

Package leaflet: Information for the user

Humalog® Mix50 100 units/ml KwikPen, suspension for injection in a pre-filled pen

(insulin lispro)

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

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Humalog Mix50 100 units/ml KwikPen, suspension for injection in a pre-filled pen but will be referred to as Humalog Mix50 KwikPen throughout this leaflet.

What is in this leaflet

1. What Humalog Mix50 KwikPen is and what it is used for
2. What you need to know before you use Humalog Mix50 KwikPen
3. How to use Humalog Mix50 KwikPen
4. Possible side effects
5. How to store Humalog Mix50 KwikPen
6. Contents of the pack and other information

1. What Humalog Mix50 KwikPen is and what it is used for

Humalog Mix50 KwikPen is used to treat diabetes. It is a premixed suspension. Its active substance is insulin lispro. 50% of the insulin lispro in Humalog Mix50 KwikPen is dissolved in water and it works more quickly than normal human insulin because the insulin molecule has been changed slightly. 50% of the insulin lispro in Humalog Mix50 KwikPen is available in a suspension together with protamine sulphate, so that its action is prolonged.

You get diabetes if your pancreas does not make enough insulin to control the level of glucose in your blood. Humalog Mix50 is a substitute for your own insulin and is used to control glucose in the long term. Humalog Mix50 works very quickly and longer than soluble insulin. You should normally use Humalog Mix50 within 15 minutes of a meal.

Your doctor may tell you to use Humalog Mix50 KwikPen as well as a longer-acting insulin. Each kind of insulin comes with another patient information leaflet to tell you about it. Do not change your insulin unless your doctor tells you to. Be very careful if you do change insulin.

The KwikPen is a disposable pre-filled pen containing 3ml (300 units, 100 units/ml) of insulin lispro. One KwikPen contains multiple doses of insulin. The KwikPen dials 1 unit at a time. **The number of units are displayed in the dose window, always check this before your injection.** You can give from 1 to 60 units in a single injection. **If your dose is more than 60 units, you will need to give yourself more than one injection.**

2. What you need to know before you use Humalog Mix50 KwikPen

Do NOT use Humalog Mix50 KwikPen

- if you think **hypoglycaemia** (low blood sugar) is starting. Further in this leaflet it tells you how to deal with mild hypoglycaemia (see section 3: If you take more Humalog Mix50 than you need).
- if you are **allergic** to insulin lispro or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

- Always check the pack and the label of the pre-filled pen for the name and type of the insulin when you get it from your pharmacy. Make sure you get the Humalog Mix50 KwikPen that your doctor has told you to use.
- If your blood sugar levels are well controlled by your current insulin therapy, you may not feel the warning symptoms when your blood sugar is falling too low. Warning signs are listed later in this leaflet. You must think carefully about when to have your meals, how often to exercise and how much to do. You must also keep a close watch on your blood sugar levels by testing your blood glucose often.
- A few people who have had hypoglycaemia after switching from animal insulin to human insulin have reported that the early warning symptoms were less obvious or different. If you often have hypoglycaemia or have difficulty recognising them, please discuss this with your doctor.

- If you answer YES to any of the following questions, tell your doctor, pharmacist or diabetes nurse
 - Have you recently become ill?
 - Do you have trouble with your kidneys or liver?
 - Are you exercising more than usual?
- The amount of insulin you need may also change if you drink alcohol.
- You should also tell your doctor, pharmacist or diabetes nurse if you are planning to go abroad. The time difference between countries may mean that you have to have your injections and meals at different times from when you are at home.
- Some patients with long-standing type 2 diabetes mellitus and heart disease or previous stroke who were treated with pioglitazone and insulin experienced the development of heart failure. Inform your doctor as soon as possible, if you experience signs of heart failure such as unusual shortness of breath or rapid increase in weight or localised swelling (oedema).
- This Pen is not recommended for use by the blind or visually impaired without the help of someone trained to use the Pen.

Skin changes at the injection site

The injection site should be rotated to prevent skin changes such as lumps under the skin. The insulin may not work very well if you inject into a lumpy area (See ‘How to use Humalog Mix50 KwikPen’). Contact your doctor if you are currently injecting into a lumpy area before you start injecting a different area. Your doctor may tell you to check your blood sugar more closely, and to adjust your insulin or your other antidiabetic medications dose.

Other medicines and Humalog Mix50 KwikPen

Your insulin needs may change if you are taking

- the contraceptive pill,
- steroids,
- thyroid hormone replacement therapy,
- oral hypoglycaemics,
- acetyl salicylic acid,
- sulpha antibiotics,
- octreotide,
- ‘beta2 stimulants’ (for example ritodrine, salbutamol or terbutaline),
- beta-blockers, or
- some antidepressants (monoamine oxidase inhibitors or selective serotonin reuptake inhibitors),
- danazol,
- some angiotensin converting enzyme (ACE) inhibitors (for example captopril, enalapril), and
- angiotensin II receptor blockers.

Please tell your doctor, if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription (see section ‘Warnings and precautions’).

Pregnancy and breast-feeding

Are you pregnant or thinking about becoming pregnant, or are you breast-feeding? The amount of insulin you need usually falls during the first three months of pregnancy and increases for the remaining six months. If you are breast-feeding, you may need to alter your insulin intake or diet. Ask your doctor for advice.

Driving and using machines

Your ability to concentrate and react may be reduced if you have hypoglycaemia. Please keep this possible problem in mind in all situations where you might put yourself and others at risk (e.g. driving a car or operating machinery). You should contact your doctor about the advisability of driving if you have:

- frequent episodes of hypoglycaemia
- reduced or absent warning signs of hypoglycaemia

Humalog Mix50 KwikPen contains sodium

This medicine contains less than 1mmol sodium (23mg) per dose, that is to say essentially ‘sodium-free’.

3. How to use Humalog Mix50 KwikPen

Always use Humalog Mix50 KwikPen exactly as your doctor has told you. You should check with your doctor if you are not sure. To prevent the possible transmission of disease, each pen must be used by you only, even if the needle is changed.

Dose

- You should normally inject Humalog Mix50 within 15 minutes of a meal. If you need to, you can inject soon after a meal. But your doctor will have told you exactly how much to use, when to use it, and how often. These instructions are only for you. Follow them exactly and visit your diabetes clinic regularly.
- If you change the type of insulin you use (for example from a human or animal insulin to a Humalog product), you may have to take more or less than before. This might just be for the first injection or it may be a gradual change over several weeks or months.
- Humalog Mix50 KwikPen is only suitable for injecting just under the skin. Speak to your doctor if you need to inject your insulin by another method.

Preparing Humalog Mix50 KwikPen

- The KwikPen should be rotated in the palms of the hands ten times and inverted 180° ten times immediately before use to resuspend 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. The cartridges 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 cartridge, giving it a frosted appearance. Check each time you inject yourself.

Getting the KwikPen ready to use (Please see user manual)

- First wash your hands.
- Read the instructions on how to use your pre-filled insulin pen. Please follow the instructions carefully. Here are some reminders.
- Use a clean needle. (Needles are not included).
- Prime your KwikPen before each use. This checks that insulin comes out and clears the air bubbles from your KwikPen. There may still be some small air bubbles left in the pen - these are harmless. But if the air bubbles are too large it may affect the insulin dose.

