

HUMULIN[®] N CARTRIDGE

Consumer Medication Information Leaflet (RiMUP)

Human Insulin, Isophane (100iu/ml)

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What Humulin N is used for

Humulin N contains human insulin and is used to treat diabetes

Your doctor may tell you to use Humulin N 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 cartridge so that you can easily tell the difference.

How Humulin N works

Humulin N 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 N is used to control glucose in the long term. Its action is prolonged by the inclusion of protamine sulphate in the suspension.

Before you use Humulin N

- When you must not use it
Do not use Humulin N if you are allergic (hypersensitive) to human insulin or any of the other ingredients of Humulin N.

Before you start to use it

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

If you are pregnant or lactating, ask your doctor or diabetes specialist nurse for advice before taking any medicine. 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.

Take special care with Humulin N

- 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. 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.

- Taking other medicines

Please tell your doctor or diabetes specialist nurse, if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. 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),
- some antidepressants (monoamine oxidase inhibitors),
- some angiotensin converting (ACE) inhibitors (for example captopril, enalapril) or angiotensin II receptor blockers.

How to use Humulin N

- How much to use

Always check the pack and the cartridge 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 Humulin N exactly as your doctor has told you. You should check with your doctor if you are not sure.

Dosage

- You should normally inject Humulin N 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 N under the skin. You should not administer it using a different administration route. Under no circumstances should Humulin N be given into a vein.

Preparing Humulin N

- Cartridges containing Humulin N should be rotated in the palms of the hands 10 times and inverted 10 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 sides of the cartridge, giving it a frosted appearance. Check each time before you inject yourself.

Getting the pen ready to use

- First wash your hands. Disinfect the rubber membrane of the cartridge.
- **You must only use Humulin N cartridges in compatible CE marked pens. Please make sure that Humulin N or Lilly cartridges are mentioned in the leaflet accompanying your pen.**

The 3 ml cartridge only fits the 3 ml pen.

- Follow the instructions that come with the pen. Put the cartridge into the pen. You will set the dose to 1 or 2 units. Then hold the pen with the needle pointing up and tap the side of the pen so that any bubbles float to the top. With the pen still pointing up, press the injection mechanism. Do this until a drop of Humulin N comes out of the needle. There may still be some small air bubbles left in the pen. These are harmless, but if the air bubble is too big, it may make the dose of your injection less accurate.

Injecting Humulin N

- 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, pull the needle out and apply gentle pressure over the injection site for several seconds. 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.

After injecting

- As soon as you have done the injection, unscrew the needle from the pen using the outer needle cap. This will keep the insulin sterile and prevent leaking. It will also stop air going back into the pen and the needle clogging up. **Do not share your needles or your pen.** Replace the cap on your pen.

Further injections

- Leave the cartridge in the pen. Before every injection, dial 1 or 2 units and press the injection mechanism with the pen pointing up until a drop of Humulin N comes out of the needle. You can see how much Humulin N is left by looking at the gauge on the side of the cartridge. The distance between each mark on the gauge is about 20 units. If there is not enough for your dose, change the cartridge.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Humulin N for as long as your doctor recommends.

- If you forget to use it

If you take less Humulin N than you need, your blood sugar levels may increase. Check your blood sugar.

- If you use too much (overdose)

If you take more Humulin N than you need, your blood sugar may become low. Check your blood sugar.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Humulin N.

Tell your doctor immediately if you become pregnant while taking this medication.

If you experience hypoglycaemia (low blood sugar), 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.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Humulin N to anyone else, even if they have the same symptoms or condition as you.

Do not mix any other insulin in a Humulin N cartridge. Once the cartridge is empty, do not use it again

- Things to be careful of

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.

Side effects

Like all medicines, Humulin N can cause side effects, although not everybody gets them.

Human insulin may cause hypoglycaemia (low blood sugar). The first symptoms of hypoglycemia come early and include the following:

- tiredness
- nervousness or shakiness
- headache
- rapid heartbeat
- feeling sick
- cold sweat

Possible side effects

Systemic allergy. 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 N, tell your doctor at once.

Local allergy. 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 (thickening or pitting of the skin). If you notice your skin thickening or pitting at the injection site, change your injection site and tell your doctor.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

Storage and Disposal of Humulin N

- Storage
- Keep out of the reach and sight of children.
- Before the first use store your Humulin N in a refrigerator (2°C – 8°C). **Do not freeze.** Keep your ‘in use’ pen and cartridge at room temperature (below 30°C) for up to 28 days. Do not keep your ‘in use’ pen or cartridges in the fridge. Do not put them near heat or in the sun.
- Do not use Humulin N 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 Humulin N, if clumps of material are present or if solid white particles stick to the bottom or sides of the cartridge, giving it a frosted appearance. Check this each time before you inject yourself.

- Disposal

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.

Product Description

- What it looks like

Humulin N (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 cartridge contains 300 units (3 millilitres).

The cartridges come in packs of 5 cartridges.

- Ingredients

- Active ingredient(s)

The **active substance** is isophane 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 N is available in a suspension together with protamine sulphate

- Inactive ingredients

Protamine sulphate, metacresol, phenol, glycerol, dibasic sodium phosphate 7H₂O, zinc oxide and water for injection. Sodium hydroxide or hydrochloric acid may have been used during manufacture to adjust the acidity.

- MAL number:

MAL19973613A Z

Manufacturer

Lilly France S.A
Rue de Colonel Lilly
67640 Fegersheim
France

Product Registration Holder

Eli Lilly (Malaysia) Sdn Bhd
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