LYUMJEV® (insulin lispro)

Lyumjev is indicated for the treatment of diabetes mellitus in adults only.
Lyumjev is not indicated for use in children.[1]

Safety

No increase in hypoglycaemia risk vs Humalog® (insulin lispro), and low incidence of injection site reactions[2,3]

Efficacy

- Lyumjev met the primary objective - noninferiority to Humalog in HbA1c change from baseline to week 26[2,3]*
- Superior post prandial glucose control in people with type 1 and type 2 diabetes at both 1 and 2 hours vs Humalog[2,3]*
- Provided a postmeal glucose response that is closer to physiological insulin when compared to Humalog[4]**

*In both T1DM and T2DM patients **In T1DM patients

Could people on mealtime insulin benefit from an **inject and eat** experience?

Lyumjev® patients receive a physical and digital support pack to get off to the best possible start.

This includes:

- Patient Leaflet
- Discovery Sheet
- ID Card
- Patient videos

Product description	List price	EAN	PIP Code
1 x 10 ml **vial** 100units/ml	£ 16.61	5014602101732	415-3839
5 x 3 ml **cartridges** 100units/ml	£ 28.31	5014602101749	415-3755
5 x 3 ml **KwikPen** 100units/ml	£ 29.46	5014602101756	415-3730
5 x 3 ml **KwikPen** 200units/ml	£ 58.92	5014602101770	415-3722
5 x 3 ml **Junior KwikPen** 100units/ml	£ 29.46	5014602101763	415-3748

To find out more you can:

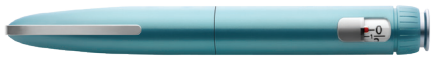
Contact your local Lilly Representative

Visit: lillydiabetes.co.uk

Call Lilly on **01256 315 000**

HumaPen® Savvio™

CE 0344



Pip-Code: 369-6564

Pip-Code: 369-6531

Pip-Code: 369-6549

BD All Lilly pens are recommended for use with BD Micro-Fine+ 5mm and 8mm Pen Needles

Lilly

LYUMJEV® VIAL, CARTRIDGE, KWIKPEN®, TEMPO PEN® AND JUNIOR KWIKPEN® (insulin lispro)

PRESCRIBING INFORMATION
United Kingdom (Great Britain)

