

Insulatard® Penfill®

Consumer Medication Information Leaflet (RIMUP)

Insulin Human, Isophane (100IU/ml)

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What Insulatard® is used for

Insulatard® is human insulin used to treat diabetes. Diabetes mellitus is a disease where your body does not produce enough insulin to control the level of your blood sugar.

How Insulatard® works

Insulatard® is a long acting insulin. This means that it will start lowering your blood sugar about 1½ hours after you take it, and the effect will remain around 24 hours. Insulatard® is often given in combination with fast or rapid-acting insulin.

Before you use Insulatard®

-When you must not use it

- ▶ **In insulin infusion pumps.**
- ▶ **If you are allergic (hypersensitive)** to human insulin or any of the other ingredients in Insulatard®
- ▶ **If you suspect hypoglycaemia** (low blood sugar) is starting
- ▶ If the cartridge or the device containing the cartridge is dropped, damaged or crushed.
- ▶ If it has not been stored correctly **or been frozen**
- ▶ If the resuspended insulin does not appear uniformly white and cloudy.

-Before you start to use it

- ▶ Check the label to make sure it **is the right type of insulin.**

- ▶ Always check **the cartridge, including the rubber stopper. Do not use it if any damage is**

seen or if there is a gap between the rubber stopper and the white label band. Take it back to your pharmacy. See your delivery system manual for further instructions.

- ▶ Always use a new needle **for each injection to prevent contamination.**
- ▶ Needles and Insulatard® Penfill® must not be shared.

-Taking other medicines

Some medicines affect the way glucose works in your body and this may influence your insulin dose. Listed below are the most common medicines which may affect your insulin treatment. Tell your doctor, nurse or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. In particular, you should tell your doctor if you are using any medicine mentioned below that may affect your blood sugar level.

Your need for insulin may change if you also take: other medicines for treatment of diabetes; monoamine oxidase inhibitors (MAOI); beta-blockers; ACE-inhibitors; acetylsalicylic acid; anabolic steroids; sulphonamides; oral contraceptives; thiazides; glucocorticoids; thyroid hormone therapy; sympathomimetics; growth hormone; danazol; octreotide or lanreotide.

Alcohol may intensify or reduce the hypoglycaemic effect of insulin.

How to use Insulatard®

-How much to use

The individual insulin requirement is usually between 0.3 and 1.0 IU/kg/day. Talk about your insulin needs with your doctor and nurse. Follow their

advice carefully. If your doctor has switched you from one type or brand of insulin to another, your dose may have to be adjusted by your doctor.

-When to use it

Use as directed by your doctor or pharmacist

Insulatard® is administered by injection under the skin (subcutaneously). Never inject your insulin directly into a vein or muscle. Always vary the sites you inject within the same region, to reduce the risk of developing lumps or skin pitting. The best places to give yourself an injection are: your buttocks; the front of your thighs or upper arms.

-How long to use it

- ▶ Continue taking Insulatard for as long as your doctor recommends.
- ▶ **Inject the insulin** under the skin. Use the injection technique advised by your doctor or nurse and as described in your delivery system manual.
- ▶ **Keep the needle under your skin** for at least 6 seconds. Keep the push-button fully depressed until the needle has been withdrawn. This will ensure correct delivery and limit possible flow of blood into the needle or insulin reservoir.
- ▶ **After each injection** be sure to remove and discard the needle and store Insulatard® without the needle attached. Otherwise the liquid may leak out which can cause inaccurate dosing.

Do not refill Insulatard® Penfill®.

Penfill® cartridges are designed to be used with Novo Nordisk insulin delivery systems and NovoFine® or NovoTwist® needles.

If you are treated with Insulatard® Penfill® and another insulin Penfill® cartridge, you should use two insulin delivery systems, one for each type of insulin.

As a precautionary measure, always carry a spare insulin delivery system in case your Penfill® is lost or damaged.

-If you forget to use it

Your blood sugar may get too high (this is called hyperglycaemia).

The warning signs appear gradually. They include: increased urination; feeling thirsty; losing your appetite; feeling sick (nausea or vomiting); feeling drowsy or tired; flushed, dry skin; dry mouth and a fruity (acetone) smell of the breath.

If you get any of these signs, test your blood sugar level and test your urine for ketones if you can. Then seek medical advice straight away.

These may be signs of a very serious condition called diabetic ketoacidosis. If you do not treat it, this could lead to diabetic coma and eventually death.