Injecting Humalog Mix50

- Before you make an injection, clean your skin as you have been instructed. Inject under the skin, as you were taught. Do not inject directly into a vein. After your injection, leave the needle in the skin for five seconds to make sure you have taken the whole dose. Do not rub the area you have just injected. Make sure you inject at least half an inch (1cm) from where you last injected and that you ‘rotate’ the places you inject, as you have been taught.

After injecting

- As soon as you have done the injection, unscrew the needle from the KwikPen using the outer needle cap. This will keep the insulin sterile and stop it leaking. It also stops air entering the pen and your needle clogging. **Do not share your needles. Do not share your pen.** Replace the cap on the pen.

Further injections

- Every time you use a KwikPen you must use a new needle. Before every injection, clear any air bubbles. You can see how much insulin is left by holding the KwikPen with the needle pointing up. The scale on the cartridge shows about how many units you have left.
- Do not mix any other insulin in your disposable pen. Once the KwikPen is empty, do not use it again. Please get rid of it carefully - your pharmacist or diabetes nurse will tell you how to do this.

If you use more Humalog Mix50 than you need

If you use more Humalog Mix50 than you need or are unsure how much you have injected, a low blood sugar may occur. Check your blood sugar.

If your blood sugar is low (**mild hypoglycaemia**), eat glucose tablets, sugar or drink a sugary drink. Then eat fruit, biscuits, or a sandwich, as your doctor has advised you and have some rest. This will often get you over mild hypoglycaemia or a minor insulin overdose. If you get worse and your breathing is shallow and your skin gets pale, tell your doctor at once. A glucagon injection can treat quite severe hypoglycaemia. Eat glucose or sugar after the glucagon injection. If you do not respond to glucagon, you will have to go to hospital. Ask your doctor to tell you about glucagon.

If you forget to use Humalog Mix50

If you take less Humalog Mix50 than you need, a high blood sugar may occur. Check your blood sugar.

If hypoglycaemia (low blood sugar) or hyperglycaemia (high blood sugar) is not treated they can be very serious and cause headaches, nausea, vomiting, dehydration, unconsciousness, coma or even death (see A and B in section 4 ‘Possible Side Effects’).

Three simple steps to avoid hypoglycaemia or hyperglycaemia are:

- Always keep a spare pen and cartridges, in case you lose your KwikPen or it gets damaged.
- Always carry something to show you are diabetic.
- Always carry sugar with you.

If you stop using Humalog Mix50.

If you take less Humalog Mix50 than you need, a high blood sugar may occur. Do not change your insulin unless your doctor tells you to.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Systemic allergy is rare ($\geq 1/10,000$ to $<1/1,000$). The symptoms are as follows:

- rash over the whole body
- difficulty in breathing
- wheezing
- blood pressure dropping
- heart beating fast
- sweating

If you think you are having this sort of insulin allergy with Humalog Mix50, tell your doctor at once.

Local allergy is common ($\geq 1/100$ to $<1/10$). Some people get redness, swelling or itching around the area of the insulin injection. This usually clears up in anything from a few days to a few weeks. If this happens to you, tell your doctor.

Lipodystrophy is uncommon ($\geq 1/1,000$ to $<1/100$). If you inject insulin too often at the same place, the fatty tissue may either shrink (lipoatrophy) or thicken (lipohypertrophy). Lumps under the skin may also be caused by build-up of a protein called amyloid (cutaneous amyloidosis). The insulin may not work very well if you inject into a lumpy area. Change the injection site with each injection to help prevent these skin changes.

Oedema (e.g. swelling in arms, ankles; fluid retention) has been reported, particularly at the start of insulin therapy or during a change in therapy to improve control of your blood glucose.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.

By reporting side effects, you can help provide more information on the safety of this medicine.

Common problems of diabetes

A. Hypoglycaemia

Hypoglycaemia (low blood sugar) means there is not enough sugar in the blood. This can be caused if:

- you take too much Humalog Mix50 or other insulin;
- you miss or delay meals or change your diet;
- you exercise or work too hard just before or after a meal;
- you have an infection or illness (especially diarrhoea or vomiting);
- there is a change in your need for insulin; or
- you have trouble with your kidneys or liver which gets worse.

Alcohol and some medicines can affect your blood sugar levels.

The first symptoms of low blood sugar usually come on quickly and include the following:

- tiredness
- nervousness or shakiness
- headache
- rapid heart beat
- feeling sick
- cold sweat

While you are not confident about recognising your warning symptoms, avoid situations, e.g. driving a car, in which you or others would be put at risk by hypoglycaemia.

B. Hyperglycaemia and diabetic ketoacidosis

Hyperglycaemia (too much sugar in the blood) means that your body does not have enough insulin. Hyperglycaemia can be brought about by:

- not taking your Humalog or other insulin;
- taking less insulin than your doctor tells you to;
- eating a lot more than your diet allows; or
- fever, infection or emotional stress.

Hyperglycaemia can lead to diabetic ketoacidosis. The first symptoms come on slowly over many hours or days. The symptoms include the following:

- feeling sleepy
- flushed face
- thirst
- no appetite
- fruity smell on the breath
- feeling or being sick

Severe symptoms are heavy breathing and a rapid pulse. **Get medical help immediately.**

C. Illness

If you are ill, especially if you feel sick or are sick, the amount of insulin you need may change. **Even when you are not eating normally, you still need insulin.** Test your urine or blood, follow your 'sick rules', and tell your doctor.

5. How to store Humalog Mix50 KwikPen

Keep out of the sight and reach of children.

Before the first use store your Humalog Mix50 KwikPen in a refrigerator (2°C – 8°C). Do not freeze.

Keep your Humalog Mix50 KwikPen in use at room temperature (below 30°C) and discard after 28 days. Do not put it near heat or in the sun. Do not keep the KwikPen that you are using in the fridge. The KwikPen should not be stored with the needle attached.

Do not use this medicine after the expiry date which is stated on the carton and pen labels after 'EXP'. The expiry date refers to the last day of that month.

Do not use this medicine if you notice clumps of material are present or if solid white particles stick to the bottom or wall of the cartridge, giving it a frosted appearance. Check each time you inject yourself.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Humalog Mix50 KwikPen contains

The active ingredient in the Humalog Mix50 KwikPen is insulin lispro. Insulin lispro is made in the laboratory by a 'recombinant DNA technology' process. It is a changed form of human insulin and so is different from other human and animal insulins. Insulin lispro is closely related to human insulin which is a natural hormone made by the pancreas. Each ml contains 100 units of insulin lispro in 100 units/ml suspension for injection. Each Humalog Mix50 KwikPen contains 300 units (3 millilitres). 50% of the insulin lispro in Humalog Mix50 is dissolved in water. 50% of the insulin lispro in Humalog Mix50 is available in a suspension together with protamine sulphate.

The other ingredients are protamine sulphate, m-cresol, phenol, glycerol, dibasic sodium phosphate 7H₂O, zinc oxide and water for injection. Sodium hydroxide or hydrochloric acid may have been used to adjust the acidity.

