

Insulatard®

100 IU/ml

Suspension for injection in pre-filled pen, FlexPen®

Insulin human (rDNA) (isophane insulin)

Consumer Medication Information Leaflet (RiMUP)

What is in this leaflet

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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 FlexPen® 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 use a new needle** for each injection to prevent contamination.
- **Needles and Insulatard® FlexPen® 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® FlexPen® 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 (intravenously) or muscle (intramuscularly). 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.

Injecting the insulin: See overleaf for detailed instructions.

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- 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.

▶ **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.

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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 user 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 npa.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

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® FlexPen® 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® FlexPen® that is being used or carried as a spare is not to be kept in a refrigerator. After removing

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FlexPen® 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 pen cap on your FlexPen® 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 pre-filled pens 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 pre-filled pen 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

MAL21066009ASZ

9. Manufacturers

Novo Nordisk A/S
Novo Allé, DK-2880,
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Novo Nordisk Produção Farmacêutica
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Novo Nordisk Production SAS
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10. Product Registration Holder

Novo Nordisk Pharma (Malaysia)
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No. 201 Jalan Tun Sambanthan
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Malaysia

11. Date of revision

23/12/2024

Serial number

NPRA(R3/01)20122024/0339

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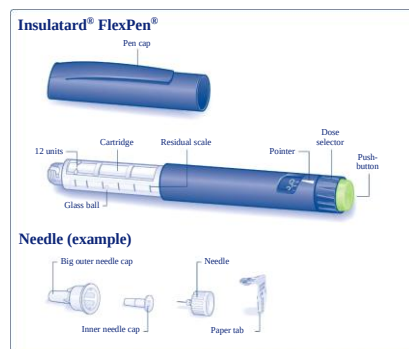
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Instructions on how to use Insulatard® suspension for injection in FlexPen®

Read the following instructions carefully before using your FlexPen®. If you do not follow the instructions carefully, you may get too little or too much insulin, which can lead to too high or too low blood sugar level.

Your FlexPen® is a pre-filled dial-a-dose insulin pen. You can select doses from 1 to 60 units in increments of 1 unit. FlexPen® is designed to be used with NovoFine® or NovoTwist® disposable needles up to a length of 8 mm. As a precautionary measure, always carry a spare insulin delivery device in case your FlexPen® is lost or damaged.



Caring for your pen

Your FlexPen® must be handled with care. If it is dropped, damaged or crushed, there is a risk of insulin leakage. This may cause inaccurate dosing, which can lead to too high or too low blood sugar level.

You can clean the exterior of your FlexPen® by wiping it with a medicinal swab. Do not soak it, wash or lubricate it as it may damage the pen.

Do not refill your FlexPen®. Once empty, it must be disposed of.

Preparing your Insulatard® FlexPen®

A

Check the name and coloured label of your pen to make sure that it contains the correct type of insulin.

This is especially important if you take more than one type of insulin. If you take the wrong type of insulin, your blood sugar level may get too high or too low.

Every time you use a new pen

Let the insulin reach room temperature before you use it. This makes it easier to resuspend. Pull off the pen cap (see A).



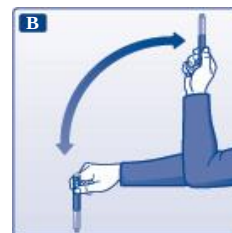
B

Before your first injection with a new pen, you must resuspend the insulin:

Move the pen up and down twenty times between the two positions as shown, so the glass ball moves from one end of the cartridge to the other. Repeat until the liquid appears uniformly white and cloudy.

For every following injection, move the pen up and down between the two positions at least 10 times until the liquid appears uniformly white and cloudy.

Always make sure that you have resuspended the insulin prior to each injection. This reduces the risk of too high or too low blood sugar level. After you have resuspended the insulin, complete all the following steps of injection without delay.



Always check there are at least 12 units of insulin left in the cartridge to allow resuspension. If there are less than 12 units left, use a new pen. 12 units are marked on the residual scale. See the big picture on top of this instruction.

Attaching a needle

C

Remove the paper tab from a new disposable needle.