-If you use too much (overdose)

Your blood sugar may get low (this is called hypoglycaemia). Hypo means your blood sugar level is too low.

The warning signs of a hypo may come on suddenly and can include: cold sweat; cool pale skin; headache; rapid heart-beat; feeling sick; feeling very hungry; vision changes; drowsiness; unusual tiredness and weakness; nervousness or tremor; feeling anxious; feeling confused; difficulty in concentrating.

If you get any of these signs, eat glucose tablets or a high sugar snack (sweets, biscuits, fruit juice), then rest. Using glucagon

You may recover more quickly from unconsciousness with an injection of the hormone glucagon by someone who knows how to use it. If you are given glucagon, you will need glucose or a sugary snack as soon as you are conscious. If you do not respond to glucagon treatment, you will have to be treated in a hospital. Seek medical advice after an injection of glucagon; you need to find the reason for your hypo to avoid getting more.

While you are using it

-Things you must do

It is recommended that you measure your blood sugar regularly.

-Things you must not do

Do not take any insulin if you feel a hypo coming on.

Carry glucose tablets, sweets, biscuits or fruit juice with you, just in case.

-Things to be careful of

If you drive or use tools or machines, watch out for signs of a hypo. Your ability to concentrate or to react will be less during a hypo. Never drive or use machinery if you feel a hypo coming on. Discuss with your doctor whether you can drive or use machines at all, if you have a lot of hypos or if you find it hard to recognise hypos.

Side effects

Like all medicines, Insulatard® can cause side effects, although not everybody gets them.

Side effects reported very commonly

(in more than 1 patient in 10)

Low blood sugar (hypoglycaemia).

Side effects reported uncommonly

(in less than 1 patient in 100)

Changes at the injection site (lipodystrophy). The fatty tissue under the skin at the injection site may shrink (lipoatrophy) or thicken (lipohypertrophy). Changing the site with each injection may help to reduce the risk of developing such skin changes. If you notice your skin pitting or thickening at the injection site, tell your doctor or nurse. These reactions can become more severe, or they may change the absorption of your insulin if you inject in such a site.

Signs of allergy.

Reactions (redness, swelling, itching) at the injection site may occur (local allergic reactions). These usually disappear after a few weeks of taking your insulin. If they do not disappear, see your doctor.

Seek medical advice immediately:

- If signs of allergy spread to other parts of the body, or
- If you suddenly feel unwell, and you: start sweating; start being sick (vomiting); have difficulty in

breathing; have a rapid heart beat; feel dizzy.

Diabetic retinopathy (eye disease related to diabetes which can lead to loss of vision). If you have diabetic retinopathy and your blood sugar levels improve very fast, the retinopathy may get worse. Ask your doctor about this.

Swollen joints. When you start taking insulin, water retention may cause swelling around your ankles and other joints. Normally this soon disappears.

Side effects reported very rarely

(in less than 1 patient in 10,000)

Painful neuropathy (pain due to nerve damage). If your blood sugar level improves very fast, you may get nerve related pain, this is called acute painful neuropathy and is usually transient.

Vision problems. When you first start your insulin treatment, it may disturb your vision, but the disturbance is usually temporary.

Serious allergic reaction to Insulatard® or one of its ingredients (called a systemic allergic reaction).

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse 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 Insulatard®

-Storage

Insulatard® Penfill® that is not being used is to be stored in the refrigerator at 2°C - 8°C, away from the cooling element. Do not freeze.

Insulatard® Penfill® that is being used or carried as a spare is not to be kept in a refrigerator. After removing Penfill® from the refrigerator, it is recommended to let it reach room temperature before resuspending the insulin as instructed for the first time

use. You can carry it with you and keep it at room temperature (below 30°C) for up to 6 weeks.

Always keep the cartridge in the outer carton when you are not using it in order to protect it from light.

Insulatard® must be protected from excessive heat and light.

Keep out of the reach and sight of children.

-Disposal

Do not use Insulatard® after the expiry date which is stated on the label and the carton after 'Expiry'. The expiry date refers to the last day of that month.

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

The suspension for injection comes as a cloudy, white, aqueous suspension.

-Ingredients

-Active ingredient
insulin human, isophane

-Inactive ingredients
zinc chloride, glycerol, metacresol, sodium hydroxide, hydrochloric acid, phenol, disodium phosphate dihydrate, protamine sulphate and water for injections.

-MAL number:

MAL13115135AS
MAL19987352A

Manufacturer

Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd
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Product Registration Holder

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