What Humalog Mix50 KwikPen looks like and contents of the pack

Humalog Mix50 KwikPen is a white, sterile suspension.

It is available in pack size of 5 x 3ml pre-filled pens.

The Humalog Mix50 in your KwikPen is the same as the Humalog Mix50, which comes in separate Humalog Mix50 cartridges. The KwikPen simply has a built in cartridge. When the KwikPen is empty you cannot use it again.

Manufactured by:

Lilly France S.A.S., Rue du Colonel Lilly, 67640 Fegersheim, France.

OR

Eli Lilly Italia S.p.A., Via Gramsci 731-733, 50019 Sesto Fiorentino, (FI) Italy.

Procured from within the EU and repackaged by the Product Licence holder:

B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

Humalog® Mix50 100 units/ml KwikPen, suspension for injection in a pre-filled pen; PLGB 18799/3223

POM

Leaflet date: 31.07.2023

'For any information about this medicine, please contact the Product Licence Holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

Tel: 0800 049 9401

Email: regulatoryaffairs@bnsthamelabs.co.uk

USER MANUAL.

Please see manual text later.

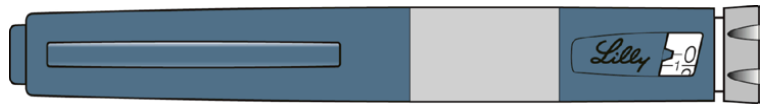
Humalog is the registered trademark of Eli Lilly and Company.

Blind or partially sighted?

Is this leaflet hard to see or read?

Call **0208 515 3763** to obtain the leaflet in a format suitable for you.

USER MANUAL
Humalog® Mix50 100 units/ml KwikPen, suspension for injection in a pre-filled pen



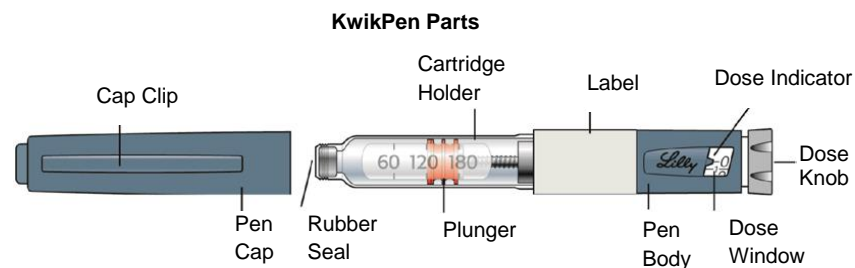
PLEASE READ THIS USER MANUAL BEFORE USE

Read the User Manual before you start taking your insulin and each time you get another KwikPen. There may be new information. This information does not take the place of talking to your healthcare professional about your medical condition or your treatment.

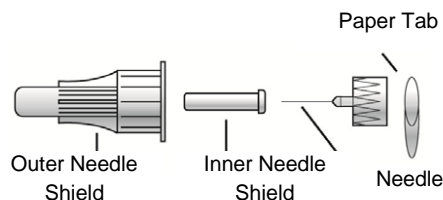
KwikPen ("Pen") is a disposable pre-filled pen containing 3ml (300 units, 100 units/ml) of insulin. You can give yourself multiple doses using one Pen. The Pen dials 1 unit at a time. You can give from 1 to 60 units in a single injection. **If your dose is more than 60 units, you will need to give yourself more than one injection.** The plunger only moves a little with each injection, and you may not notice that it moves. The plunger will only reach the end of the cartridge when you have used all 300 units in the Pen.

Do not share your pen with other people, even if the needle has been changed. Do not reuse or share needles with other people. You may give an infection to them or get an infection from them.




This Pen is not recommended for use by the blind or visually impaired without the help of someone trained to use the Pen.



Pen Needle Parts
(Needles Not Included)



How to recognise your KwikPen:

	Humalog Solution	Humalog Mix25 Suspension (cloudy insulin)	Humalog Mix50 Suspension (cloudy insulin)
Pen colour:	Blue	Blue	Blue
Dose Knob:	 Burgundy	 Yellow	 Red
Labels:	White with Burgundy Colour Bar	White with Yellow Colour Bar	White with Red Colour Bar

Supplies needed to give your injection:

- KwikPen containing your insulin.
- KwikPen compatible Needle (BD [Becton, Dickinson and Company] Pen Needles recommended)
- Swab

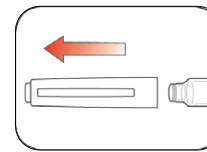
Needles and swab are not included.

Preparing your Pen

- Wash your hands with soap and water.
- Check the Pen to make sure you are taking the right type of insulin. This is especially important if you use more than 1 type of insulin.
- **Do not** use your Pen past the expiration date printed on the Label. After you start using the Pen, throw your Pen away after the in-use time specified in the Package Leaflet.
- Always use a **new Needle** for each injection to help prevent infections and blocked Needles.

Step 1:

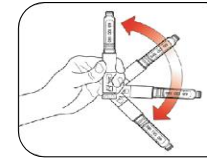
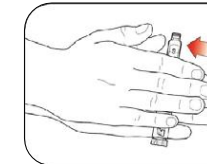
- Pull the Pen Cap straight off.
- **Do not** remove the Pen Label.
- Wipe the Rubber Seal with a swab.



Step 2:

(For HUMALOG suspensions cloudy insulins only)

- Gently roll the Pen 10 times.
- AND
- Invert the Pen 10 times.



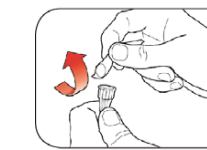
Mixing is important to make sure you get the right dose. The insulin should look evenly mixed.

Step 3:

- Check the appearance of the insulin.
 - HUMALOG solution should look clear and colourless. Do not use if it is cloudy, coloured, or has particles or clumps in it.
 - HUMALOG suspensions - cloudy insulins - should look white after mixing. **Do not** use if it looks clear or contains any clumps or particles.

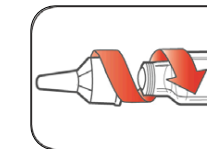
Step 4:

- Select a new Needle.
- Pull off the Paper Tab from the Outer Needle Shield.



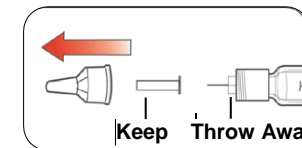
Step 5:

- Push the capped Needle straight onto the Pen and twist the Needle on until it is tight.



Step 6:

- Pull off the Outer Needle Shield. **Do not** throw it away.
- Pull off the Inner Needle Shield and throw it away.



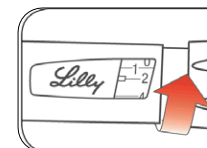
Priming your Pen

Prime before each injection.

- Priming your Pen means removing the air from the Needle and Cartridge that may collect during normal use and ensures that the Pen is working correctly.
- If you **do not** prime before each injection, you may get too much or too little insulin.

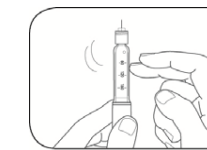
Step 7:

- To prime your Pen, turn the Dose Knob to select 2 units.



