

Humalog^{mix}25™

25% insulin lispro (rDNA origin) injection
75% insulin lispro protamine suspension

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A GUIDE TO STARTING HUMALOG® MIX25™

If you experience side effects talk to your doctor or other healthcare professional. This includes any possible side effects not listed in the package leaflet. To report a side effect or product complaint with a Lilly product please call Lilly on **+44 (0) 1256 315000** (UK) or **+353 (0)1 664 0446** (ROI).

Additionally 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 (UK) or www.hpra.ie (ROI). By reporting side effects you can help provide more information on the safety of medicines.

This booklet has been developed and printed by Lilly as a service to patients.

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This booklet is intended only for those who have been prescribed Humalog® Mix25™. It is intended to be used in addition to the Patient Information Leaflet (PIL) which is included in your medicine and should also be read.

Lilly

Why have I been given this booklet?

You have been prescribed Humalog® Mix25™ by your Healthcare Professional to help manage your diabetes. This booklet summarises useful points about taking Humalog® Mix25™ and will help answer any questions you may have about your new insulin.

This booklet is not intended to replace the Patient Information Leaflet found in your medicine pack, which should also be read thoroughly and understood before you start taking this insulin.

Your Healthcare Professional will provide you with your Humalog® Mix25™ insulin ID card. This card will help you identify what the insulin should look like.

Keep this card with you at all times as a reminder of what type of insulin you have been prescribed and show this to the pharmacist to ensure you receive the correct insulin when you collect your prescription.

Your details

Name

Diabetes Nurse Specialist

Hospital Doctor

GP

Who to call in an emergency

Telephone number of contact

Dose of Humalog® Mix25™ to be taken: (Healthcare Professional to complete)

	Time	Dose
Before breakfast		
Before evening meal		
Other		

Why have I been prescribed Humalog® Mix25™?

You have been prescribed Humalog® Mix25™, a mixed insulin to help provide your daily insulin requirements.



This booklet will allow you to learn more about your insulin and help you make the right decisions about adjusting your insulin and taking control of your diabetes.

How does Humalog® Mix25™ work?

Humalog® Mix25™ contains a combination of two types of insulin:

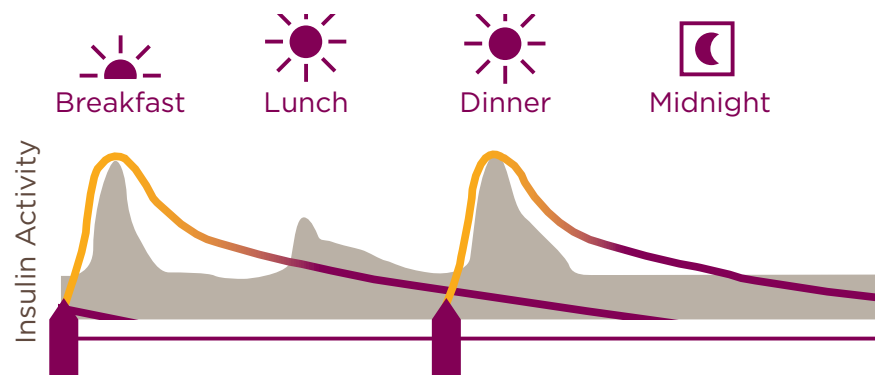
- 25% insulin lispro, a rapid-acting insulin
- 75% insulin lispro protamine suspension, a slower acting insulin

Humalog® Mix25™ copies the way the body's own insulin works in people without diabetes, which means that it provides glucose control between and after meals.

Humalog® Mix25™ acts quickly, so should be taken directly before your meal. However, if you need to, you can inject up to 15 minutes after a meal.

How does Humalog® Mix25™ work?

How Humalog® Mix25™ works



- Humalog® Mix25™ gives you mealtime cover
- Expected insulin changes in people without diabetes
- Time of injection of Humalog® Mix25™

This diagram shows theoretical representations of insulin activity in people without diabetes and in people with diabetes in whom Humalog® Mix25™ has been given twice daily. It is based on information from different clinical studies and is not intended to show direct comparisons.

What does Humalog® Mix25™ look like?