Screw the needle straight and tightly onto your FlexPen®.



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D

Pull off the big outer needle cap and keep it for later.



E

Pull off the inner needle cap and dispose of it.



Never try to put the inner needle cap back on the needle. You may stick yourself with the needle.

⚠ Always use a new needle for each injection. This reduces the risk of contamination, infection, leakage of insulin, blocked needles and inaccurate dosing.

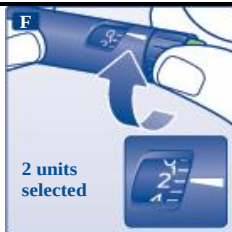
⚠ Be careful not to bend or damage the needle before use.

Checking the insulin flow

F

Prior to each injection, small amounts of air may collect in the cartridge during normal use. To avoid injection of air and ensure proper dosing:

Turn the dose selector to select 2 units.



G

Hold your FlexPen® with the needle pointing upwards and tap the cartridge gently with your finger a few times to make any air bubbles collect at the top of the cartridge.



H

Keeping the needle upwards, press the push-button all the way in. The dose selector returns to 0.

A drop of insulin should appear at the needle tip. If not, change the needle and repeat the procedure no more than 6 times.

If a drop of insulin still does not appear, the pen is defective, and you must use a new one.



⚠ Always make sure that a drop appears at the needle tip before you inject. This makes sure that the insulin flows. If

no drop appears, you will not inject any insulin, even though the dose selector may move. This may indicate a blocked or damaged needle.

⚠ Always check the flow before you inject. If you do not check the flow, you may get too little insulin or no insulin at all. This may lead to too high blood sugar level.

Selecting your dose

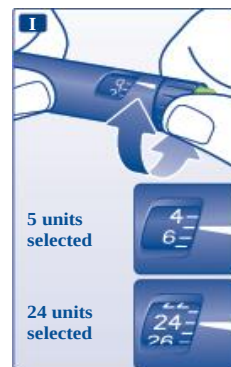
I

Check that the dose selector is set at 0.

Turn the dose selector to select the number of units you need to inject.

The dose can be corrected either up or down by turning the dose selector in either direction until the correct dose lines up with the pointer. When turning the dose selector, be careful not to push the push-button as insulin will come out.

You cannot select a dose larger than the number of units left in the cartridge.



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⚠ Always use the dose selector and the pointer to see how many units you have selected before injecting the insulin.

⚠ Do not count the pen clicks. If you select and inject the wrong dose, your blood sugar level may get too high or too low. Do not use the residual scale, it only shows approximately how much insulin is left in your pen.

Making the injection

J
Insert the needle into your skin.
Use the injection technique shown by your doctor or nurse.

Inject the dose by pressing the push-button all the way in until 0 lines up with the pointer. Be careful only to push the push-button when injecting.

Turning the dose selector will not inject insulin.



K
Keep the push-button fully depressed and let the needle remain under the skin for at least 6 seconds. This will make sure you get the full dose.

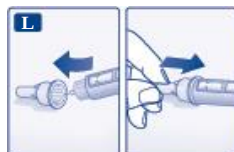
Withdraw the needle from the skin, then release the pressure on the push-button.

Always make sure that the dose selector returns to 0 after the injection. If the dose selector stops before it returns to 0, the full dose has not been delivered, which may result in too high blood sugar level.



L
Lead the needle into the big outer needle cap without touching it. When the needle is covered, carefully push the big outer needle cap completely on and then unscrew the needle.

Dispose of it carefully and put the pen cap back on.



⚠ Always remove the needle after each injection and store your FlexPen® without the needle attached. This reduces the risk of contamination, infection, leakage of insulin, blocked needles and inaccurate dosing.

Further important information

⚠ Caregivers must be very careful when handling used needles – to reduce the risk of needle sticks and cross-infection.

⚠ Dispose of your used FlexPen® carefully without the needle attached.

⚠ Never share your pen or your needles with other people. It might lead to cross-infection.

⚠ Never share your pen with other people. Your medicine might be harmful to their health.

⚠ Always keep your pen and needles out of sight and reach of others, especially children.