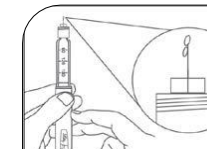
Step 8:

- Hold your Pen with the Needle pointing up. Tap the Cartridge Holder gently to collect air bubbles at the top



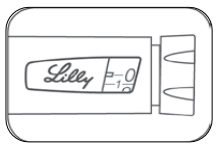
Step 9:

- Continue holding your Pen with Needle pointing up. Push the Dose Knob in until it stops, and '0' is seen in the Dose Window. Hold the Dose Knob in and count to 5 slowly.



You should see insulin at the tip of the Needle.

- If you **do not** see insulin, repeat the priming steps, but not more than 4 times.
- If you **still do not** see insulin, change the Needle and repeat the priming steps.



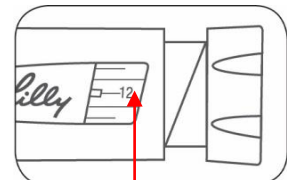
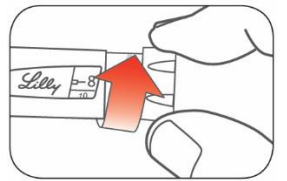
Small air bubbles are normal and will not affect your dose.

Selecting your dose

- You can give from 1 to 60 units in a single injection.
- If your dose is more than 60 units, you will need to give more than one injection.
 - If you need help deciding how to divide up your dose, ask your healthcare professional.
 - You should use a new Needle for each injection and repeat the priming step.

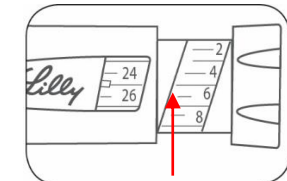
Step 10:

- Turn the Dose Knob to select the number of units you need to inject. The Dose Indicator should line up with your dose.
 - The Pen dials 1 unit at a time.
 - The Dose Knob clicks as you turn it.
 - **DO NOT** dial your dose by counting the clicks because you may dial the wrong dose.
 - The dose can be corrected by turning the Dose Knob in either direction until the correct dose lines up with the Dose Indicator.
 - The even numbers are printed on the dial.
 - The odd numbers, after the number 1, are shown as full lines.



(Example: 12 units shown in the Dose Window)

- **Always check the number in the Dose Window to make sure you have dialled the correct dose.**



(Example: 25 units shown in the Dose Window)

- The Pen will not let you dial more than the number of units left in the Pen.
- If you need to inject more than the number of units left in the Pen, you may either:
 - inject the amount left in your Pen and then use a new Pen to give the rest of your dose, **or**
 - get a new Pen and inject the full dose.
- It is normal to see a small amount of insulin left in the Pen that you cannot inject.

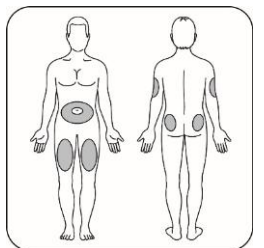
Giving your injection

- Inject your insulin as your healthcare professional has shown you.
- Change (rotate) your injection site for each injection.
- **Do not** try to change your dose while injecting.

Step 11:

- Choose your injection site.

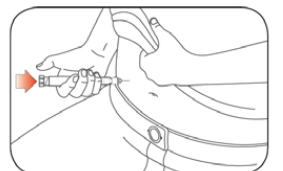
Your insulin is injected under the skin (subcutaneously) of your stomach area, buttocks, upper legs or upper arms.



- Wipe your skin with a swab, and let the injection site dry before you inject your dose.

Step 12:

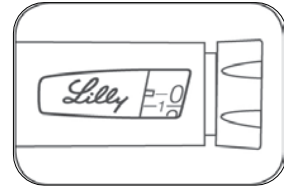
- Insert the Needle into your skin.
- Push the Dose Knob all the way in.
- Continue to hold the Dose Knob in and **slowly count to 5** before removing the Needle.



Do not try to inject your insulin by turning the Dose Knob. You will **NOT** receive your insulin by turning the Dose Knob.

Step 13:

- Pull the Needle out of your skin.
 - A drop of insulin at the Needle tip is normal. It will not affect your dose.
- Check the number in the Dose Window
 - If you see '0' in the Dose window, you have received the full amount you dialled.
 - If you do not see '0' in the Dose window, do not redial. Insert the needle into your skin and finish your injection.
 - If you **still** do not think you received the full amount you dialled for your injection, **do not start over or repeat that injection**. Monitor your blood glucose as instructed by your healthcare professional.
 - If you normally need to give 2 injections for your full dose, be sure to give your second injection.



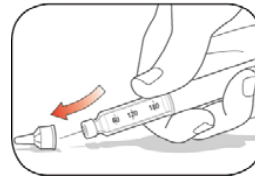
The plunger only moves a little with each injection, and you may not notice that it moves.

If you see blood after you take the Needle out of your skin, press the injection site lightly with a piece of gauze or a swab. **Do not** rub the area.

After your injection

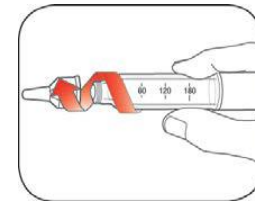
Step 14:

- Carefully replace the Outer Needle Shield.



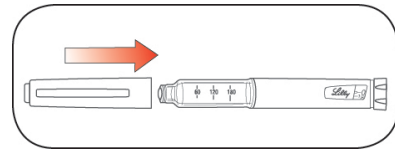
Step 15:

- Unscrew the capped Needle and dispose of it as described below (see **Disposing of Pens and Needles** section).
- Do not store the Pen with the Needle attached to prevent leaking, blocking the Needle, and air from entering the Pen.



Step 16:

- Replace the Pen Cap by lining up the Cap Clip with the Dose Indicator and pushing straight on.



Disposing of pens and needles

- Put used Needles in a sharps container or a hard plastic container with a secure lid. **Do not** throw needles directly into your household waste.
- **Do not** recycle the filled sharps container.
- Ask your healthcare professional about options to dispose of the Pen and the sharps container properly.
- The directions regarding needle handling are not intended to replace local, healthcare professional or institutional policies.

Storing your pen

Unused pens

- Store unused Pens in the refrigerator at 2°C to 8°C.
- **Do not** freeze your insulin. **Do not** use if it has been frozen.
- Unused Pens may be used until the expiration date printed on the Label, if the Pen has been kept in the refrigerator.

In-use Pen

- Store the Pen you are currently using at room temperature (below 30°C) and away from dust, food and liquids, heat and light.
- Throw away the Pen you are using after the time specified in the Package Leaflet, even if it still has insulin left in it.

General information about the safe and effective use of your pen

- **Keep your Pen and Needles out of the sight and reach of children.**
- **Do not** use your Pen if any part looks broken or damaged.
- Always carry an extra Pen in case yours is lost or damaged.

Troubleshooting

- If you cannot remove the Pen Cap, gently twist the cap back and forth, and then pull the cap straight off.
- If the Dose Knob is hard to push:
 - Pushing the Dose Knob more slowly will make it easier to inject.
 - Your Needle may be blocked. Put on a new Needle and prime the Pen.
 - You may have dust, food, or liquid inside the Pen. Throw the Pen away and get a new Pen. You may need to get a prescription from your healthcare professional.

If you have any questions or problems with your KwikPen, call your healthcare professional for help or contact your local Lilly affiliate.