Presentation Lyumjev is available as a solution of 100 units/mL insulin lispro in either 10 mL vial, 3 mL cartridge, 3 mL KwikPen, 3 mL Junior KwikPen or 3 mL Tempo Pen (each pen contains 300 units of insulin lispro in 3 mL solution). It is also available as a solution of 200 units/mL in 3 mL KwikPen (each pen contains 600 units of insulin lispro in 3 mL solution). **Uses** Treatment of diabetes mellitus in adults. **Dosage and Administration** Lyumjev is not indicated for use in children and adolescents below 18 years of age. Lyumjev is a mealtime insulin for subcutaneous injection and should be administered zero to two minutes before the start of the meal, with the option to administer up to 20 minutes after starting the meal. Lyumjev 100 units/mL is suitable for continuous subcutaneous insulin infusion (CSII) and is used for both the bolus and basal insulin requirement. The initial dose should take into account the type of diabetes, weight of the patient and their blood glucose levels. The early onset of action must be considered when prescribing Lyumjev. The time course of action of any insulin may vary considerably in different individuals or at different times in the same individual. If converting from another mealtime insulin to Lyumjev, the change can be done on a unit-to-unit basis. The potency of insulin analogues, including Lyumjev, is expressed in units. One (1) unit of Lyumjev corresponds to 1 international unit (IU) of human insulin or 1 unit of other fast-acting insulin analogues. Patients who forget a mealtime dose should monitor their blood glucose level to decide if an insulin dose is needed, and to resume their usual dosing schedule at the next meal. Patients should be trained on proper use and injection technique before initiating Lyumjev. Lyumjev should be injected subcutaneously into the abdomen, upper arm, thigh or buttocks. Injection or infusion sites should always be rotated within the same region in order to reduce the risk of lipodystrophy and cutaneous amyloidosis. Lyumjev is available in two concentrations: Lyumjev 100 units/mL KwikPen and Lyumjev 200 units/mL KwikPen. The number of insulin units is shown in the dose window of the pen regardless of concentration and no dose conversion should be done when transferring a patient to a new concentration or to a pen with a different dose step. The Lyumjev 100 units/ml Tempo Pen delivers 1 – 60 units in steps of 1 unit in a single injection. *Use of Lyumjev in an insulin infusion pump* Use a pump suitable for insulin infusion. Fill the pump reservoir from a Lyumjev 100 units/mL vial. *Intravenous use* Lyumjev 100 units/mL is available in vials if administration of intravenous injection is necessary and must be performed under medical supervision. **Contra-indications** Hypoglycaemia. Hypersensitivity to the active substance or to any of the excipients. **Warnings and Special Precautions** *Traceability:* In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded. *Hypoglycaemia:* Hypoglycaemia is the most common adverse reaction of insulin therapy. *Hyperglycaemia:* The use of inadequate doses or discontinuation of treatment, may lead to hyperglycaemia and diabetic ketoacidosis. *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 dose adjustments:* Changes in insulin, insulin concentration, manufacturer, type, or method of administration may affect glycaemic control and predispose to hypoglycaemia or hyperglycaemia. These changes should be made cautiously under close medical supervision and the frequency of glucose monitoring should be increased. For patients with type 2 diabetes, dose adjustments in concomitant anti-diabetic treatment may be needed. *Thiazolidinediones (TZDs) used in combination with insulin:* TZDs can cause dose-related fluid retention, particularly when used in combination with insulin. Fluid retention may lead to or exacerbate heart failure. Patients treated with insulin and a TZD should be observed for signs and symptoms of heart failure. If heart failure develops, consider discontinuation of the TZD. *Hypersensitivity and allergic reactions:* Severe, life-threatening, generalised allergy, including anaphylaxis, can occur with insulin medicinal products, including Lyumjev. If hypersensitivity reactions occur, discontinue Lyumjev. *Medication errors:* Do not transfer insulin from the Lyumjev Pen 200 units/mL to a syringe. The markings on the insulin syringe will not measure the dose correctly and can result in overdose and severe hypoglycaemia. *Tempo Pen:* The Tempo Pen contains a magnet (see SmPC) that may interfere with the functions of an implantable electronic medical device, such as a pacemaker. The magnetic field extends to approximately 1.5 cm. Fertility, Pregnancy, and Lactation *Pregnancy:* A large amount of data on pregnant women indicate no malformative nor feto/neonatal toxicity of insulin lispro. Lyumjev can be used during pregnancy if clinically needed. Effects on ability to drive and use machines The patient's ability to concentrate and react may be impaired as a result of hyperglycaemia. This may constitute a risk in situations where these abilities are of special importance (eg, driving a car or using machines). **Undesirable Effects** *Very Common (≥ 1/10):* Hypoglycaemia, Infusion site reactions. *Common (≥ 1/100 to <1/10):* Injection site reactions, Allergic reactions. *Uncommon (≥ 1/1,000 to <1/100):* Lipodystrophy, Rash, Pruritus, Oedema. *Not known (cannot be estimated from the available data):* Cutaneous amyloidosis *For full details of these and other side-effects, please see the Summary of Product Characteristics, which is available at http://www.medicines.org.uk/emc/.* **Legal Category:** POM **Marketing Authorisation Numbers:**
PLGB 14895/0281
PLGB 14895/0282
PLGB 14895/0283
PLGB 14895/0284
PLGB 14895/0285
PLGB 14895/0315
Cost: Lyumjev
£16.61 - 1 X 10 mL, Lyumjev 100 units/mL vial
£28.31 - 5 X 3 mL, Lyumjev 100 units/mL cartridge
£29.46 - 5 X 3 mL, Lyumjev 100 units/mL KwikPen
£29.46 - 5 X 3 mL, Lyumjev 100 units/mL Junior KwikPen
£58.92 - 5 X 3 mL, Lyumjev 200 units/mL KwikPen
£29.46 – 5 X 3 mL, Lyumjev 100 units/mL Tempo Pen
Date of Preparation or Last Review September 2022 **Full Prescribing Information is Available From** Eli Lilly and Company Limited, Lilly House, Basing View, Basingstoke, Hampshire, RG21 4FA. Telephone: **UK (Great Britain):** + 44-(0) 1256 315000, E-mail: ukmedinfo@lilly.com, Website: www.lilly.co.uk

Adverse events and product complaints should be reported. Reporting forms and further information can be found at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events and product complaints should also be reported to Lilly: please call Lilly UK on 01256 315 000.

