1. NAME OF THE MEDICINAL PRODUCT

Humalog 100 units/ml solution for injection in vial
Humalog 100 units/ml solution for injection in cartridge
Humalog 100 units/ml KwikPen solution for injection in a pre-filled pen
Humalog 100 units/ml Junior KwikPen solution for injection in a pre-filled pen

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains 100 units of insulin lispro* (equivalent to 3.5mg).

Vial

Each vial contains 1000 units insulin lispro in 10 ml solution.

Cartridge

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

KwikPen

Each pre-filled pen contains 300 units of insulin lispro in 3 ml solution. Each KwikPen delivers 1-60 units in steps of 1 unit.

Junior KwikPen

Each pre-filled pen contains 300 units of insulin lispro in 3 ml solution. Each Junior KwikPen delivers 0.5 – 30 units in steps of 0.5 units.

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

For a full list of excipients, see section 6.1.

Not all presentations may be marketed.

3. PHARMACEUTICAL FORM

Solution for injection.

Clear, colourless, aqueous solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of adults and children with diabetes mellitus who require insulin for the maintenance of normal glucose homeostasis. Humalog is also indicated for the initial stabilisation of diabetes mellitus.

4.2 Posology and method of administration

Posology
The dose should be determined by the physician, according to the requirement of the patient.

Junior KwikPen
Humalog 100 units/ml Junior KwikPen is suitable for patients who may benefit from finer insulin dose adjustments.

Humalog may be given shortly before meals. When necessary Humalog can be given soon after meals.

Humalog takes effect rapidly and has a shorter duration of activity (2 to 5 hours) given subcutaneously as compared with soluble insulin. This rapid onset of activity allows a Humalog injection (or, in the case of administration by continuous subcutaneous infusion, a Humalog bolus) to be given very close to mealtime. The time course of action of any insulin may vary considerably in different individuals or at different times in the same individual. The faster onset of action compared to soluble human insulin is maintained regardless of injection site. As with all insulin preparations, the duration of action of Humalog is dependent on dose, site of injection, blood supply, temperature, and physical activity.

Humalog can be used in conjunction with a longer-acting insulin or oral sulphonylurea agents, on the advice of a physician.

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
Humalog can be used in adolescents and children (see section 5.1).

Method of administration

Subcutaneous use

Humalog preparations should be given by subcutaneous injection.

The KwikPen and Junior KwikPen are only suitable for subcutaneous injections. Humalog in cartridges is only suitable for subcutaneous injections from a Lilly reusable pen or compatible pump systems for continuous subcutaneous insulin infusion (CSII).

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 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 KwikPens
Humalog KwikPen is available in two strengths. The Humalog 100 units/ml KwikPen (and Humalog
200 units/ml KwikPen) delivers 1 – 60 units in steps of 1 unit in a single injection. The Humalog 100 units/ml Junior KwikPen delivers 0.5 – 30 units in steps of 0.5 units in a single injection. **The number of insulin units is shown in the dose window of the pen regardless of strength and no** dose conversion should be done when transferring a patient to a new strength or to a pen with a different dose step.

Use of Humalog in an insulin infusion pump
For subcutaneous injection of Humalog using a continuous infusion pump, you may fill the pump reservoir from a Humalog 100 units/ml vial. Some pumps are compatible with cartridges that can be inserted intact into the pump.

Only certain CE-marked insulin infusion pumps may be used to infuse insulin lispro. Before infusing insulin lispro, the pump manufacturer's instructions should be studied to ascertain the suitability for the particular pump. Use the correct reservoir and catheter for the pump. When filling the pump reservoir avoid damaging it by using the correct needle length on the filling system. The infusion set (tubing and cannula) should be changed in accordance with the instructions in the product information supplied with the infusion set. In the event of a hypoglycaemic episode, the infusion should be stopped until the episode is resolved. If repeated or severe low blood glucose levels occur consider the need to reduce or stop an insulin infusion. A pump malfunction or obstruction of the infusion set can result in a rapid rise in glucose levels. If an interruption to insulin flow is suspected, follow the instructions in the pump product literature. When used with an insulin infusion pump, Humalog should not be mixed with any other insulin.

Intravenous administration of insulin

If necessary, Humalog may also be administered intravenously, for example: for the control of blood glucose levels during ketoacidosis, acute illnesses or during intra and post operative periods.

Humalog 100 units /ml is available in vials if administration of intravenous injection is necessary.

Intravenous injection of insulin lispro should be carried out following normal clinical practise for intravenous injections, for example by an intravenous bolus or by an infusion system. Frequent monitoring of the blood glucose levels is required.

Infusion systems at concentrations from 0.1 units/ml to 1.0 units/ml insulin lispro in 0.9% sodium chloride or 5% dextrose are stable at room temperature for 48 hours. It is recommended that the system is primed before starting the infusion to the patient.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

Hypoglycaemia.

4.4 Special warnings and precautions for use

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered medicinal product should be clearly recorded.

Transferring 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. For fast-acting insulins, any patient also on basal insulin must optimise dosage of both insulins to obtain glucose control across the whole day, particularly nocturnal/fasting glucose control.