Humalog is the registered trademark of Eli Lilly and Company.

Package leaflet: Information for the user

Humalog® Mix50 100 units/ml KwikPen, suspension for injection in a pre-filled pen

(insulin lispro)

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

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Humalog Mix50 100 units/ml KwikPen, suspension for injection in a pre-filled pen but will be referred to as Humalog Mix50 KwikPen throughout this leaflet.

What is in this leaflet

1. What Humalog Mix50 KwikPen is and what it is used for
2. What you need to know before you use Humalog Mix50 KwikPen
3. How to use Humalog Mix50 KwikPen
4. Possible side effects
5. How to store Humalog Mix50 KwikPen
6. Contents of the pack and other information

1. What Humalog Mix50 KwikPen is and what it is used for

Humalog Mix50 KwikPen is used to treat diabetes. It is a premixed suspension. Its active substance is insulin lispro. 50% of the insulin lispro in Humalog Mix50 KwikPen is dissolved in water and it works more quickly than normal human insulin because the insulin molecule has been changed slightly. 50% of the insulin lispro in Humalog Mix50 KwikPen is available in a suspension together with protamine sulphate, so that its action is prolonged.

You get diabetes if your pancreas does not make enough insulin to control the level of glucose in your blood. Humalog Mix50 is a substitute for your own insulin and is used to control glucose in the long term. Humalog Mix50 works very quickly and longer than soluble insulin. You should normally use Humalog Mix50 within 15 minutes of a meal.

Your doctor may tell you to use Humalog Mix50 KwikPen as well as a longer-acting insulin. Each kind of insulin comes with another patient information leaflet to tell you about it. Do not change your insulin unless your doctor tells you to. Be very careful if you do change insulin.

The KwikPen is a disposable pre-filled pen containing 3ml (300 units, 100 units/ml) of insulin lispro. One KwikPen contains multiple doses of insulin. The KwikPen dials 1 unit at a time. **The number of units are displayed in the dose window, always check this before your injection.** You can give from 1 to 60 units in a single injection. **If your dose is more than 60 units, you will need to give yourself more than one injection.**

2. What you need to know before you use Humalog Mix50 KwikPen

Do NOT use Humalog Mix50 KwikPen

- if you think **hypoglycaemia** (low blood sugar) is starting. Further in this leaflet it tells you how to deal with mild hypoglycaemia (see section 3: If you take more Humalog Mix50 than you need).
- if you are **allergic** to insulin lispro or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

- Always check the pack and the label of the pre-filled pen for the name and type of the insulin when you get it from your pharmacy. Make sure you get the Humalog Mix50 KwikPen that your doctor has told you to use.
- If your blood sugar levels are well controlled by your current insulin therapy, you may not feel the warning symptoms when your blood sugar is falling too low. Warning signs are listed later in this leaflet. You must think carefully about when to have your meals, how often to exercise and how much to do. You must also keep a close watch on your blood sugar levels by testing your blood glucose often.
- A few people who have had hypoglycaemia after switching from animal insulin to human insulin have reported that the early warning symptoms were less obvious or different. If you often have hypoglycaemia or have difficulty recognising them, please discuss this with your doctor.

- If you answer YES to any of the following questions, tell your doctor, pharmacist or diabetes nurse
 - Have you recently become ill?
 - Do you have trouble with your kidneys or liver?
 - Are you exercising more than usual?
- The amount of insulin you need may also change if you drink alcohol.
- You should also tell your doctor, pharmacist or diabetes nurse if you are planning to go abroad. The time difference between countries may mean that you have to have your injections and meals at different times from when you are at home.
- Some patients with long-standing type 2 diabetes mellitus and heart disease or previous stroke who were treated with pioglitazone and insulin experienced the development of heart failure. Inform your doctor as soon as possible, if you experience signs of heart failure such as unusual shortness of breath or rapid increase in weight or localised swelling (oedema).
- This Pen is not recommended for use by the blind or visually impaired without the help of someone trained to use the Pen.

Skin changes at the injection site

The injection site should be rotated to prevent skin changes such as lumps under the skin. The insulin may not work very well if you inject into a lumpy area (See ‘How to use Humalog Mix50 KwikPen’). Contact your doctor if you are currently injecting into a lumpy area before you start injecting a different area. Your doctor may tell you to check your blood sugar more closely, and to adjust your insulin or your other antidiabetic medications dose.

Other medicines and Humalog Mix50 KwikPen

Your insulin needs may change if you are taking

- the contraceptive pill,
- steroids,
- thyroid hormone replacement therapy,
- oral hypoglycaemics,
- acetyl salicylic acid,
- sulpha antibiotics,
- octreotide,
- ‘beta2 stimulants’ (for example ritodrine, salbutamol or terbutaline),
- beta-blockers, or
- some antidepressants (monoamine oxidase inhibitors or selective serotonin reuptake inhibitors),
- danazol,
- some angiotensin converting enzyme (ACE) inhibitors (for example captopril, enalapril), and
- angiotensin II receptor blockers.

Please tell your doctor, if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription (see section ‘Warnings and precautions’).

Pregnancy and breast-feeding

Are you pregnant or thinking about becoming pregnant, or are you breast-feeding? The amount of insulin you need usually falls during the first three months of pregnancy and increases for the remaining six months. If you are breast-feeding, you may need to alter your insulin intake or diet. Ask your doctor for advice.

Driving and using machines

Your ability to concentrate and react may be reduced if you have hypoglycaemia. Please keep this possible problem in mind in all situations where you might put yourself and others at risk (e.g. driving a car or operating machinery). You should contact your doctor about the advisability of driving if you have:

- frequent episodes of hypoglycaemia
- reduced or absent warning signs of hypoglycaemia

Humalog Mix50 KwikPen contains sodium

This medicine contains less than 1mmol sodium (23mg) per dose, that is to say essentially ‘sodium-free’.

3. How to use Humalog Mix50 KwikPen

Always use Humalog Mix50 KwikPen exactly as your doctor has told you. You should check with your doctor if you are not sure. To prevent the possible transmission of disease, each pen must be used by you only, even if the needle is changed.

Dose

- You should normally inject Humalog Mix50 within 15 minutes of a meal. If you need to, you can inject soon after a meal. But your doctor will have told you exactly how much to use, when to use it, and how often. These instructions are only for you. Follow them exactly and visit your diabetes clinic regularly.
- If you change the type of insulin you use (for example from a human or animal insulin to a Humalog product), you may have to take more or less than before. This might just be for the first injection or it may be a gradual change over several weeks or months.
- Humalog Mix50 KwikPen is only suitable for injecting just under the skin. Speak to your doctor if you need to inject your insulin by another method.

Preparing Humalog Mix50 KwikPen

- The KwikPen should be rotated in the palms of the hands ten times and inverted 180° ten times immediately before use to resuspend 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. The cartridges 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 cartridge, giving it a frosted appearance. Check each time you inject yourself.

Getting the KwikPen ready to use (Please see user manual)

- First wash your hands.
- Read the instructions on how to use your pre-filled insulin pen. Please follow the instructions carefully. Here are some reminders.
- Use a clean needle. (Needles are not included).
- Prime your KwikPen before each use. This checks that insulin comes out and clears the air bubbles from your KwikPen. There may still be some small air bubbles left in the pen - these are harmless. But if the air bubbles are too large it may affect the insulin dose.