LYUMJEV® VIAL, CARTRIDGE, KWIKPEN®, TEMPO PEN® AND JUNIOR KWIKPEN® (insulin lispro)

PRESCRIBING INFORMATION
United Kingdom (Northern Ireland)

Presentation Lyumjev is available as a solution of 100 units/mL insulin lispro in either 10 mL vial, 3 mL cartridge, 3 mL KwikPen 3 mL Junior KwikPen or 3 mL Tempo Pen (each pen contains 300 units of insulin lispro in 3 mL solution). It is also available as a solution of 200 units/mL in 3 mL KwikPen (each pen contains 600 units of insulin lispro in 3 mL solution). **Uses** Treatment of diabetes mellitus in adults. **Dosage and Administration** Lyumjev is not indicated for use in children and adolescents below 18 years of age. Lyumjev is a mealtime insulin for subcutaneous injection and should be administered zero to two minutes before the start of the meal, with the option to administer up to 20 minutes after starting the meal. Lyumjev 100 units/mL is suitable for continuous subcutaneous insulin infusion (CSII) and is used for both the bolus and basal insulin requirement. The initial dose should take into account the type of diabetes, weight of the patient and their blood glucose levels. The early onset of action must be considered when prescribing Lyumjev. The time course of action of any insulin may vary considerably in different individuals or at different times in the same individual. If converting from another mealtime insulin to Lyumjev, the change can be done on a unit-to-unit basis. The potency of insulin analogues, including Lyumjev, is expressed in units. One (1) unit of Lyumjev corresponds to 1 international unit (IU) of human insulin or 1 unit of other fast-acting insulin analogues. Patients who forget a mealtime dose should monitor their blood glucose level to decide if an insulin dose is needed, and to resume their usual dosing schedule at the next meal. Patients should be trained on proper use and injection technique before initiating Lyumjev. Lyumjev should be injected subcutaneously into the abdomen, upper arm, thigh or buttocks. Injection or infusion sites should always be rotated within the same region in order to reduce the risk of lipodystrophy and cutaneous amyloidosis. Lyumjev is available in two concentrations: Lyumjev 100 units/mL KwikPen and Lyumjev 200 units/mL KwikPen. The number of insulin units is shown in the dose window of the pen regardless of concentration and no dose conversion should be done when transferring a patient to a new concentration or to a pen with a different dose step. The Lyumjev 100 units/ml Tempo Pen delivers 1 – 60 units in steps of 1 unit in a single injection. *Use of Lyumjev in an insulin infusion pump* Use a pump suitable for insulin infusion. Fill the pump reservoir from a Lyumjev 100 units/mL vial. *Intravenous use* Lyumjev 100 units/mL is available in vials if administration of intravenous injection is necessary and must be performed under medical supervision. **Contra-indications** Hypoglycaemia. Hypersensitivity to the active substance or to any of the excipients. **Warnings and Special Precautions** *Traceability:* In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded. *Hypoglycaemia:* Hypoglycaemia is the most common adverse reaction of insulin therapy. *Hyperglycaemia:* The use of inadequate doses or discontinuation of treatment, may lead to hyperglycaemia and diabetic ketoacidosis. *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 dose adjustments:* Changes in insulin, insulin concentration, manufacturer, type, or method of administration may affect glycaemic control and predispose to hypoglycaemia or hyperglycaemia. These changes should be made cautiously under close medical supervision and the frequency of glucose monitoring should be increased. For patients with type 2 diabetes, dose adjustments in concomitant anti-diabetic treatment may be needed. *Thiazolidinediones (TZDs) used in combination with insulin:* TZDs can cause dose-related fluid retention, particularly when used in combination with insulin. Fluid retention may lead to or exacerbate heart failure. Patients treated with insulin and a TZD should be observed for signs and symptoms of heart failure. If heart failure develops, consider discontinuation of the TZD. *Hypersensitivity and allergic reactions:* Severe, life-threatening, generalised allergy, including anaphylaxis, can occur with insulin medicinal products, including Lyumjev. If hypersensitivity reactions occur, discontinue Lyumjev. *Medication errors:* Do not transfer insulin from the Lyumjev Pen 200 units/mL to a syringe. The markings on the insulin syringe will not measure the dose correctly and can result in overdose and severe hypoglycaemia. *Tempo Pen:* The Tempo Pen contains a magnet (see SmPC) that may interfere with the functions of an implantable electronic medical device, such as a pacemaker. The magnetic field extends to approximately 1.5 cm. Fertility, Pregnancy, and Lactation *Pregnancy:* A large amount of data on pregnant women indicate no malformative nor feto/neonatal toxicity of insulin lispro. Lyumjev can be used during pregnancy if clinically needed. Effects on ability to drive and use machines The patient's ability to concentrate and react may be impaired as a result of hyperglycaemia. This may constitute a risk in situations where these abilities are of special importance (eg, driving a car or using machines). **Undesirable Effects** *Very Common (≥ 1/10):* Hypoglycaemia, Infusion site reactions. *Common (≥ 1/100 to <1/10):* Injection site reactions, Allergic reactions. *Uncommon (≥1/1,000 to <1/100):* Lipodystrophy, Rash, Pruritus, Oedema. *Not known (cannot be estimated from the available data):* Cutaneous amyloidosis *For full details of these and other side-effects, please see the Summary of Product Characteristics, which is available at https://www.emcmedicines.com/en-GB/northernireland.* **Legal Category:** POM **Marketing Authorisation Numbers:**
EU/1/20/1422/001
EU/1/20/1422/005
EU/1/20/1422/008
EU/1/20/1422/011
EU/1/20/1422/014
EU/1/20/1422/016
Cost: Lyumjev
£16.61 - 1 X 10 mL, Lyumjev 100 units/mL vial
£28.31 - 5 X 3 mL, Lyumjev 100 units/mL cartridge
£29.46 - 5 X 3 mL, Lyumjev 100 units/mL KwikPen
£29.46 - 5 X 3 mL, Lyumjev 100 units/mL Junior KwikPen
£58.92 - 5 X 3 mL, Lyumjev 200 units/mL KwikPen
£29.46 – 5 X 3 mL, Lyumjev 100 units/mL Tempo Pen
Date of Preparation or Last Review September 2022 **Full Prescribing Information is Available From** Eli Lilly and Company Limited, Lilly House, Basing View, Basingstoke, Hampshire, RG21 4FA. Telephone: **UK (Northern Ireland):** + 44-(0) 1256 315000, E-mail: ukmedinfo@lilly.com, Website: www.lilly.co.uk, ; www.lilly.ie