Your Humalog® Mix25™ will come in a 3ml cartridge or a pre-filled device, the KwikPen®

Your insulin should be (please tick)

- 3ml Humalog® Mix25™ cartridge for use in the durable pen device, the HumaPen® Savvio™
- 3ml Humalog® Mix25™ KwikPen®

Please review this in detail, alongside the Patient Information Leaflet found within the medicine pack, before using this insulin.



When do I take my Humalog® Mix25™ dose?

Humalog® Mix25™ can be taken in several ways, often once or twice daily.

When starting Humalog® Mix25™, you should take the number of injections your Healthcare Professional has advised you to, as your insulin regimen has been tailored for your needs.

Make sure you/your healthcare provider write down when you should take your injection. You can make a note in your insulin diary and at the front of this booklet.

If I miss my meal, should I still take my Humalog® Mix25™?

No. Humalog® Mix25™ is meant to be taken before eating. If you miss a meal, taking it may put you at risk of hypoglycaemia.

When do I check my blood glucose levels?

It is likely that you will need to check your blood glucose levels first thing in the morning before breakfast (fasting blood glucose).

Your Healthcare Professional will discuss with you how often and when to test.

You should record your blood glucose levels in your Humalog® Mix25™ diary.

I forgot to take my Humalog® Mix25™, what should I do?

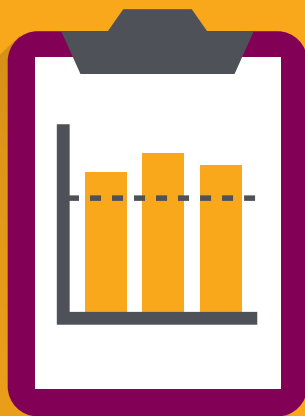
Don't panic, forgetting your Humalog® Mix25™ is rarely an emergency situation. However, you may notice that your blood glucose levels are higher and you may feel tired, thirsty or pass more urine than usual. You should seek advice from your Healthcare Professional. The advice will vary depending on when you realised you have forgotten to take your Humalog® Mix25™.



Instruction for self-adjustment of my insulin

When testing your blood glucose, if you have a consistently high reading for more than three days at any testing point, then you will need to adjust your insulin.

Your Healthcare Professional will explain to you how to adjust your insulin and will complete the following table for your needs.



Twice daily Humalog [®] Mix25 [™]				
Twice daily Humalog [®] Mix25 [™]	Fasting (before breakfast) mmol/l		Before evening meal mmol/l	
	Above	Below	Above	Below
Adjust units of insulin				
	adjust evening dose		adjust morning dose	

Dose reduction is recommended if any results are consistently less than 4mmol/l ('hypo') at any time.

