

100 IU/ml

Suspension for injection in cartridge, Penfill®

Insulin human (rDNA) (isophane insulin)

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1. 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.

2. How Insulatard® works

Insulatard® is a long-acting insulin. This means that it will start to lower your blood sugar about 1½ hours after you take it, and the effect will last for approximately 24 hours. Insulatard® is often given alone or in combination with fast-acting insulin products.

3. 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® (see section 8. *Product description*).
- **If you suspect hypoglycaemia** (low blood sugar) is starting (see section 4. *How to use Insulatard®*).
- **If the cartridge or the device containing the cartridge is dropped, damaged or crushed.**
- **If it has not been stored correctly** or been frozen (see section 7. *Storage and Disposal of Insulatard®*).
- **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; angiotensin-converting enzyme (ACE) inhibitors; acetylsalicylic acid; anabolic steroids; sulphonamides; oral contraceptives; thiazides; glucocorticoids; thyroid hormone therapy; sympathomimetics; growth hormone; danazol; octreotide or lanreotide.

Thiazolidinediones (class of oral antidiabetic medicines used for the treatment of type 2 diabetes mellitus). Some patients with long-standing type 2 diabetes mellitus and heart disease or previous stroke who are treated with

thiazolidinediones in combination with insulin may develop 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).

4. How to use Insulatard®

- How much to use

Talk about your insulin needs with your doctor and nurse. Make sure you take Insulatard® Penfill® as instructed by your doctor or nurse and 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

Make sure you take Insulatard® as instructed by your doctor or nurse and follow their advice carefully

- How to use it

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 (see section 6. *Side effects*). The best places to give yourself an injection are: the front of your waist (abdomen); your buttocks; the front of your thighs or upper arms. Your insulin will work more quickly if you inject it around the waist.

Resuspending the insulin

Resuspending is easier when the insulin has reached room temperature. Before you put the Penfill® cartridge into the insulin delivery system, move it up and down between positions **a** and **b** and back (see the picture) so that the glass ball moves from one end of the cartridge to the other at least 20 times.

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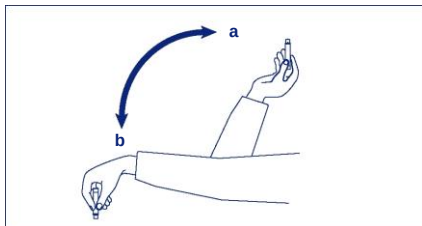
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Repeat this movement at least 10 times before each injection. The movement must always be repeated until the liquid appears uniformly white and cloudy.

Complete the other stages of injection without delay.



Check there are at least 12 units of insulin left in the cartridge to allow even resuspending. If there are less than 12 units left, use a new one.

- **How to inject this insulin**

- ▶ **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.

- **How long to use it**

Continue taking Insulatard® for as long as your doctor recommends.

Inadequate dosing or discontinuation of treatment, especially in type 1 diabetes, may lead to hyperglycemia and diabetic ketoacidosis.

- **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.

Causes of hyperglycaemia

- ▶ Having forgotten to take your insulin
- ▶ Repeatedly taking less insulin than you need
- ▶ An infection or a fever
- ▶ Eating more than usual
- ▶ Less exercise than usual

- **If you use too much (overdose)**

Your blood sugar may get too low (this is called hypoglycaemia).

The warning signs of a hypoglycaemia may come on suddenly and can include: cold sweat; cool pale skin; headache; rapid heartbeat; feeling sick; feeling very hungry; temporary changes in vision; 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.

Causes of a hypoglycaemia

You get a hypoglycaemia if your blood sugar gets too low. This might happen:

- ▶ If you take too much insulin.
- ▶ If you eat too little or miss a meal.
- ▶ If you exercise more than usual.

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 hypoglycaemia to avoid getting more.

5. 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 hypoglycaemia coming on. Carry glucose tablets, sweets, biscuits or fruit juice with you, just in case.