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Adverse events and product complaints should also be reported to Lilly: please call Lilly UK on 01256 315 000.

References:
1. Lyumjev® Summary of Product Characteristics
2. Klaff L *et al. Diabetes Obes Metab*. 2020;22:1799-1807
3. Blevins T *et al. Diabetes Care*. 2020; 43:2991-2998
4. Heise T, Linnebjerg H, Cao D, et al. Diabetes, Obesity and Metabolism 2020. epub doi: 10.1111/dom.14094.

HUMALOG® VIAL, CARTRIDGE, TEMPO PEN®, KWIKPEN® AND JUNIOR KWIKPEN® (insulin lispro)

Presentation Humalog is available as a solution of 100 units/ml insulin lispro in either 10 ml vial, 3 ml cartridge, 3 ml Tempo Pen, 3 ml KwikPen or 3 ml Junior KwikPen (each pen contains 300 units of insulin lispro in 3 ml solution). It is also available as a solution of 200 units/ml in 3 ml KwikPen (each pen contains 600 units of insulin lispro in 3 ml solution). **Uses** *100 units/ml:* 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. Humalog 100 units/ml Junior KwikPen is suitable for patients who may benefit from finer insulin dose adjustments (half insulin unit increments). *200 units/ml KwikPen:* Treatment of adults with diabetes mellitus who require insulin for the maintenance of normal glucose homeostasis. Humalog 200 units/ml KwikPen is also indicated for the initial stabilisation of diabetes mellitus. **Dosage and Administration** Humalog may be given shortly before meals and, when necessary, soon after meals. It takes effect rapidly (approximately 15 minutes) and has a shorter duration of activity (2 to 5 hours) as compared with soluble insulin. Humalog 100 units/ml should be given by subcutaneous injection or by continuous subcutaneous infusion pump. If necessary, Humalog may also be administered intravenously, for example, for the control of blood glucose levels during ketoacidosis, acute illness, or perioperatively. Humalog 100 units/ml is available in vials if administration of intravenous injection or infusion pump is necessary. Humalog 100 units/ml KwikPen, Humalog 200 units/ml KwikPen, Humalog 100 units/ml Tempo Pen and Humalog 100 units/ml Junior KwikPen should be given subcutaneously. They should not be used in an insulin infusion pump, or given intravenously. *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. *Humalog KwikPens* Humalog KwikPen is available in two strengths. For both, the needed dose is dialled in units. The Humalog 100 units/ml KwikPen and the Humalog 200 units/ml KwikPen deliver 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 pen with a different dose step. Humalog 200 units/ml KwikPen should be reserved for the treatment of patients with diabetes requiring daily doses of more than 20 units of rapid-acting insulin. The insulin lispro solution containing 200 units/ml should not be withdrawn from the pre-filled pen. **Warnings and Special Precautions** *Usage in 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. Humalog 100 units/ml can be used in adolescents and children. *Avoidance of medication errors when using insulin lispro (200 units/ml) in pre-filled pen:* The insulin lispro solution for injection containing 200 units/ml must not be transferred from the pre-filled pen, the KwikPen, to a syringe. The markings on the insulin syringe will not measure the dose correctly. Overdose can result causing severe hypoglycaemia. The insulin lispro solution for injection containing 200 units/ml must not be transferred from the KwikPen to any other insulin delivery device, including insulin infusion pumps. 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 as well as other insulin products. *Humalog Tempo Pen* The Humalog 100 units/ml Tempo Pen delivers 1 – 60 units in steps of 1 unit 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. The Tempo Pen can be used with the optional transfer module Tempo Smart Button (see SmPC). As with any insulin injection, when using the Tempo Pen, Tempo Smart Button and the mobile application, the patient should be instructed to check their blood sugar levels when considering or making decisions about another injection if they are unsure how much they have injected.

