

Package leaflet: Information for the user

Insulatard® InnoLet®
100 IU/ml (international units/ml) suspension for injection in pre-filled pen
human insulin

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

1. *What Insulatard® is and what it is used for*

Insulatard® is human insulin with a gradual onset and long duration of action.

Insulatard® is used to **reduce the high blood sugar level** in patients with diabetes mellitus (diabetes). Diabetes is a disease where your body does not produce enough insulin to control the level of your blood sugar. Treatment with Insulatard® helps to prevent complications from your diabetes.

Insulatard® will start to lower your blood sugar about 1½ hours after you inject it, and the effect will last for approximately 24 hours. Insulatard® is often given in combination with fast-acting insulin preparations.

2. *What you need to know before you use Insulatard®*

Do not use Insulatard®

- ▶ If you are allergic to human insulin or any of the other ingredients in this medicine, see section 6.
- ▶ If you suspect hypoglycaemia (low blood sugar) is starting, see *Summary of serious and very common side effects* in section 4.
- ▶ In insulin infusion pumps.
- ▶ If InnoLet® is dropped, damaged or crushed.
- ▶ If it has not been stored correctly or if it has been frozen, see section 5.
- ▶ If the resuspended insulin does not appear uniformly white and cloudy.

If any of these apply, **do not use Insulatard®**. Talk to your doctor, pharmacist or nurse for advice.

Before using Insulatard®

- ▶ 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® InnoLet® must not be shared.
- ▶ Insulatard® InnoLet® is only suitable for injecting under the skin. Speak to your doctor if you need to inject your insulin by another method.

Warnings and precautions

Some conditions and activities can affect your need for insulin. Consult your doctor:

- ▶ If you have trouble with your kidneys or liver, or with your adrenal, pituitary or thyroid glands.
- ▶ 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 hereof.

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 3). 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.

Other medicines and Insulatard®

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.

Some medicines affect your blood sugar level, and this may mean that your insulin dose has to change. Listed below are the most common medicines which may affect your insulin treatment.

Your blood sugar level may fall (hypoglycaemia) if you take:

- Other medicines for the treatment of diabetes
- Monoamine oxidase inhibitors (MAOI) (used to treat depression)
- Beta-blockers (used to treat high blood pressure)
- Angiotensin converting enzyme (ACE) inhibitors (used to treat certain heart conditions or high blood pressure)
- Salicylates (used to relieve pain and lower fever)
- Anabolic steroids (such as testosterone)
- Sulfonamides (used to treat infections).

Your blood sugar level may rise (hyperglycaemia) if you take:

- Oral contraceptives (birth control pills)
- Thiazides (used to treat high blood pressure or excessive fluid retention)
- Glucocorticoids (such as 'cortisone' used to treat inflammation)
- Thyroid hormone (used to treat thyroid gland disorders)
- Sympathomimetics (such as epinephrine [adrenaline], salbutamol or terbutaline used to treat asthma)

- Growth hormone (medicine for stimulation of skeletal and somatic growth and pronounced influence on the body's metabolic processes)
- Danazol (medicine acting on ovulation).

Octreotide and lanreotide (used for treatment of acromegaly, a rare hormonal disorder that usually occurs in middle-aged adults, caused by the pituitary gland producing excess growth hormone) may either increase or decrease your blood sugar level.

Beta-blockers (used to treat high blood pressure) may weaken or suppress entirely the first warning symptoms which help you to recognise low blood sugar.

Pioglitazone (tablets used for the treatment of type 2 diabetes)

Some patients with long-standing type 2 diabetes 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).

If you have taken any of the medicines listed here, **tell your doctor, pharmacist or nurse.**

Insulatard® with alcohol

- ▶ If you drink alcohol, your need for insulin may change as your blood sugar level may either rise or fall. Careful monitoring is recommended.

