

Protaphane® InnoLet

Mixtard® 30/70 InnoLet®

Human insulin (rys)

Consumer Medicine Information

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This leaflet answers some common questions about human insulin InnoLet®. It does not contain all the available information. It does not take the place of talking to your doctor, diabetes education nurse or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using human insulin against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor, diabetes education nurse or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What human insulin is used for

Human insulin is used to treat diabetes mellitus. Diabetes mellitus is a condition where your pancreas does not produce enough insulin to control your blood sugar (glucose) level. Extra insulin is therefore needed.

There are two types of diabetes mellitus:

Type 1 diabetes - also called juvenile onset diabetes

Type 2 diabetes - also called maturity onset diabetes

Patients with type 1 diabetes always require insulin to control their blood sugar levels.

Some patients with type 2 diabetes may also require insulin after initial treatment with diet, exercise and tablets.

Human insulin lowers your blood sugar level after injection. Each of the following human insulins is available in InnoLet® , a 3mL compact pre-filled insulin pen able to deliver 1- 50 units in increments of 1 unit:

Protaphane® is Isophane Insulin Injection, an intermediate-acting insulin. This means that it will start to lower your blood sugar level about one and a half hours after you inject it, and the effect will last for approximately 24 hours.

Protaphane® is often used in combination with fast- or rapid-acting insulin products.

Mixtard® 30/70 is Biphasic Isophane Insulin Injection, a mixture of fast- and longer-acting insulins. Mixtard® 30/70 will start to lower your blood sugar level about half an hour after you inject, and the effect will last for approximately 24 hours.

As with all insulins, the duration of action will vary according to the type of insulin, the dose, injection site, blood flow, temperature and level of physical activity.

Human insulin is not addictive.

Human insulin is available only with a doctor's prescription.

Ask your doctor if you have any questions about why human insulin InnoLet® has been prescribed for you.

Before you use human insulin InnoLet®

When you must not use it

Do not use InnoLet® if:

1. you have an allergy to:

- any medicine containing insulin
- any of the ingredients listed in the "Ingredients" section of this leaflet.

Some of the symptoms of an allergic reaction may include:

- redness, swelling, rash and itching at the injection site;
- rash, itching or hives on the skin;
- shortness of breath;
- wheezing or difficulty breathing;

- swelling of the face, lips, tongue or other parts of the body.
2. **you are experiencing a low blood sugar level (a "hypo") when the dose is due.**

If you have a lot of hypos discuss appropriate treatment with your doctor.

If you are not sure whether you should start using this medicine, talk to your doctor.

Do not inject Protaphane® or Mixtard® 30/70 into a vein.

Do not use Protaphane® or Mixtard® 30/70 to treat a condition known as diabetic ketoacidotic coma.

Do not use this medicine after the expiry date printed on the label and carton, or if the packaging is torn or shows signs of tampering or does not look quite right.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- kidney problems
- liver problems
- adrenal, pituitary or thyroid gland problems

Tell your doctor if you are pregnant or planning to become pregnant.

Pregnancy may make managing your diabetes more difficult. Insulin needs usually decrease during the first three months of pregnancy and increase during the last six months. Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are breast-feeding or planning to breast-feed .

Your doctor or pharmacist can discuss with you the risks and benefits involved.

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).

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.

If you have not told your doctor about any of the above, tell them before you use InnoLet®.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and human insulin may interfere with each other. These include:

- oral hypoglycaemic agents - used to treat type 2 diabetes
- monoamine oxidase inhibitors (MAOI) - used to treat depression
- non-selective beta-blockers - used to treat certain heart conditions and high blood pressure
- alpha-blockers - used to treat high blood pressure and to relieve difficulty in passing urine caused by an enlarged prostate
- angiotensin converting enzyme (ACE) inhibitors - used to treat certain heart conditions, high blood pressure or elevated protein/albumin in the urine
- salicylates e.g. aspirin - used to relieve pain and lower fever
- anabolic steroids - used to promote growth
- glucocorticoids (except when applied locally) - used to treat inflammatory conditions
- oral contraceptives ("the pill") - used for birth control
- thiazides, frusemide or ethacrynic acid - used to treat high blood pressure or fluid retention (oedema)

- thyroid hormones - used to treat malfunction of the thyroid gland
- sympathomimetics - used to treat asthma
- sulphonamides - used to treat bacterial infections

Or other specific medicines including:

- danazol - used to treat endometriosis, menorrhagia, fibrocystic breast disease and hereditary angioedema
- oxymetholone - used to treat certain blood disorders
- octreotide - used to treat gastrointestinal endocrine tumours and enlargement of parts of the body (e.g. hands, feet, head) caused by abnormal growth hormone levels
- lanreotide - used to treat enlargement of parts of the body (e.g. hands, feet, head) caused by abnormal growth hormone levels
- diazoxide - used to treat high blood pressure
- nicotinic acid - used to treat high cholesterol levels in the blood
- asparaginase - used to treat leukaemia and lymph gland tumours
- quinine - used to treat malaria and relieve muscle cramps
- quinidine - used to treat heart problems
- growth hormone - used to treat growth disorders

Tell your doctor about any other medicines that you are taking.

