Package leaflet: Information for the user

HUMULIN® I (Isophane) 100 IU/ml suspension for injection in vial

(Insulin human)

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Humulin I is and what it is used for

Humulin I contains the active substance human insulin, which is used to treat diabetes. You get diabetes if your pancreas does not make enough insulin to control the level of glucose in your blood (blood sugar). Humulin I is used to control glucose in the long term. Its action is prolonged by the inclusion of protamine sulfate in the suspension.

Your doctor may tell you to use Humulin I as well as a fast-acting insulin. Each kind of insulin comes with its own 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. Each type of insulin has a different colour and symbol on the pack and the vial so that you can easily tell the difference.

2. What you need to know before you use Humulin I

Do not use Humulin I:
- **If you think hypoglycaemia (low blood sugar) is starting.** Further in this leaflet it tells you how to deal with mild hypoglycaemia (*see A in Section 4*).
- If you are allergic to human insulin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist, or nurse before using Humulin I

- 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 (low blood sugar) 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 the symptoms, please discuss this with your doctor.
- If you answer YES to any of the following questions, tell your diabetes specialist nurse, doctor or pharmacist.
    - 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 diabetes specialist nurse, doctor or pharmacist 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 to 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).

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 well if you inject into a lumpy area (See How to use Humulin I). Contact your doctor if you are currently injecting into a lumpy area before you start injecting into 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 Humulin I
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Your insulin needs may change if you are taking any of the following:
- steroids,
- thyroid hormone replacement therapy,
- oral hypoglycaemics (antidiabetic medication),
- acetylsalicylic acid (aspirin),
- growth hormone,
- octreotide, lanreotide,
- $beta_2$ stimulants (for example ritodrine, salbutamol or terbutaline),
- beta-blockers,
- thiazides or some antidepressants (monoamine oxidase inhibitors),
- danazol,
- some angiotensin converting (ACE) inhibitors (for example captopril, enalapril) or angiotensin II receptor blockers.

Pregnancy, breast-feeding and fertility
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.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Driving and using machines
Your ability to concentrate and react may be reduced if you have hypoglycaemia (low blood

sugar). Please remember this in all situations where you might put yourself and others at risk (e.g. driving a car or operating machinery). You should contact your diabetes specialist nurse or doctor about the advisability of driving if you have:

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

Humulin I contains Sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose unit, that is to say essentially 'sodium-free'.

3. How to use Humulin I

Always check the pack and the vial label for the name and type of the insulin when you get it from your pharmacy. Make sure you get the Humulin that your doctor has told you to use.

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Dosage

- You should normally inject Humulin I as your basal insulin. Your doctor has told you which insulin to use, how much, when and how often to inject. These instructions are only for you. Follow them exactly and visit your diabetes clinic regularly.
- If you change your insulin type (for example from animal to human), 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.
- Inject Humulin I under the skin. You should not administer it using a different administration route. Under no circumstances should Humulin I be given into a vein.

Preparing Humulin I

- Vials containing Humulin I should be rotated several times in the palms of the hands before use to resuspend insulin until it appears uniformly cloudy or milky. If not, repeat the above procedure until contents are mixed. **Do not** shake vigorously as this may cause frothing which may interfere with the correct measurement of the dose. The vials 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 sides of the vial, giving it a frosted appearance. Check each time you inject yourself.

Injecting Humulin I

- First wash your hands.
- Before you make an injection, clean your skin as you have been instructed. Clean the rubber stopper on the vial, but do not remove the stopper.
- Use a clean, sterile syringe and needle to pierce the rubber stopper and draw in the amount of Humulin I you want. Your doctor or clinic will tell you how to do this. **Do not share your needles and syringes.**
- 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 5 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 (1 cm) from where you last injected and that you 'rotate' the places you inject, as you have been taught.
- Your doctor will tell you if you have to mix Humulin S with Humulin I. For example if you do need to inject a mixture, draw the Humulin S into the syringe before the long acting insulin. Inject the liquid as soon as you have mixed it. Do the same thing every time. You should not normally mix Humulin I with a mixture of human insulins. You should never mix Humulin I with insulins produced by other manufacturers or animal insulins.