Vial

When mixing Humalog with a longer acting insulin, the shorter-acting Humalog should be drawn into the syringe first, to prevent contamination of the vial by the longer-acting insulin. Mixing of the insulins ahead of time or just before the injection should be on advice of the physician. However, a consistent routine must be followed.

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. A consequence of the pharmacodynamics of rapid-acting insulin analogues is that if hypoglycaemia occurs, it may occur earlier after an injection when compared with soluble human insulin.

Combination of Humalog 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 heart failure. This should be kept in mind, if treatment with the combination of pioglitazone and Humalog 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.

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

4.5 Interaction with other medicinal products and other forms of interaction

Insulin requirements may be increased by medicinal products 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 reduced in the presence of medicinal products with hypoglycaemic activity, such as oral hypoglycaemics, salicylates (for example, acetylsalicylic acid), sulpha antibiotics, certain antidepressants (monoamine oxidase inhibitors, selective serotonin reuptake inhibitors), certain angiotensin converting enzyme inhibitors (captopril, enalapril), angiotensin II receptor blockers, betablockers, octreotide or alcohol.

The physician should be consulted when using other medications in addition to Humalog (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.

Breast-feeding

Patients with diabetes who are breast-feeding 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 classes	**Very common**	**Common**	**Uncommon**	**Rare**	**Very rare**	**Not known**
Immune system disorders						
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: Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org'

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, fast-acting, ATC code: A10AB04

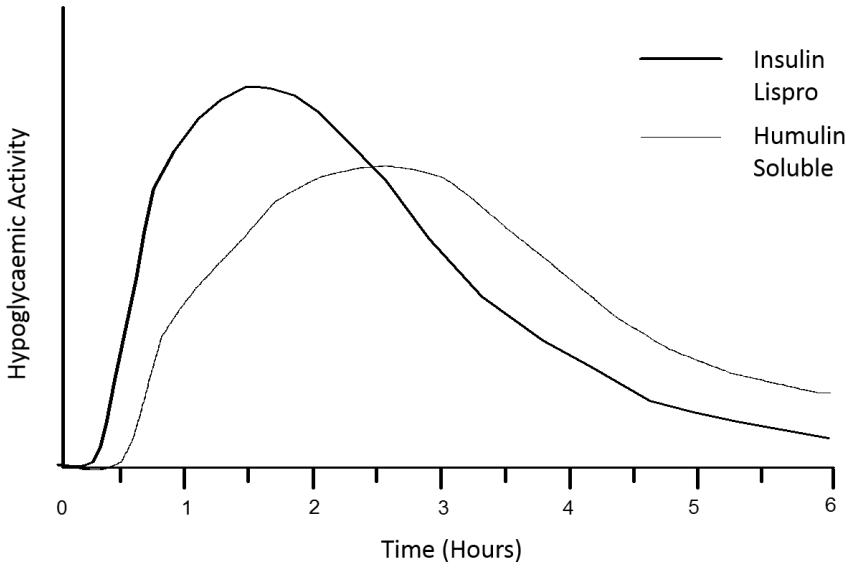
The primary activity of insulin lispro is the regulation of glucose metabolism.

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). Insulin lispro takes effect rapidly and has a shorter duration of activity (2 to 5 hours) when compared to soluble insulin.

Clinical trials in patients with type 1 and type 2 diabetes have demonstrated reduced postprandial hyperglycaemia with insulin lispro compared to soluble human insulin.

As with all insulin preparations, the time course of insulin lispro action may vary in different individuals or at different times in the same individual and is dependent on dose, site of injection, blood supply, temperature and physical activity. The typical activity profile following subcutaneous injection is illustrated below.



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

Clinical trials have been performed in children (61 patients aged 2 to 11) and children and adolescents
(481 patients aged 9 to 19 years), comparing insulin lispro to human soluble insulin. The pharmacodynamic profile of insulin lispro in children is similar to that seen in adults.

When used in subcutaneous infusion pumps, treatment with insulin lispro has been shown to result in lower glycosylated haemoglobin levels compared to soluble insulin. In a double-blind, crossover study, the reduction in glycosylated haemoglobin levels after 12 weeks dosing was 0.37 percentage points with insulin lispro, compared to 0.03 percentage points for soluble insulin ($p = 0.004$).

In patients with type 2 diabetes on maximum doses of sulphonyl urea agents, studies have shown that the addition of insulin lispro significantly reduces HbA_{1c} compared to sulphonyl urea alone. The reduction of HbA_{1c} would also be expected with other insulin products e.g. soluble or isophane insulins.

Clinical trials in patients with type 1 and type 2 diabetes have demonstrated a reduced number of episodes of nocturnal hypoglycaemia with insulin lispro compared to soluble human insulin. In some studies, reduction of nocturnal hypoglycaemia was associated with increased episodes of daytime hypoglycaemia.

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.

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. 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

m-Cresol
Glycerol
Dibasic sodium phosphate. $7H_2O$
Zinc oxide
Water for injections
Hydrochloric acid and sodium hydroxide maybe used to adjust pH.