Cost (UK only): Humalog
£16.61 - 1 X 10 ml vials
£28.31 - 5 X 3 ml cartridges
£29.46 - 5 X 3 ml Humalog 100 units/ml KwikPens
£58.92 - 5 X 3 ml Humalog 200 units/ml KwikPens
£29.46 - 5 X 3 ml Humalog 100 units/ml Junior KwikPens
£29.46 – 5 X 3 ml Humalog 100 units/ml Tempo Pen

An Irish price is available on request; please see section below for contact information.

Marketing Authorisation Numbers and Holder

Humalog vial:	PLGB 14985/0244
Humalog cartridge:	PLGB 14985/0245
Humalog 100 units/ml KwikPen:	PLGB 14985/0247
Humalog 200 units/ml KwikPen:	PLGB 14985/0248
Humalog 100 units/ml Junior KwikPen:	PLGB 14985/0246
Humalog 100 units/ml Tempo Pen	PLGB14985/0254

Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands.

HUMALOG® MIX25™ VIAL, CARTRIDGE, AND KWIKPEN® HUMALOG MIX50™ CARTRIDGE AND KWIKPEN® (insulin lispro)

Presentation Humalog Mix25 is a white, sterile suspension of 100 units/ml 25 % insulin lispro solution and 75 % insulin lispro protamine suspension available as either 10 ml vial, 3 ml cartridge, or 3 ml KwikPen. Humalog Mix50 is a white, sterile suspension of 100 units/ml 50 % insulin lispro solution and 50 % insulin lispro protamine suspension available as either 3 ml cartridge or 3 ml KwikPen. **Uses** Treatment of patients with diabetes mellitus who require insulin for the maintenance of normal glucose homeostasis. **Dosage and Administration** Humalog Mix25 or Humalog Mix50 may be given shortly before meals and, when necessary, can be given soon after meals. Humalog Mix25 or Humalog Mix50 should only be given by subcutaneous injection. The rapid onset and early peak of activity of Humalog itself is observed following the subcutaneous administration of Humalog Mix25 or Humalog Mix50. The duration of action of the insulin lispro protamine suspension component is similar to that of a basal insulin. **Warnings and Special Precautions** *Usage in 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. Administration of Humalog Mix50 and Humalog Mix25 to children below 12 years of age should be considered only in case of an expected benefit when compared to soluble insulin.

Cost (UK only): Humalog Mix25/Mix50
£16.61 - 1 X 10 ml Mix25 vial
£29.46 - 5 X 3 ml Mix25 cartridges
£30.98 - 5 X 3 ml Mix25 KwikPens
£29.46 - 5 X 3 ml Mix50 cartridges
£30.98 - 5 X 3 ml Mix50 KwikPens

An Irish price is available on request; please see section below for contact information.

Marketing Authorisation Numbers and Holder

Humalog Mix25 vial:	PLGB 14895/0249
Humalog Mix25 cartridge:	PLGB 14985/0250
Humalog Mix50 cartridge:	PLGB 14985/0252
Humalog Mix25 KwikPen:	PLGB 14895/0251
Humalog Mix50 KwikPen:	PLGB 14895/0253

Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands.

HUMALOG (insulin lispro) GENERAL INFORMATION

See Summaries of Product Characteristics for additional information, including time-action profiles of all formulations.