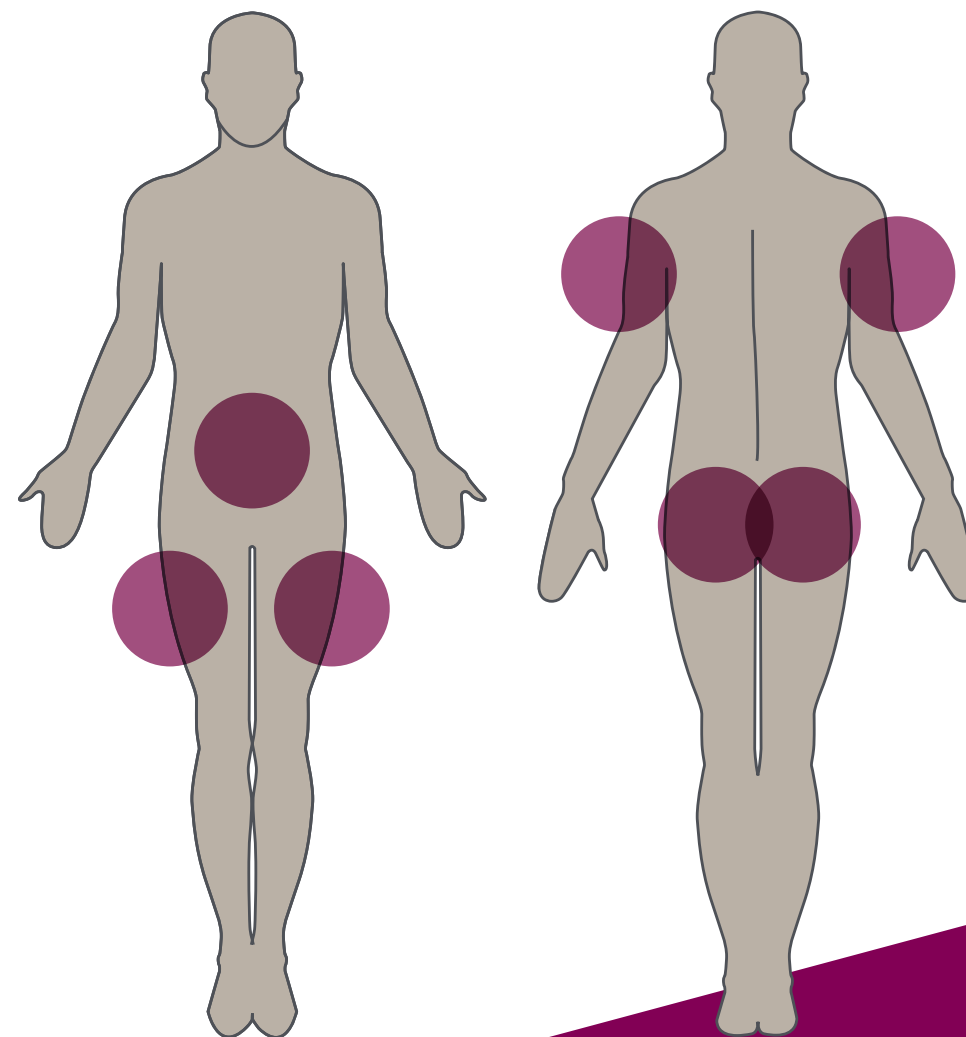
Where do I inject my Humalog® Mix25™?

Your Healthcare Professional will explain how to inject your insulin.

We recommend that you also fully review the Patient Information Leaflet found within your medicine pack, for specific details on how to inject this insulin.

Where do I inject it?

Humalog® Mix25™ can be injected into any of the places shown opposite. The site of injection should be rotated within an area to avoid irritation and aid absorption.



Humalog® Mix25™ 100 units/ml KwikPen®, suspension for injection in a pre-filled pen Available from: <https://www.medicines.org.uk/emc/product/7475/smpc> [Accessed August 2018]

Humalog® Mix25™ 100 units/ml Kwikpen® suspension for injection Available from: <https://www.medicines.ie/medicines/humalog-mix25-100-units-ml-kwikpen-suspension-for-injection-32373/> [Accessed August 2018]

What is hypoglycaemia?

Humalog® Mix25™ may cause hypoglycaemia if you take too much. It is very important that you understand what hypoglycaemia is, what the symptoms are, and how to manage it if it occurs. If untreated, hypoglycaemia can be life-threatening.

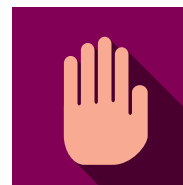
What is a 'hypo'?

Hypoglycaemia (or 'hypos') occurs when your blood glucose levels drop below what the body needs to function normally (below 4mmol/l). 'Hypos' begin quickly, but there are usually warning signs. Symptoms can vary from person to person, but may include the following:

- **Trembling and feeling shaky**
- **Sweating**
- **Being anxious or irritable**
- **Going pale**
- **Palpitations (fast heart beat) and a fast pulse**
- **Lips feeling tingly**
- **Blurred sight**
- **Being hungry**
- **Feeling tearful**
- **Tiredness**
- **Having a headache**
- **Lack of concentration**

Diabetes UK. What is a hypo? Available from: <https://www.diabetes.org.uk/Guide-to-diabetes/Complications/Hypos>. [Accessed August 2018]

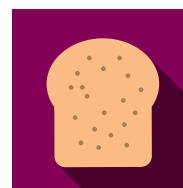
What do I do if I have a 'hypo'?



Stop: it is important that you stop what you are doing and immediately deal with the 'hypo', if hypoglycaemia isn't corrected it can lead to more serious conditions such as unconsciousness and convulsions.