Tell your relatives, friends and close colleagues that if you pass out (become unconscious), they must turn you on your side and seek medical advice straight away. They must not give you any food or drink as it could choke you.

▶ **If severe hypoglycaemia** is not treated, it can cause brain damage (temporary or permanent) and even death.

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► **If you have a hypoglycaemia** that makes you pass out, or a lot of hypoglycaemias, talk to your doctor. The amount or timing of insulin, food or exercise may need to be adjusted.

- Things to be careful of

► **If you have trouble** with your kidneys or liver, or with your adrenal, pituitary or thyroid glands.

► **If you drink alcohol** watch for signs of a hypoglycaemia and never drink alcohol on an empty stomach.

► **If you exercise** more than usual or if you want to change your usual diet, as this may affect your blood sugar level.

► **If you are ill** carry on taking your insulin and consult your doctor.

► **If you are going abroad**, travelling over time zones may affect your insulin needs and the timing of your injections. Consult your doctor if you are planning such travelling.

Pregnancy and breast-feeding

There is no restriction on treatment with Insulatard® during pregnancy or breast-feeding, please contact your doctor for advice.

Driving and using machines

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

Skin changes at the injection site

The injection site should be rotated to help prevent changes to the fatty tissue under the skin, such as skin thickening, skin shrinking or lumps under the skin. The insulin may not work very well if you inject into a lumpy, shrunken or thickened area (see section 4. *How to use Insulatard®*). Tell your doctor if you notice any skin changes at the injection site. Tell your doctor if you are

currently injecting into these affected areas before you start injecting in 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.

6. Side effects

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

Side effects may occur with certain frequencies, which are defined as follows:

► Very common: affects more than 1 user in 10

► Uncommon: affects 1 users in 100

► Very rare: affects less than 1 user in 10,000

Very common side effects

Low blood sugar (hypoglycaemia).

See the advice in 'If you use too much (overdose)' under section 4. *How to use Insulatard®*.

Uncommon side effects

Skin changes at the injection site. If you inject insulin at the same place, the fatty tissue may shrink (lipoatrophy) or thicken (lipohypertrophy) (in less than 1 patient in 100). 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, shrunken or thickened area. Change the injection site with each injection to help prevent these skin changes.

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 heartbeat; 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.

Very rare side effects

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

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.

Serious allergic reaction to Insulatard® or one of its ingredients (called a systemic allergic reaction). See also the warning in section 3. *Before you use Insulatard®*.

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 visiting the website nprra.moh.gov.my [Consumer → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

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7. Storage and Disposal of Insulatard®

- Storage

Keep out of the reach and sight of children.

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.

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. If there are 6 months or more until the expiry date, the product may be stored outside of the refrigerator (below 30°C) for up to 4 weeks before it is taken into use or carried as a spare. The product must not be returned to the refrigerator after it has been stored outside of the refrigerator. Please record the beginning of storage outside of the refrigerator on the product carton.

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.

- 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.

8. Product Description

- What it looks like

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

It is supplied in packs of 1, 5 or 10 cartridges of 3 ml (not all packs may be marketed).

- Ingredients

-Active ingredient

Insulin human, made by recombinant biotechnology. Insulatard® is an isophane insulin suspension (NPH). 1 ml contains 100 IU of insulin human. 1 cartridge contains 3 ml equivalent to 300 IU.

-Inactive ingredients

Zinc chloride, glycerol, metacresol, phenol, disodium phosphate dihydrate, sodium hydroxide, hydrochloric acid, protamine sulphate and water for injections.

- MAL number

MAL13115135ASZ

MAL19987352AZ

9. Manufacturer

Novo Nordisk A/S

Novo Allé

DK-2880 Bagsværd

Denmark

Novo Nordisk Produção Farmacêutica do Brasil Ltda.

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Montes Claros - Minas Gerais

Brazil 39404-004

10. Product Registration Holder

Novo Nordisk Pharma (Malaysia) Sdn. Bhd.

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Malaysia

11. Date of revision

23/12/2024

Serial Number

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