- You must not inject Humulin I into a vein. Inject Humulin I as your diabetes specialist nurse or doctor has taught you.

If you use more Humulin I than you should
If you use more Humulin I than you should, your blood sugar may become low. Check your blood sugar (see A in Section 4).

If you forget to use Humulin I
If you use less Humulin I than you should, your blood sugar levels may increase. Check your blood sugar. Do not inject a double dose to make up for a forgotten dose.

If you stop using Humulin I
If you use less Humulin I than you should, your blood sugar levels may become too high. Do not change your insulin unless your doctor tells you to.

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

4. Possible side effects

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

Human insulin may cause hypoglycaemia (low blood sugar). See more information on hypoglycaemia below in the subsection "Common problems of diabetes".

Possible side effects

Systemic allergy is very rare (affects less than 1 person in 10,000). The symptoms are as follows:

- fall in blood pressure
- difficulty in breathing
- fast heart beat
- rash over the whole body
- wheezing
- sweating

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

Local allergy is common (affects less than 1 person in 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.

Skin changes at the injection site:
If you inject insulin too often at the same place, the fatty tissue may shrink (lipoatrophy) or thicken (lipohypertrophy) (*may affect up to 1 in 100 people*). Lumps under the skin may also be caused by build-up of a protein called amyloid (cutaneous amyloidosis; how often this occurs is not known). 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.

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 Humulin I or other insulin;
- miss or delay meals or change your diet;
- exercise or work too hard just before or after a meal;
- have an infection or illness (especially diarrhoea or vomiting);
- have a change in your need for insulin; or
- 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 heartbeat
- feeling sick
- cold sweat

Until you become confident in recognising your warning symptoms, avoid situations such as driving a car, in which you or others would be put at risk by hypoglycaemia.

Do not use Humulin I if you think hypoglycaemia (low blood sugar) is starting.

If your blood sugar is low, 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.

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 Humulin I 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.**

If hypoglycaemia (low blood sugar) or hyperglycaemia (high blood sugar) are not treated they can be very serious and cause headaches, nausea, vomiting, dehydration, unconsciousness, coma or even death.

Three simple steps *to avoid hypoglycaemia or hyperglycaemia are:*

- Always keep spare syringes and a spare vial of Humulin I.
- Always carry something to show you are diabetic.
- Always carry sugar with you.

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 diabetes specialist nurse or doctor.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via **United Kingdom:** Yellow Card Scheme, Website: 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.

5. How to store Humulin I

Keep this medicine out of the sight and reach of children.

Before the first use store your Humulin I in a refrigerator (2°C – 8°C). **Do not freeze.** You can keep your 'in use' vial at room temperature (below 30°C) for up to 28 days. Do not put it near heat or in the sun.

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

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

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Humulin I contains

- The **active substance** is human insulin. Human insulin is made in the laboratory by a 'recombinant DNA technology' process. It has the same structure as the natural hormone made by the pancreas. It is therefore different from animal insulins. The human insulin in Humulin I is available in a suspension together with protamine sulfate.

- The other ingredients are protamine sulfate, metacresol, phenol, glycerol, dibasic sodium phosphate $7H_2O$, zinc oxide and water for injection. Sodium hydroxide or hydrochloric acid may have been used during manufacture to adjust the acidity.

What Humulin I looks like and contents of the pack

Humulin I (Isophane) 100 IU/ml suspension for injection is a white, sterile suspension and contains 100 units of insulin in each millilitre (100 IU/ml). Each vial contains 1000 units (10 millilitres).

Humulin I 100 IU/ml comes in a pack of 1 vial.

Marketing Authorisation Holder and Manufacturer
Humulin I in vial is made by:
- Lilly S.A., Avda. de la Industria 30, 28108 Alcobendas, Madrid, Spain
- Lilly France S.A.S., Rue du Colonel Lilly, 67640 Fegersheim, France

The marketing authorisation is held by: Eli Lilly Nederland B.V., Orteliuslaan 1000, 3528 BD Utrecht, The Netherlands.

This leaflet was last revised in August 2026.

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

United Kingdom
Eli Lilly and Company Limited, Tel: + 44-(0) 1256 315000