Pregnancy and breast-feeding

- ▶ If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.
Insulatard® can be used during pregnancy. Your insulin dose may need to be changed during pregnancy and after delivery. Careful control of your diabetes, particularly prevention of hypoglycaemia, is important for the health of your baby.
- ▶ There are no restrictions on treatment with Insulatard® during breast-feeding.

Ask your doctor, pharmacist or nurse for advice before taking this medicine while pregnant or breast-feeding.

Driving and using machines

- ▶ Please ask your doctor whether you can drive a car or operate a machine:
 - If you have frequent hypoglycaemia.
 - If you find it hard to recognise hypoglycaemia.

If your blood sugar is low or high, it might affect your concentration and ability to react and therefore also your ability to drive or operate a machine. Bear in mind that you could endanger yourself or others.

Insulatard® contains sodium

Insulatard® contains less than 1 mmol sodium (23 mg) per dose, i.e. Insulatard® is essentially 'sodium-free'.

3. *How to use Insulatard®*

Dose and when to take your insulin

Always use your insulin and adjust your dose exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Do not change your insulin unless your doctor tells you to. 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.

Use in children and adolescents

Insulatard® can be used in children and adolescents.

Use in special patient groups

If you have reduced kidney or liver function, or if you are above 65 years of age, you need to check your blood sugar more regularly and discuss changes in your insulin dose with your doctor.

How and where to inject

Insulatard® is administered **by injection under the skin** (subcutaneously). You must never inject yourself directly into a vein (intravenously) or muscle (intramuscularly). Insulatard® InnoLet® is only suitable for injecting under the skin. Speak to your doctor if you need to inject your insulin by another method.

With each injection, change the injection site within the particular area of skin that you use. This may reduce the risk of developing lumps or skin pitting, see section 4. 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. The insulin will work more quickly if you inject into the waist (abdomen). You should always measure your blood sugar regularly.

How to handle Insulatard® InnoLet®

Insulatard® InnoLet® is a pre-filled disposable pen containing human insulin as isophane (NPH).

Read carefully the Instructions on how to use Insulatard® InnoLet® included in this package leaflet. You must use the pen as described in the Instructions on how to use Insulatard® InnoLet®.

Always ensure you use the correct pen before you inject your insulin.

If you take more insulin than you should

If you take too much insulin your blood sugar gets too low (hypoglycaemia). See *Summary of serious and very common side effects* in section 4.

If you forget to take your insulin

If you forget to take your insulin your blood sugar may get too high (hyperglycaemia). See *Effects from diabetes* in section 4.

If you stop taking your insulin

Do not stop taking your insulin without speaking with a doctor, who will tell you what needs to be done. This could lead to very high blood sugar (severe hyperglycaemia) and ketoacidosis. See *Effects from diabetes* in section 4.

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.

Summary of serious and very common side effects

Low blood sugar (hypoglycaemia) is a very common side effect. It may affect more than 1 in 10 people.

Low blood sugar may occur if you:

- Inject too much insulin.
- Eat too little or miss a meal.
- Exercise more than usual.
- Drink alcohol, see *Insulatard® with alcohol* in section 2.

Signs of low blood sugar: 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.

Severe low blood sugar can lead to unconsciousness. If prolonged severe low blood sugar is not treated, it can cause brain damage (temporary or permanent) and even death. 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 sugar snack as soon as you are conscious. If you do not respond to glucagon treatment, you will have to be treated in a hospital.

What to do if you experience low blood sugar:

- ▶ If you experience low blood sugar, eat glucose tablets or another high sugar snack (e.g. sweets, biscuits, fruit juice). Measure your blood sugar if possible and rest. Always carry glucose tablets or high sugar snacks with you, just in case.
- ▶ When the symptoms of low blood sugar have disappeared or when your blood sugar level is stabilised, continue insulin treatment as usual.
- ▶ If you have such low blood sugar that it makes you pass out, if you have had the need for an injection of glucagon, or if you have experienced many incidents of low blood sugar, talk to a doctor. The amount or timing of insulin, food or exercise may need to be adjusted.

