose of it safely.
7. Use of injection sites should be rotated so that the same site is not used more than approximately once a month.

Any unused product or waste material should be disposed of in accordance with local requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Eli Lilly (S.A.) (Pty) Ltd

First Floor, Golden Oak House, Ballyoaks Office Park,

35 Ballyclare Drive,

Bryanston, 2191

Johannesburg,

RSA.

8. REGISTRATION NUMBER(S)

HUMALOG MIX 25: 33/21.1/0073

HUMALOG MIX 50: 33/21.1/0074

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

HUMALOG MIX 25: 17 June 1999

HUMALOG MIX 50: 25 October 2001

10. DATE OF REVISION OF THE TEXT

13 October 2023

Registration Details for Botswana		
Humalog Mix 25 Vial	Reg. No.: BOT0200501	Schedule 2
Humalog Mix 25 Prefilled Pens (KwikPens)	Reg. No.: BOT0200501A	Schedule 2
Humalog Mix 25 Cartridges	Reg. No.: BOT0200501B	Schedule 2
Humalog Mix 50 Prefilled Pens (KwikPens)	Reg. No.: BOT0700979	Schedule 2
Humalog Mix 50 Cartridges	Reg. No.: BOT0700979A	Schedule 2
Please report any suspected ADRs to BoMRA through e-reporting https://primaryreporting.who-umc.org/BW and e-mail reportadr@bomra.co.bw.		

Registration Details for Namibia		
Humalog Mix 25 Vial	Reg. No.: 04/21.1/0645	Schedule NS2

Humalog Mix 25 Prefilled Pens (KwikPens)	Reg. No.: 04/21.1/0645	Schedule NS2
Humalog Mix 25 Cartridges	Reg. No.: 04/21.1/0645	Schedule NS2
Humalog Mix 50 Prefilled Pens (KwikPens)	Reg. No.: 06/21.1/0254	Schedule NS2
Humalog Mix 50 Cartridges	Reg. No.: 06/21.1/0254	Schedule NS2