Treat: if you experience a 'hypo', you should eat or drink approximately 15g of sugary quick-acting carbohydrate, such as: A small carton (200 ml) of pure fruit juice, 3 glucose or dextrose tablets or a tube of glucose gel (Speak to your HCP as specific quantities may vary.).



Recover: if you start to feel better after 10-15 minutes, have some longer-acting carbohydrates, such as a sandwich or a bowl of cereal. This will help prevent your blood glucose from going down again.

If you feel you aren't getting better, contact your Healthcare Professional.

Diabetes UK. Having a Hypo. Available from: <https://www.diabetes.org.uk/Guide-to-diabetes/Complications/Hypos/Having-a-hypo>. [Accessed June 2018]

What should I do if I fall ill?

A number of common illnesses can cause your blood glucose to rise. When you are unwell you may not want to eat or take your insulin treatment as normal, but it is important to follow these basic rules in case of sickness:

Keep on taking your insulin

During illness your insulin requirements may go up. Ask your Healthcare Professional for specific advice on what action to take when you are ill.

Monitor your blood glucose and check for ketones

Monitor your blood glucose. Test 2-4 hourly as your blood sugar will indicate whether you require extra insulin doses. Always check your urine or blood for ketones. If you have moderate or high ketones and high blood glucose levels, this is a good indication that you may need more insulin and should consult your Healthcare Professional.

If high blood glucose and ketones lead to vomiting and dehydration, you may require hospital admission. **You must contact your Healthcare Professional.**

Take carbohydrates in liquid form

Take unsweetened fluids if your blood glucose is high. If you still do not feel like eating as your blood glucose returns to normal then substitute food with sweetened fruit juices or drinks that contain glucose.



What considerations should I take when exercising?

Physical exercise is beneficial for people with diabetes. That's because exercise lowers your blood glucose levels. However, it is important to understand how exercise may affect the amount of insulin that you need to take.

When is it best to exercise?

If you do exercise within 1–2 hours after injecting Humalog® Mix25™, the fall in blood glucose will be greater than if you did not exercise. This is because exercising uses energy and therefore helps to reduce your blood glucose levels.

Due to this, you may need to reduce your pre-meal dose of Humalog® Mix25™. Check with your Healthcare Professional for advice if you are unsure.

By monitoring your blood glucose (together with advice from Healthcare Professionals) you will learn the best way to combine exercise and Humalog® Mix25™.

How much and what sort of exercise should I be doing?

It is currently recommended that you aim to do 150 minutes of moderate-to-vigorous exercise a week (i.e. 30 minutes on five days a week).

However, it's OK to start slow and build up to this target. Aiming to do a small amount of light exercise a day (e.g. a short walk) would be a great start!

All physical activity counts, so try to be more active during your day-to-day life. For example, take the stairs instead of the lift.



Global Strategy on Diet, Physical Activity and Health Available from: http://www.who.int/dietphysicalactivity/factsheet_adults/en/ [Accessed August 2018]

What considerations are there for driving?

If you are taking insulin, in most cases this should not affect your ability to drive. However, there are extra rules and considerations.

What are the risks?

The major risk of driving whilst taking insulin is the possibility of having a 'hypo'. To understand more about 'hypos' please turn to page 14.

If you are experiencing frequent 'hypos', or you find it difficult to spot when you are going into a 'hypo', you will have to stop driving until you and your Healthcare Professional get your blood glucose levels under control.

What do I do if I have a 'hypo' whilst driving?

You should pull over, park safely and follow the normal procedure for dealing with 'hypos' (see page 15). You should then wait at least 45 minutes after you feel better before driving.

If you are currently living in the United Kingdom

You can be fined up to £1,000 if you don't tell DVLA about a medical condition that affects your driving. You may be prosecuted if you're involved in an accident as a result.

Check with your nurse or doctor if you don't know what type of medication you're on.

Read leaflet **INF188/2** for more information about driving a car or motorbike with diabetes.

Insulin treated diabetes

You need to tell DVLA if:

- your insulin treatment lasts (or will last) over 3 months
- you had gestational diabetes (diabetes associated with pregnancy) and your insulin treatment lasts over 3 months after the birth
- you get disabling hypoglycaemia (low blood sugar) - or a medical professional has told you that you're at risk of developing it

You can report your condition online, or fill in form **DIAB1** and send it to DVLA.