Tell relevant people that you have diabetes and what the consequences may be, including the risk of passing out (becoming unconscious) due to low blood sugar. Let them know that if you pass out, they must turn you on your side and get medical help straight away. They must not give you any food or drink, because you may choke.

Serious allergic reaction to Insulatard® or one of its ingredients (called a systemic allergic reaction) is a very rare side effect, but it can potentially be life threatening. It may affect less than 1 in 10,000 people.

Seek medical advice immediately:

- If signs of allergy spread to other parts of your body.
- If you suddenly feel unwell, and you: start sweating; start being sick (vomiting); have difficulty in breathing; have a rapid heartbeat; feel dizzy.
- ▶ If you notice any of these signs, seek medical advice immediately.

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

List of other side effects

Uncommon side effects

May affect less than 1 in 100 people.

Signs of allergy: Local allergic reactions (pain, redness, hives, inflammation, bruising, swelling and itching) at the injection site may occur. These usually disappear after a few weeks of taking your insulin. If they do not disappear, or if they spread throughout your body, talk to your doctor immediately. See also *Serious allergic reactions* above.

Diabetic retinopathy (an eye disease related to diabetes which can lead to loss of vision): If you have diabetic retinopathy and your blood sugar level improves 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. If not, talk to your doctor.

Very rare side effects

May affect less than 1 in 10,000 people.

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.

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 via

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

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.

Effects from diabetes

High blood sugar (hyperglycaemia)

High blood sugar may occur if you:

- Have not injected enough insulin.
- Forget to inject your insulin or stop taking insulin.
- Repeatedly inject less insulin than you need.
- Get an infection and/or a fever.
- Eat more than usual.
- Exercise less than usual.

Warning signs of high blood sugar:

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.

What to do if you experience high blood sugar:

- ▶ If you get any of the above signs: test your blood sugar level, test your urine for ketones if you can, then seek medical advice immediately.
- ▶ These may be signs of a very serious condition called diabetic ketoacidosis (build-up of acid in the blood because the body is breaking down fat instead of sugar). If you do not treat it, this could lead to diabetic coma and eventually death.

5. *How to store Insulatard®*

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

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

Before opening: Store in a refrigerator at 2°C – 8°C. Keep away from the cooling element. Do not freeze.

During use or when carried as a spare: Do not refrigerate or freeze. 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 InnoLet® when you are not using it, in order to protect from light.

Discard the needle after each injection.

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 protect the environment.

6. **Contents of the pack and other information**

What Insulatard® contains

- The active substance is human insulin. Insulatard® is an isophane (NPH) human insulin suspension. Each ml contains 100 IU of human insulin. Each pre-filled pen contains 300 IU of human insulin in 3 ml suspension for injection.
- The other ingredients are zinc chloride, glycerol, metacresol, phenol, disodium phosphate dihydrate, sodium hydroxide, hydrochloric acid, protamine sulfate and water for injections.

What Insulatard® looks like and contents of the pack

Insulatard® is presented as a suspension for injection. After resuspension, the liquid should appear uniformly white and cloudy.

Pack sizes of 1, 5 and 10 pre-filled pens of 3 ml. Not all pack sizes may be marketed.

The suspension is cloudy, white and aqueous.

Marketing Authorisation Holder and Manufacturer

Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd, Denmark

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency website <http://www.ema.europa.eu>.

Now turn over for information on how to use your InnoLet®.