6.2 Incompatibilities

Vial

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.

Cartridge, KwikPen and Junior KwikPen
These medicinal products should not be mixed with any other insulin or any other medicinal product.

6.3 Shelf life

Before use

The expiration date of this medicinal product 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.

Before use
Store in a refrigerator (2°C - 8°C).

After first use / after cartridge insertion

Vial

Store in a refrigerator (2°C - 8°C) or below 30°C.

Cartridge

Store below 30°C. Do not refrigerate. The pen with the inserted cartridge should not be stored with the needle attached.

KwikPen and Junior KwikPen

Store below 30°C. Do not refrigerate. The pre-filled pen should not be stored with the needle attached.

6.5 Nature and contents of container

Vial

The solution is contained in type I flint glass vials, sealed with butyl or halobutyl stoppers and secured with aluminium seals. Dimeticone or silicone emulsion may be used to treat the vial stoppers.

10 ml vial: Packs of 1 or 2 or a multipack of 5 (5 packs of 1). Not all packs may be marketed

Cartridge

The solution is contained in type I flint glass cartridges, sealed with butyl or halobutyl disc seals and plunger heads, and are secured with aluminium seals. Dimeticone or silicone emulsion may be used to treat the cartridge plungers, and/or the glass cartridges.

3 ml cartridge: Packs of 2, 5 or a multipack of 10 (2 packs of 5). Not all packs may be marketed

KwikPen

The solution is contained in type I flint glass cartridges, sealed with butyl or halobutyl disc seals and plunger heads and are secured with aluminium seals. Dimeticone or silicone emulsion may be used to treat the cartridge plunger, and/or the glass cartridge. The 3 ml cartridges are sealed in a disposable pen injector, called the “KwikPen”. Needles are not included.

3 ml KwikPen: Packs of 1, 5 or a multipack of 10 (2 packs of 5). Not all packs may be marketed

Junior KwikPen

Type I glass cartridges, sealed with halobutyl disc seals secured with aluminium seals and bromobutyl plunger heads. Dimeticone or silicone emulsion may be used to treat the cartridge plunger. The 3 ml cartridges are sealed in a disposable pen injector, called the “Junior KwikPen”. Needles are not included.

3 ml Junior KwikPen: Packs of 1 prefilled pen, 5 prefilled pens or a multipack of 10 (2 packs of 5) prefilled pens. Not all packs may be marketed

6.6 Special precautions for disposal and other handling

Instructions for use and handling

To prevent the possible transmission of disease, each cartridge or pre-filled 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.

The Humalog solution should be clear and colourless. Humalog should not be used if it appears cloudy, thickened, or slightly coloured or if solid particles are visible.

Do not mix insulin in vials with insulin in cartridges. See section 6.2.

Preparing a dose

Vial

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

i) Humalog

1. Wash your hands.

2. If using a new vial, flip off the plastic protective cap, but **do not** remove the stopper.

3. If the therapeutic regimen requires the injection of basal insulin and Humalog at the same time, the two can be mixed in the syringe. If mixing insulins, refer to the instructions for mixing that follow in Section (ii) and 6.2.

4. Draw air into the syringe equal to the prescribed Humalog dose. Wipe the top of the vial with a swab. Put the needle through the rubber top of the Humalog vial and inject the air into the vial.

5. Turn the vial and syringe upside down. Hold the vial and syringe firmly in one hand.

6. Making sure the tip of the needle is in the Humalog, withdraw the correct dose into the syringe.

7. Before removing the needle from the vial, check the syringe for air bubbles that reduce the amount of Humalog 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.

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

ii) Mixing Humalog with longer-acting Human Insulins (see section 6.2)

1. Humalog should be mixed with longer-acting human insulins only on the advice of a doctor.

2. Draw air into the syringe equal to the amount of longer-acting insulin being taken. Insert the needle into the longer-acting insulin vial and inject the air. Withdraw the needle.

3. Now inject air into the Humalog vial in the same manner, but **do not** withdraw the needle.

4. Turn the vial and syringe upside down.

5. Making sure the tip of the needle is in the Humalog, withdraw the correct dose of Humalog into the syringe.

6. Before removing the needle from the vial, check the syringe for air bubbles that reduce the amount of Humalog 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.

7. Remove the needle from the vial of Humalog and insert it into the vial of the longer-acting insulin. Turn the vial and syringe upside down. Hold the vial and syringe firmly in one hand and shake gently. Making sure

the tip of the needle is in the insulin, withdraw the dose of longer-acting insulin.

8. Withdraw the needle and lay the syringe down so that the needle does not touch anything.

Cartridge
Humalog 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.

*Kwi*kPen and Junior KwikPen
Before using the pre-filled pen the user manual included in the package leaflet must be read carefully. The pre-filled pen 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. Dispose of the syringe and needle safely. For an injection device use the outer needle cap, unscrew the needle and dispose of it safely.

7. Use of the injection sites should be rotated so that the same is not used more than approximately once a month.

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

9. DATE OF RENEWAL OF AUTHORISATION

26-01-2026

10. DATE OF REVISION OF THE TEXT

26-01-2026