Dosage and Administration (general)
The dosage or type of insulin should be determined according to the requirements of the patient. The time course of action of any insulin may vary considerably in different individuals or at different times in the same individual. 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. Vials are packed with instructions regarding dose preparation and administration, and these should be carefully followed. Humalog in cartridges is only suitable for subcutaneous injections from a Lilly reusable pen or compatible pump systems for continuous subcutaneous insulin infusion (CSII). Patients should be advised to always keep a spare syringe and vial, or a spare pen and cartridge. *Renal and hepatic impairment:* Insulin requirements may be reduced in the presence of renal impairment or hepatic impairment. However, in patients with chronic hepatic impairment, an increase in insulin resistance may lead to increased insulin requirements. Prefilled pens are packed with instructions on how to use them. These directions should be followed carefully. Do not use if, after resuspension, the insulin remains at the bottom, if there are clumps in the insulin, or if solid white particles stick to the bottom or wall giving the container a frosted appearance. Instructions for use and handling: *Cartridges:* To prevent the possible transmission of disease, each cartridge must be used by one patient only, even if the needle on the delivery device is changed. *KwikPens and Tempo Pens:* To prevent the possible transmission of disease, each pen must be used by one patient only, even if the needle is changed. *Vials:* Patients using vials must never share needles or syringes. The patient should discard the needle after every injection. **Contra-indications** Hypersensitivity to the active ingredient or to any of the excipients. Hypoglycaemia. **Warnings and Special Precautions (general)** *Traceability:* In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded. Transferring a patient to another type or brand of insulin should be done under strict medical supervision. Changes in strength, brand, type, species, and/or method of manufacture 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. Changes in early warning symptoms of hypoglycaemia may occur on transfer between different types of insulin products. *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 may be increased during illness or emotional disturbances. Cases of cardiac failure have been reported when pioglitazone was used in combination with insulin. If the combination is used, patients should be observed for signs and symptoms of heart failure and pioglitazone discontinued if any deterioration occurs. *Avoidance of medication errors with Humalog KwikPen:* 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. *Tempo Pen:* The Tempo Pen contains a magnet (see SmPC) that may interfere with the functions of an implantable electronic medical device, such as a pacemaker. The magnetic field extends to approximately 1.5 cm. **Fertility, Pregnancy, and Lactation** Insulin requirements usually fall during the first trimester and increase during the second and third trimesters. Patients should be advised to inform their doctors if they are pregnant or contemplating pregnancy. **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 (eg, driving a car or operating machinery). **Undesirable Effects** Hypoglycaemia is the most frequent undesirable effect of insulin therapy. Local allergy is common and usually resolves. Systemic allergy is rare but potentially more serious since severe cases may be life-threatening. Lipodystrophy is uncommon. *For full details of these and other side-effects, please see the Summary of Product Characteristics, which is available at* ***United Kingdom:*** *http://www.medicines.org.uk/emc/* **Legal Category** POM **Date of Preparation or Last Review** September 2022 **Further Information is Available From** Eli Lilly and Company Limited, Lilly House, Basing View, Basingstoke, Hampshire, RG21 4FA. Telephone: **UK (Great Britain):** + 44-(0) 1256 315 000. E-mail: ukmedinfo@lilly.com Website: www.lilly.co.uk

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Adverse events and product complaints should also be reported to Lilly: please call Lilly UK on 01256 315 000.

HUMALOG® VIAL, CARTRIDGE, TEMPO PEN®, KWIKPEN® AND JUNIOR KWIKPEN® (insulin lispro)