Injecting Humalog Mix50

- Before you make an injection, clean your skin as you have been instructed. Inject under the skin, as you were taught. Do not inject directly into a vein. After your injection, leave the needle in the skin for five seconds to make sure you have taken the whole dose. Do not rub the area you have just injected. Make sure you inject at least half an inch (1cm) from where you last injected and that you ‘rotate’ the places you inject, as you have been taught.

After injecting

- As soon as you have done the injection, unscrew the needle from the KwikPen using the outer needle cap. This will keep the insulin sterile and stop it leaking. It also stops air entering the pen and your needle clogging. **Do not share your needles. Do not share your pen.** Replace the cap on the pen.

Further injections

- Every time you use a KwikPen you must use a new needle. Before every injection, clear any air bubbles. You can see how much insulin is left by holding the KwikPen with the needle pointing up. The scale on the cartridge shows about how many units you have left.
- Do not mix any other insulin in your disposable pen. Once the KwikPen is empty, do not use it again. Please get rid of it carefully - your pharmacist or diabetes nurse will tell you how to do this.

If you use more Humalog Mix50 than you need

If you use more Humalog Mix50 than you need or are unsure how much you have injected, a low blood sugar may occur.

Check your blood sugar.

If your blood sugar is low (**mild hypoglycaemia**), eat glucose tablets, sugar or drink a sugary drink. Then eat fruit, biscuits, or a sandwich, as your doctor has advised you and have some rest. This will often get you over mild hypoglycaemia or a minor insulin overdose. If you get worse and your breathing is shallow and your skin gets pale, tell your doctor at once. A glucagon injection can treat quite severe hypoglycaemia. Eat glucose or sugar after the glucagon injection. If you do not respond to glucagon, you will have to go to hospital. Ask your doctor to tell you about glucagon.

If you forget to use Humalog Mix50

If you take less Humalog Mix50 than you need, a high blood sugar may occur. Check your blood sugar.

If hypoglycaemia (low blood sugar) or hyperglycaemia (high blood sugar) is not treated they can be very serious and cause headaches, nausea, vomiting, dehydration, unconsciousness, coma or even death (see A and B in section 4 ‘Possible Side Effects’).

Three simple steps to avoid hypoglycaemia or hyperglycaemia are:

- Always keep a spare pen and cartridges, in case you lose your KwikPen or it gets damaged.
- Always carry something to show you are diabetic.
- Always carry sugar with you.

If you stop using Humalog Mix50.

If you take less Humalog Mix50 than you need, a high blood sugar may occur. Do not change your insulin unless your doctor tells you to.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Systemic allergy is rare ($\geq 1/10,000$ to $<1/1,000$). The symptoms are as follows:

- rash over the whole body
- difficulty in breathing
- wheezing
- blood pressure dropping
- heart beating fast
- sweating

If you think you are having this sort of insulin allergy with Humalog Mix50, tell your doctor at once.

Local allergy is common ($\geq 1/100$ to $<1/10$). Some people get redness, swelling or itching around the area of the insulin injection. This usually clears up in anything from a few days to a few weeks. If this happens to you, tell your doctor.

Lipodystrophy is uncommon ($\geq 1/1,000$ to $<1/100$). If you inject insulin too often at the same place, the fatty tissue may either shrink (lipoatrophy) or thicken (lipohypertrophy). Lumps under the skin may also be caused by build-up of a protein called amyloid (cutaneous amyloidosis). The insulin may not work very well if you inject into a lumpy area. Change the injection site with each injection to help prevent these skin changes.

Oedema (e.g. swelling in arms, ankles; fluid retention) has been reported, particularly at the start of insulin therapy or during a change in therapy to improve control of your blood glucose.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.

By reporting side effects, you can help provide more information on the safety of this medicine.

Common problems of diabetes

A. Hypoglycaemia

Hypoglycaemia (low blood sugar) means there is not enough sugar in the blood. This can be caused if:

- you take too much Humalog Mix50 or other insulin;
- you miss or delay meals or change your diet;
- you exercise or work too hard just before or after a meal;
- you have an infection or illness (especially diarrhoea or vomiting);
- there is a change in your need for insulin; or
- you have trouble with your kidneys or liver which gets worse.

Alcohol and some medicines can affect your blood sugar levels.

The first symptoms of low blood sugar usually come on quickly and include the following:

- tiredness
- nervousness or shakiness
- headache
- rapid heart beat
- feeling sick
- cold sweat

While you are not confident about recognising your warning symptoms, avoid situations, e.g. driving a car, in which you or others would be put at risk by hypoglycaemia.

B. Hyperglycaemia and diabetic ketoacidosis

Hyperglycaemia (too much sugar in the blood) means that your body does not have enough insulin. Hyperglycaemia can be brought about by:

- not taking your Humalog or other insulin;
- taking less insulin than your doctor tells you to;
- eating a lot more than your diet allows; or
- fever, infection or emotional stress.

Hyperglycaemia can lead to diabetic ketoacidosis. The first symptoms come on slowly over many hours or days. The symptoms include the following:

- feeling sleepy
- flushed face
- thirst
- no appetite
- fruity smell on the breath
- feeling or being sick

Severe symptoms are heavy breathing and a rapid pulse. **Get medical help immediately.**

C. Illness

If you are ill, especially if you feel sick or are sick, the amount of insulin you need may change. **Even when you are not eating normally, you still need insulin.** Test your urine or blood, follow your 'sick rules', and tell your doctor.

5. How to store Humalog Mix50 KwikPen

Keep out of the sight and reach of children.

Before the first use store your Humalog Mix50 KwikPen in a refrigerator (2°C – 8°C). Do not freeze.

Keep your Humalog Mix50 KwikPen in use at room temperature (below 30°C) and discard after 28 days. Do not put it near heat or in the sun. Do not keep the KwikPen that you are using in the fridge. The KwikPen should not be stored with the needle attached.

Do not use this medicine after the expiry date which is stated on the carton and pen labels after 'EXP'. The expiry date refers to the last day of that month.

Do not use this medicine if you notice clumps of material are present or if solid white particles stick to the bottom or wall of the cartridge, giving it a frosted appearance. Check each time you inject yourself.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Humalog Mix50 KwikPen contains

The active ingredient in the Humalog Mix50 KwikPen is insulin lispro. Insulin lispro is made in the laboratory by a 'recombinant DNA technology' process. It is a changed form of human insulin and so is different from other human and animal insulins. Insulin lispro is closely related to human insulin which is a natural hormone made by the pancreas. Each ml contains 100 units of insulin lispro in 100 units/ml suspension for injection. Each Humalog Mix50 KwikPen contains 300 units (3 millilitres). 50% of the insulin lispro in Humalog Mix50 is dissolved in water. 50% of the insulin lispro in Humalog Mix50 is available in a suspension together with protamine sulphate.

The other ingredients are protamine sulphate, m-cresol, phenol, glycerol, dibasic sodium phosphate 7H₂O, zinc oxide and water for injection. Sodium hydroxide or hydrochloric acid may have been used to adjust the acidity.