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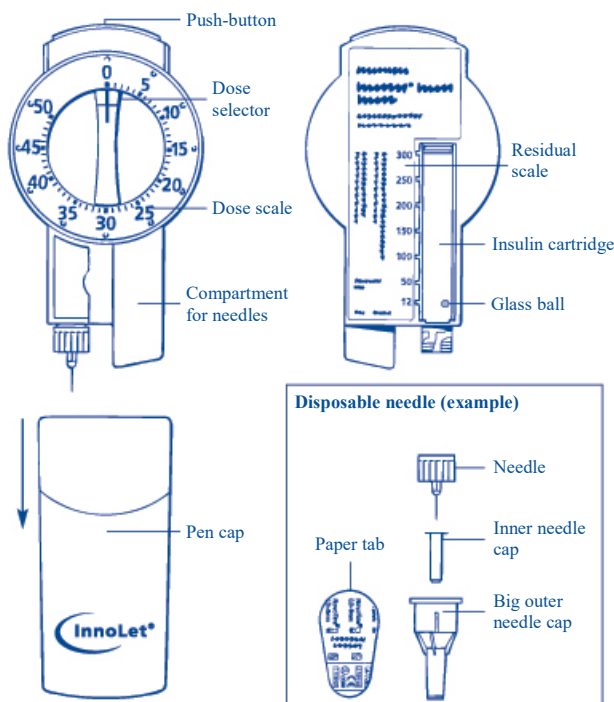
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Instructions on how to use Insulatard® suspension for injection in InnoLet®

Read the instructions carefully before using your InnoLet®. 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 InnoLet® is a simple, compact pre-filled pen able to deliver 1 to 50 units in increments of 1 unit.

InnoLet® 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 InnoLet® is lost or damaged.



Getting started

Check the name and coloured label of your InnoLet® 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. Take off the pen cap.

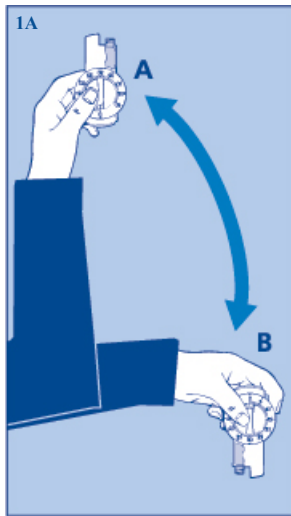
Resuspending is easier when the insulin has reached room temperature.

Resuspending the insulin

Before every injection:

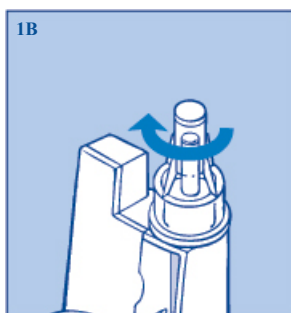
- **Check there are at least 12 units** of insulin left in the cartridge to allow even resuspension. If there are less than 12 units left, use a new InnoLet®.
- **Move the pen up and down** between positions A and B and back so that the glass ball moves from one end of the cartridge to the other (picture 1A) at least 20 times. Repeat this movement at least 10 times before each injection. The movement must always be repeated until the liquid appears uniformly white and cloudy.

- Always make sure that you have resuspended the insulin prior to each injection. If you do not resuspend the insulin, this may cause inaccurate dosing, which can lead to too high or too low blood sugar level. **After resuspending, complete all of the following stages of injection without delay.**



Attaching 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.
- **Remove the paper tab** from a new disposable needle.
- **Screw the needle straight and tightly** onto your InnoLet® (picture 1B).
- **Pull off the big outer needle cap and the inner needle cap.** You may want to store the big outer needle cap in the compartment. Never try to put the inner needle cap back on the needle. You may stick yourself with the needle.



Priming to expel air prior to each injection

Small amounts of air may collect in the needle and cartridge during normal use.

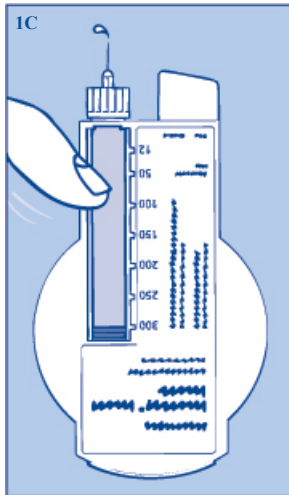
To avoid injection of air and ensure proper dosing:

- **Dial 2 units** by turning the dose selector clockwise.
- **Hold your InnoLet® with the needle upwards and tap the cartridge gently** with your finger a few times (picture 1C) to make any air bubbles collect at the top of the cartridge.
- **Keeping the needle upwards, press the push-button** and the dose selector returns to 0.