Bus, coach or lorry licence.

You must tell DVLA if your diabetes is treated with insulin.

Fill in form **VDIAB11** and send it to DVLA.

Read leaflet **INS186** if you want to apply for vocational entitlement to drive larger vehicles (C1, C1E, D1, D1E, C, CE, D or DE).

The DVLA leaflets and forms listed above can be found at: [GOV.UK](https://www.gov.uk).
Diabetes and driving. Available from:
<https://www.gov.uk/diabetes-driving>.
[Accessed June 2018].



If you are currently living in the Republic of Ireland

Informing the NDLS (National Driving Licence Service)

Group 1 - Driving a car, motor cycle or Tractor

You must inform NDLS if:

- you suffer more than one episode of severe hypoglycaemia within the last 12 months.

Group 2 - Driving a bus or truck

You must inform NDLS if:

- you suffer one episode of severe hypoglycaemia
- you are at high risk of developing hypoglycaemia;
- you begin to have difficulty in recognising warning symptoms of low blood sugar
- you suffer severe hypoglycaemia while driving; an existing medical condition gets worse, or you develop any other condition that may affect safe driving.

If you are a Group 1 or Group 2 driver you must inform NDLS if:

- you are treated by insulin, or if your diabetes is additionally managed by tablets which carry a risk of inducing hypoglycaemia
- you develop any problems with your circulation or sensation in your legs or feet which makes it necessary for you to drive certain types of vehicles only

If, following consultation with your GP, your medical condition is one that needs to be notified to the NDLS, you need to complete a Driver Licence Application Form and a Medical Report Form (D501) completed by your Doctor and return in person to any NDLS centre.

The NDLS forms listed above can be found at: NDLS. Form & Reports. Available from: <https://www.ndls.ie/forms-reports.html> [Accessed August 2018].

NDLS. Diabetes and Driving. Available from: <https://www.ndls.ie/images/Documents/Forms/Diabetes-and-Driving.pdf>. [Accessed August 2018]

What considerations are there when travelling?

Taking insulin should not affect your ability to travel abroad but you need to plan ahead to ensure you:

Take enough Humalog® Mix25™ for the duration of your trip

You should carry spare Humalog® Mix25™ KwikPens® and other equipment (needles, insulin etc.) in the event of unforeseen circumstances.

Carry your diabetes equipment in your hand luggage, not your main luggage

Your diabetes equipment should always be accessible. 'In use' pens may be kept at room temperature (up to 30°C) for up to 28 days. In very hot climates, or for long hot journeys, it is advisable to keep your Humalog® Mix25™ in a cool bag. Do not allow your insulin to freeze.

If you are carrying insulin, it is also advisable to carry your diabetes ID and a letter from your GP stating you have diabetes and the medication you need to treat it.

Plan ahead for changing time zones

You may need to speak to your diabetes Healthcare Professional about this.



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Carry your diabetes information, a letter from your GP and identity card

It is important you carry these at all times.

Have travel insurance

Make sure you are covered for existing medical conditions and any diabetes-related emergency which might occur.

Carry extra food for snacks

Sometimes travel can be unpredictable and you should be prepared in case of delays or for when food is not readily accessible or even if you don't like the food on the plane! Don't forget your usual glucose for 'hypos'.

How do I store my Humalog® Mix25™?

Storing unused Humalog® Mix25™

Store in a refrigerator (2-8°C). Do not freeze.

After first use

Store at room temperature (15-30°C) for up to 28 days. The pen should not be stored with the needle attached and a new needle should be used before every injection.

If you have any further questions about Humalog® Mix25™ or about your diabetes in general, ask your Healthcare Professional.

Humalog® Mix25™ 100 units/ml KwikPen®, suspension for injection in a pre-filled pen Available from: <https://www.medicines.org.uk/emc/product/7475/smpc> [Accessed August 2018]

Humalog® Mix25™ 100 units/ml Kwikpen® suspension for injection Available from: <https://www.medicines.ie/medicines/humalog-mix25-100-units-ml-kwikpen-suspension-for-injection-32373/> [Accessed August 2018]



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