What Humalog Mix50 KwikPen looks like and contents of the pack

Humalog Mix50 KwikPen is a white, sterile suspension.

It is available in pack size of 5 x 3ml pre-filled pens.

The Humalog Mix50 in your KwikPen is the same as the Humalog Mix50, which comes in separate Humalog Mix50 cartridges. The KwikPen simply has a built in cartridge. When the KwikPen is empty you cannot use it again.

Manufacturer and Product Licence Holder

Manufactured by:

Lilly France S.A.S., Rue du Colonel Lilly, 67640 Fegersheim, France.

OR

Eli Lilly Italia S.p.A., Via Gramsci 731-733, 50019 Sesto Fiorentino, (FI) Italy.

Procured from within the EU by: Drugsrus Ltd, 5 Sandridge Close, Harrow, Middlesex, HA1 1XD & Repackaged by: P.I.E Pharma Ltd.

Product Licence holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

Humalog® Mix50 100 units/ml KwikPen, suspension for injection in a pre-filled pen; PLGB 18799/3223

POM

Leaflet date: 31.07.2023

'For any information about this medicine, please contact the Product Licence Holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

Tel: 0800 049 9401

Email: regulatoryaffairs@bnsthamelabs.co.uk

USER MANUAL.

Please see manual text later.

Humalog is the registered trademark of Eli Lilly and Company.

Blind or partially sighted?

Is this leaflet hard to see or read?

Call 020 8423 2111 to obtain the leaflet in a format suitable for you.

USER MANUAL
Humalog® Mix50 100 units/ml KwikPen, suspension for injection in a pre-filled pen



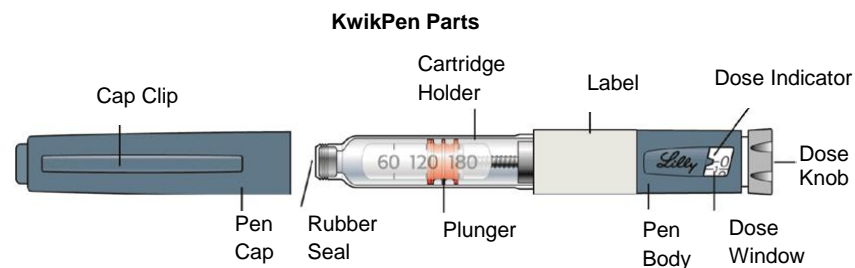
PLEASE READ THIS USER MANUAL BEFORE USE

Read the User Manual before you start taking your insulin and each time you get another KwikPen. There may be new information. This information does not take the place of talking to your healthcare professional about your medical condition or your treatment.

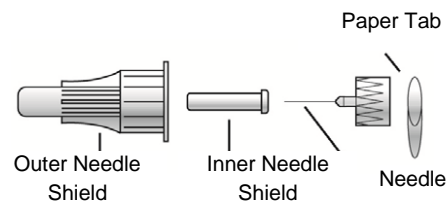
KwikPen ("Pen") is a disposable pre-filled pen containing 3ml (300 units, 100 units/ml) of insulin. You can give yourself multiple doses using one Pen. The Pen dials 1 unit at a time. You can give from 1 to 60 units in a single injection. **If your dose is more than 60 units, you will need to give yourself more than one injection.** The plunger only moves a little with each injection, and you may not notice that it moves. The plunger will only reach the end of the cartridge when you have used all 300 units in the Pen.

Do not share your pen with other people, even if the needle has been changed. Do not reuse or share needles with other people. You may give an infection to them or get an infection from them.




This Pen is not recommended for use by the blind or visually impaired without the help of someone trained to use the Pen.



Pen Needle Parts
(Needles Not Included)



How to recognise your KwikPen:

	Humalog Solution	Humalog Mix25 Suspension (cloudy insulin)	Humalog Mix50 Suspension (cloudy insulin)
Pen colour:	Blue	Blue	Blue
Dose Knob:	 Burgundy	 Yellow	 Red
Labels:	White with Burgundy Colour Bar	White with Yellow Colour Bar	White with Red Colour Bar

Supplies needed to give your injection:

- KwikPen containing your insulin.
- KwikPen compatible Needle (BD [Becton, Dickinson and Company] Pen Needles recommended)
- Swab

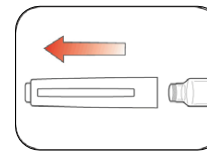
Needles and swab are not included.

Preparing your Pen

- Wash your hands with soap and water.
- Check the Pen to make sure you are taking the right type of insulin. This is especially important if you use more than 1 type of insulin.
- **Do not** use your Pen past the expiration date printed on the Label. After you start using the Pen, throw your Pen away after the in-use time specified in the Package Leaflet.
- Always use a **new Needle** for each injection to help prevent infections and blocked Needles.

Step 1:

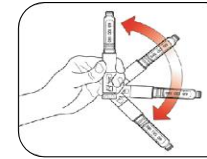
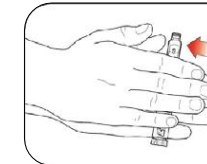
- Pull the Pen Cap straight off.
- **Do not** remove the Pen Label.
- Wipe the Rubber Seal with a swab.



Step 2:

(For HUMALOG suspensions cloudy insulins only)

- Gently roll the Pen 10 times.
- AND
- Invert the Pen 10 times.



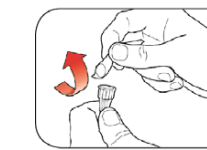
Mixing is important to make sure you get the right dose. The insulin should look evenly mixed.

Step 3:

- Check the appearance of the insulin.
 - HUMALOG solution should look clear and colourless. Do not use if it is cloudy, coloured, or has particles or clumps in it.
 - HUMALOG suspensions - cloudy insulins - should look white after mixing. **Do not** use if it looks clear or contains any clumps or particles.

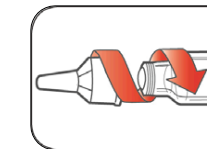
Step 4:

- Select a new Needle.
- Pull off the Paper Tab from the Outer Needle Shield.



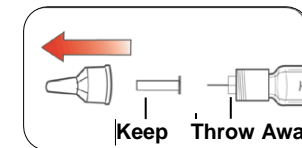
Step 5:

- Push the capped Needle straight onto the Pen and twist the Needle on until it is tight.



Step 6:

- Pull off the Outer Needle Shield. **Do not** throw it away.
- Pull off the Inner Needle Shield and throw it away.



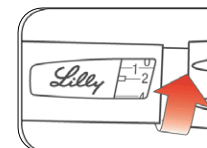
Priming your Pen

Prime before each injection.

- Priming your Pen means removing the air from the Needle and Cartridge that may collect during normal use and ensures that the Pen is working correctly.
- If you **do not** prime before each injection, you may get too much or too little insulin.

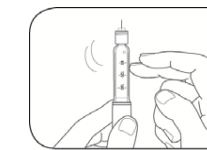
Step 7:

- To prime your Pen, turn the Dose Knob to select 2 units.