- **Always make sure that a drop appears at the needle tip** before injection (picture 1C). This makes sure the insulin flows. If not, change the needle and repeat the procedure no more than 6 times.

If a drop of insulin still does not appear, the device is defective and must not be used.

- 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 prime InnoLet® before you inject. If you do not prime InnoLet®, you may get too little insulin or no insulin at all. This may lead to too high blood sugar level.

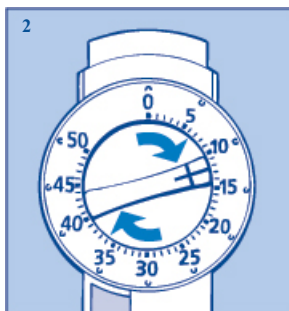


Setting the dose

- **Always check that the push-button is fully depressed and the dose selector is set to 0.**
- **Dial the number of units required** by turning the dose selector clockwise (picture 2).
- **You will hear a click for every single unit dialled.** The dose can be corrected by turning the dial either way. Make sure not to turn the dial or correct the dose when the needle is inserted in the skin. This may lead to inaccurate dosing that can make your blood sugar level too high or too low.

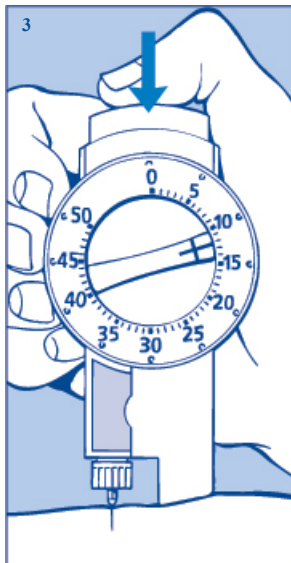
Always use the dose scale and the dose selector to see how many units you have selected before injecting the insulin. Do not count the pen clicks. If you select and inject the wrong dose, your blood sugar level may get too high or too low. Do not use the residual scale, it only shows approximately how much insulin is left in your pen.

You cannot set a dose larger than the number of units remaining in the cartridge.



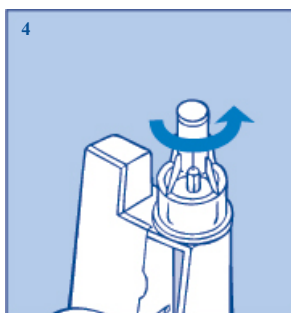
Injecting the insulin

- **Insert the needle into your skin.** Use the injection technique advised by your doctor.
- **Deliver the dose by pressing the push-button fully down** (picture 3). You will hear clicks as the dose selector returns to 0.
- **After the injection, the needle should remain under the skin for at least 6 seconds** to ensure that the full dose has been delivered.
- **Make sure not to block the dose selector while injecting,** as the dose selector must be allowed to return to 0 when you press 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.
- Discard the needle after each injection.



Removing the needle

- **Replace the big outer needle cap and unscrew the needle** (picture 4). **Dispose of it carefully.**
- Put the pen cap back on your InnoLet® to protect the insulin from light.



Always use a new needle for each injection.

Always remove and discard the needle after each injection and store your InnoLet® 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 InnoLet® 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 InnoLet® and needles out of sight and reach of others, especially children.

Caring for your pen

Your InnoLet® is designed to work accurately and safely. It 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 your InnoLet® by wiping it with a medicinal swab. Do not soak, wash or lubricate it. This may damage the mechanism and may cause inaccurate dosing, which can lead to too high or too low blood sugar level.

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