Presentation Humalog is available as a solution of 100 units/ml insulin lispro in either 10 ml vial, 3 ml cartridge, 3 ml Tempo Pen, 3 ml KwikPen or 3 ml Junior KwikPen (each pen contains 300 units of insulin lispro in 3 ml solution). It is also available as a solution of 200 units/ml in 3 ml KwikPen (each pen contains 600 units of insulin lispro in 3 ml solution). **Uses** *100 units/ml:* 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. Humalog 100 units/ml Junior KwikPen is suitable for patients who may benefit from finer insulin dose adjustments (half insulin unit increments). *200 units/ml KwikPen:* Treatment of adults with diabetes mellitus who require insulin for the maintenance of normal glucose homeostasis. Humalog 200 units/ml KwikPen is also indicated for the initial stabilisation of diabetes mellitus. **Dosage and Administration** Humalog may be given shortly before meals and, when necessary, soon after meals. It takes effect rapidly (approximately 15 minutes) and has a shorter duration of activity (2 to 5 hours) as compared with soluble insulin. Humalog 100 units/ml should be given by subcutaneous injection or by continuous subcutaneous infusion pump. If necessary, Humalog may also be administered intravenously, for example, for the control of blood glucose levels during ketoacidosis, acute illness, or perioperatively. Humalog 100 units/ml is available in vials if administration of intravenous injection or infusion pump is necessary. Humalog 100 units/ml KwikPen, Humalog 200 units/ml KwikPen, Humalog 100 units/ml Tempo Pen and Humalog 100 units/ml Junior KwikPen should be given subcutaneously. They should not be used in an insulin infusion pump,or given intravenously. *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. *Humalog KwikPens* Humalog KwikPen is available in two strengths. For both, the needed dose is dialled in units. The Humalog 100 units/ml KwikPen and the Humalog 200 units/ml KwikPen deliver 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 pen with a different dose step. *Humalog Tempo Pen* The Humalog 100 units/ml Tempo Pen delivers 1 – 60 units in steps of 1 unit 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. The Tempo Pen can be used with the optional transfer module Tempo Smart Button (see SmPC). As with any insulin injection, when using the Tempo Pen, Tempo Smart Button and the mobile application, the patient should be instructed to check their blood sugar levels when considering or making decisions about another injection if they are unsure how much they have injected. Humalog 200 units/ml KwikPen should be reserved for the treatment of patients with diabetes requiring daily doses of more than 20 units of rapid-acting insulin. The insulin lispro solution containing 200 units/ml should not be withdrawn from the pre-filled pen. **Warnings and Special Precautions** *Usage in 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. Humalog 100 units/ml can be used in adolescents and children. *Avoidance of medication errors when using insulin lispro (200 units/ml) in pre-filled pen:* The insulin lispro solution for injection containing 200 units/ml must not be transferred from the pre-filled pen, the KwikPen, to a syringe. The markings on the insulin syringe will not measure the dose correctly. Overdose can result causing severe hypoglycaemia. The insulin lispro solution for injection containing 200 units/ml must not be transferred from the KwikPen to any other insulin delivery device, including insulin infusion pumps. 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 as well as other insulin products.

Cost (UK (Northern Ireland) only): Humalog
£16.61 - 1 X 10 ml vials
£28.31 - 5 X 3 ml cartridges
£29.46 - 5 X 3 ml Humalog 100 units/ml KwikPens
£58.92 - 5 X 3 ml Humalog 200 units/ml KwikPens
£29.46 - 5 X 3 ml Humalog 100 units/ml Junior KwikPens
£29.46 – 5 X 3 ml Humalog 100 units/ml Tempo Pen
An Irish price is available on request; please see section below for contact information.

Marketing Authorisation Numbers and Holder

Humalog vial:	EU/1/96/007/002
Humalog cartridge:	EU/1/96/007/004
Humalog 100 units/ml KwikPen:	EU/1/96/007/031
Humalog 200 units/ml KwikPen:	EU/1/96/007/041
Humalog 100 units/ml Junior KwikPen:	EU/1/96/007/044
Humalog 100 units/ml Tempo Pen	EU/1/96/007/046

Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands.

HUMALOG® MIX25™ VIAL, CARTRIDGE, AND KWIKPEN® HUMALOG MIX50™ CARTRIDGE AND KWIKPEN® (insulin lispro)

Presentation Humalog Mix25 is a white, sterile suspension of 100 units/ml 25 % insulin lispro solution and 75 % insulin lispro protamine suspension available as either 10 ml vial, 3 ml cartridge, or 3 ml KwikPen. Humalog Mix50 is a white, sterile suspension of 100 units/ml 50 % insulin lispro solution and 50 % insulin lispro protamine suspension available as either 3 ml cartridge or 3 ml KwikPen. **Uses** Treatment of patients with diabetes mellitus who require insulin for the maintenance of normal glucose homeostasis. **Dosage and Administration** Humalog Mix25 or Humalog Mix50 may be given shortly before meals and, when necessary, can be given soon after meals. Humalog Mix25 or Humalog Mix50 should only be given by subcutaneous injection. The rapid onset and early peak of activity of Humalog itself is observed following the subcutaneous administration of Humalog Mix25 or Humalog Mix50. The duration of action of the insulin lispro protamine suspension component is similar to that of a basal insulin. **Warnings and Special Precautions** *Usage in 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. Administration of Humalog Mix50 and Humalog Mix25 to children below 12 years of age should be considered only in case of an expected benefit when compared to soluble insulin.