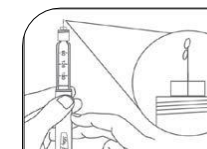
Step 8:

- Hold your Pen with the Needle pointing up. Tap the Cartridge Holder gently to collect air bubbles at the top



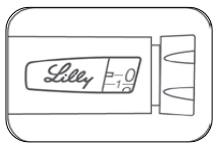
Step 9:

- Continue holding your Pen with Needle pointing up. Push the Dose Knob in until it stops, and '0' is seen in the Dose Window. Hold the Dose Knob in and count to 5 slowly.



You should see insulin at the tip of the Needle.

- If you **do not** see insulin, repeat the priming steps, but not more than 4 times.
- If you **still do not** see insulin, change the Needle and repeat the priming steps.



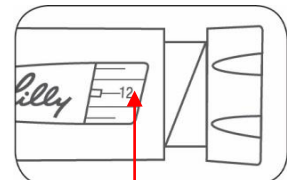
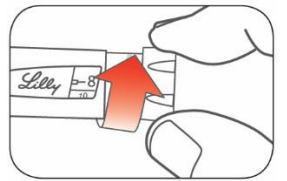
Small air bubbles are normal and will not affect your dose.

Selecting your dose

- You can give from 1 to 60 units in a single injection.
- If your dose is more than 60 units, you will need to give more than one injection.
 - If you need help deciding how to divide up your dose, ask your healthcare professional.
 - You should use a new Needle for each injection and repeat the priming step.

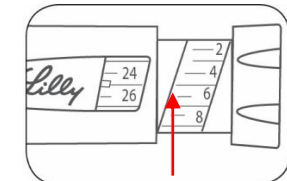
Step 10:

- Turn the Dose Knob to select the number of units you need to inject. The Dose Indicator should line up with your dose.
 - The Pen dials 1 unit at a time.
 - The Dose Knob clicks as you turn it.
 - **DO NOT** dial your dose by counting the clicks because you may dial the wrong dose.
 - The dose can be corrected by turning the Dose Knob in either direction until the correct dose lines up with the Dose Indicator.
 - The even numbers are printed on the dial.
 - The odd numbers, after the number 1, are shown as full lines.



(Example: 12 units shown in the Dose Window)

- **Always check the number in the Dose Window to make sure you have dialled the correct dose.**



(Example: 25 units shown in the Dose Window)

- The Pen will not let you dial more than the number of units left in the Pen.
- If you need to inject more than the number of units left in the Pen, you may either:
 - inject the amount left in your Pen and then use a new Pen to give the rest of your dose, **or**
 - get a new Pen and inject the full dose.
- It is normal to see a small amount of insulin left in the Pen that you cannot inject.

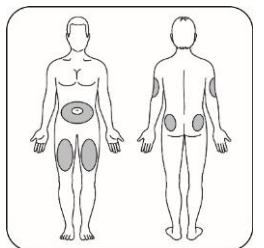
Giving your injection

- Inject your insulin as your healthcare professional has shown you.
- Change (rotate) your injection site for each injection.
- **Do not** try to change your dose while injecting.

Step 11:

- Choose your injection site.

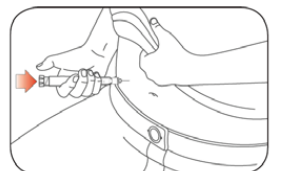
Your insulin is injected under the skin (subcutaneously) of your stomach area, buttocks, upper legs or upper arms.



- Wipe your skin with a swab, and let the injection site dry before you inject your dose.

Step 12:

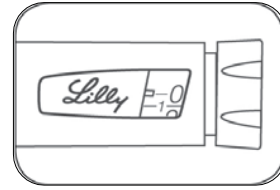
- Insert the Needle into your skin.
- Push the Dose Knob all the way in.
- Continue to hold the Dose Knob in and **slowly count to 5** before removing the Needle.



Do not try to inject your insulin by turning the Dose Knob. You will **NOT** receive your insulin by turning the Dose Knob.

Step 13:

- Pull the Needle out of your skin.
 - A drop of insulin at the Needle tip is normal. It will not affect your dose.
- Check the number in the Dose Window
 - If you see '0' in the Dose window, you have received the full amount you dialled.
 - If you do not see '0' in the Dose window, do not redial. Insert the needle into your skin and finish your injection.
 - If you **still** do not think you received the full amount you dialled for your injection, **do not start over or repeat that injection**. Monitor your blood glucose as instructed by your healthcare professional.
 - If you normally need to give 2 injections for your full dose, be sure to give your second injection.



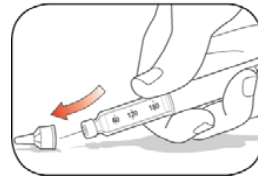
The plunger only moves a little with each injection, and you may not notice that it moves.

If you see blood after you take the Needle out of your skin, press the injection site lightly with a piece of gauze or a swab. **Do not** rub the area.

After your injection

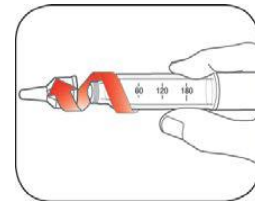
Step 14:

- Carefully replace the Outer Needle Shield.



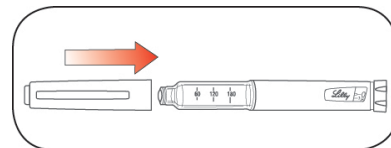
Step 15:

- Unscrew the capped Needle and dispose of it as described below (see **Disposing of Pens and Needles** section).
- Do not store the Pen with the Needle attached to prevent leaking, blocking the Needle, and air from entering the Pen.



Step 16:

- Replace the Pen Cap by lining up the Cap Clip with the Dose Indicator and pushing straight on.



Disposing of pens and needles

- Put used Needles in a sharps container or a hard plastic container with a secure lid. **Do not** throw needles directly into your household waste.
- **Do not** recycle the filled sharps container.
- Ask your healthcare professional about options to dispose of the Pen and the sharps container properly.
- The directions regarding needle handling are not intended to replace local, healthcare professional or institutional policies.

Storing your pen

Unused pens

- Store unused Pens in the refrigerator at 2°C to 8°C.
- **Do not** freeze your insulin. **Do not** use if it has been frozen.
- Unused Pens may be used until the expiration date printed on the Label, if the Pen has been kept in the refrigerator.

In-use Pen

- Store the Pen you are currently using at room temperature (below 30°C) and away from dust, food and liquids, heat and light.
- Throw away the Pen you are using after the time specified in the Package Leaflet, even if it still has insulin left in it.

General information about the safe and effective use of your pen

- **Keep your Pen and Needles out of the sight and reach of children.**
- **Do not** use your Pen if any part looks broken or damaged.
- Always carry an extra Pen in case yours is lost or damaged.

Troubleshooting

- If you cannot remove the Pen Cap, gently twist the cap back and forth, and then pull the cap straight off.
- If the Dose Knob is hard to push:
 - Pushing the Dose Knob more slowly will make it easier to inject.
 - Your Needle may be blocked. Put on a new Needle and prime the Pen.
 - You may have dust, food, or liquid inside the Pen. Throw the Pen away and get a new Pen. You may need to get a prescription from your healthcare professional.

If you have any questions or problems with your KwikPen, call your healthcare professional for help or contact your local Lilly affiliate.

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