Cost (UK (Northern Ireland) only): Humalog Mix25/Mix50
£16.61 - 1 X 10 ml Mix25 vial
£29.46 - 5 X 3 ml Mix25 cartridges
£30.98 - 5 X 3 ml Mix25 KwikPens
£29.46 - 5 X 3 ml Mix50 cartridges
£30.98 - 5 X 3 ml Mix50 KwikPens
An Irish price is available on request; please see section below for contact information.

Marketing Authorisation Numbers and Holder

Humalog Mix25 vial:	EU/1/96/007/005
Humalog Mix25 cartridge:	EU/1/96/007/008
Humalog Mix50 cartridge:	EU/1/96/007/006
Humalog Mix25 KwikPen:	EU/1/96/007/033
Humalog Mix50 KwikPen:	EU/1/96/007/035

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HUMALOG (insulin lispro) GENERAL INFORMATION

See Summaries of Product Characteristics for additional information, including time-action profiles of all formulations.

Dosage and Administration (general)
The dosage or type of insulin should be determined according to the requirements of the patient. The time course of action of any insulin may vary considerably in different individuals or at different times in the same individual. 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. Vials are packed with instructions regarding dose preparation and administration, and these should be carefully followed. Humalog in cartridges is only suitable for subcutaneous injections from a Lilly reusable pen or compatible pump systems for continuous subcutaneous insulin infusion (CSII). Patients should be advised to always keep a spare syringe and vial, or a spare pen and cartridge. *Renal and hepatic impairment:* Insulin requirements may be reduced in the presence of renal impairment or hepatic impairment. However, in patients with chronic hepatic impairment, an increase in insulin resistance may lead to increased insulin requirements. Prefilled pens are packed with instructions on how to use them. These directions should be followed carefully. Do not use if, after resuspension, the insulin remains at the bottom, if there are clumps in the insulin, or if solid white particles stick to the bottom or wall giving the container a frosted appearance. Instructions for use and handling: *Cartridges:* To prevent the possible transmission of disease, each cartridge must be used by one patient only, even if the needle on the delivery device is changed. *KwikPens and Tempo Pens:* To prevent the possible transmission of disease, each pen must be used by one patient only, even if the needle is changed. *Vials:* Patients using vials must never share needles or syringes. The patient should discard the needle after every injection. **Contra-indications** Hypersensitivity to the active ingredient or to any of the excipients. Hypoglycaemia. **Warnings and Special Precautions (general)** *Traceability:* In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded. Transferring a patient to another type or brand of insulin should be done under strict medical supervision. Changes in strength, brand, type, species, and/or method of manufacture 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. Changes in early warning symptoms of hypoglycaemia may occur on transfer between different types of insulin products. *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 may be increased during illness or emotional disturbances. Cases of cardiac failure have been reported when pioglitazone was used in combination with insulin. If the combination is used, patients should be observed for signs and symptoms of heart failure and pioglitazone discontinued if any deterioration occurs. *Avoidance of medication errors with Humalog KwikPen:* 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. *Tempo Pen:* The Tempo Pen contains a magnet (see SmPC) that may interfere with the functions of an implantable electronic medical device, such as a pacemaker. The magnetic field extends to approximately 1.5 cm. **Fertility, Pregnancy, and Lactation** Insulin requirements usually fall during the first trimester and increase during the second and third trimesters. Patients should be advised to inform their doctors if they are pregnant or contemplating pregnancy. **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 (eg, driving a car or operating machinery). **Undesirable Effects** Hypoglycaemia is the most frequent undesirable effect of insulin therapy. Local allergy is common and usually resolves. Systemic allergy is rare but potentially more serious since severe cases may be life-threatening. Lipodystrophy is uncommon. *For full details of these and other side-effects, please see the Summary of Product Characteristics, which is available at* ***United Kingdom (Northern Ireland):*** *https://www.emcmedicines.com/en-GB/northernireland, or* ***Ireland:*** *http://www.medicines.ie/.* **Legal Category** POM **Date of Preparation or Last Review** September 2022 **Further Information is Available From** Eli Lilly and Company Limited, Lilly House, Basing View, Basingstoke, Hampshire, RG21 4FA. Telephone: **UK (Northern Ireland):** + 44-(0) 1256 315 000, **Ireland:** + 353-(0) 1 661 4377, E-mail: ukmedinfo@lilly.com Website: www.lilly.co.uk; www.lilly.ie

Adverse events and product complaints should be reported. Reporting forms and information can be found at UK (Northern Ireland): www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store, or Ireland: www.hpra.ie.

Adverse events and product complaints should also be reported to Lilly: please call Lilly UK on 01256 315 000, or Lilly Ireland on 01 664 0446.