This is very important. Your doctor will advise you if it is alright to keep taking them or if you should stop taking them.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

How to use human insulin InnoLet®

Your doctor, diabetes education nurse or pharmacist will have given you advice on how to use your medicine. Carefully follow all the directions.

They may differ from the information contained in this leaflet.

Any change in dose or type of insulin should be made cautiously and only under medical supervision.

If you change the type of insulin that you use, you may have to use more or less than before. This may happen with the first dose or over a period of time.

If you do not understand the instructions, ask your doctor, diabetes education nurse or pharmacist for help.

How much to use

Your doctor or diabetes education nurse will tell you how much of this medicine you need to use.

It is very important that you manage your diabetes carefully. Too much or too little insulin can cause serious effects.

When to use it

Your doctor or diabetes education nurse will tell you when and how often to inject the insulin. If you are using Mixtard® 30/70 InnoLet®, it is recommended that you eat a meal or a snack containing carbohydrate within 30 minutes of the injection.

How to use it

- Check your human insulin InnoLet® before each preparation and injection. Make sure you are using the correct type and strength of insulin.
- Do not use your InnoLet® if the medicine is no longer a cloudy, white suspension after resuspending, or if it has bits in it.

- You should inject human insulin under the skin (subcutaneous injection) as shown to you by your doctor or diabetes education nurse.
- You will feel the effect more quickly if the insulin is injected into your abdomen; however, you can inject into your thigh, buttock or upper arm.
- The best place to inject longer-acting insulin (Protaphane®) is in the thigh.
- Remember to regularly change your injection site as shown to you by your doctor or diabetes education nurse.
- Protaphane® and Mixtard® 30/70 InnoLet® are suitable for intramuscular administration in emergency **under medical guidance**. Discard InnoLet® after emergency use.
- Take care not to drop or knock InnoLet®.
- Do not use Protaphane® or Mixtard® 30/70 in insulin pumps.
- Always use a new NovoFine® or NovoTwist® needle for each injection to prevent contamination.

Read the instructions printed at the end of this leaflet carefully in order to correctly prepare and handle your InnoLet®.

How long to use it

Do not stop using your insulin unless your doctor tells you to.

If you use too much (overdose) - Hypoglycaemia

Your blood sugar level may become too low (you may experience hypoglycaemia or a "hypo") if you:

- accidentally use too much of this medicine
- have too much or unexpected exercise
- delay eating meals or snacks
- eat too little food
- are ill

The first symptoms of mild to moderate hypos can come on suddenly. They may include:

- cold sweat, cool pale skin
- fatigue, drowsiness, unusual tiredness and weakness
- nervousness, anxious feeling, tremor, rapid heart beat
- confusion, difficulty concentrating
- excessive hunger
- vision changes
- headache, nausea

Always carry some sugary food or fruit juice with you.

If you experience any of these symptoms of a hypo, immediately eat some sugary food or have a sugary drink e.g. lollies, biscuits or fruit juice.

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

Tell your relatives, friends, close workmates or carers that you have diabetes. It is important that they recognise the signs and symptoms of a hypo.

Make sure they know to give you some sugary food or fruit juice for mild to moderate symptoms of a hypo.

If you lose consciousness, make sure they know:

- to turn you on your side and get medical help immediately
- not to give you anything to eat or drink

This is because you could choke.

An injection of the hormone glucagon may speed up recovery from unconsciousness. This can be given by a relative, friend, workmate or carer who knows how to give it.

If glucagon is used, eat some sugary food or have a sugary drink as soon as you are conscious again.

If you do not feel better after this, contact your doctor, diabetes education nurse, or the closest hospital.

If you do not respond to glucagon treatment, you will require medical attention.

See your doctor if you keep having hypo reactions, or if you have ever become unconscious after using insulin.

Your insulin dose may need to be changed.

If a severe hypo is not treated, it can cause convulsions, brain damage and even death.

*If you miss a dose -
Hyperglycaemia*

If you forget to inject your insulin dose, test your blood sugar level as soon as possible.

If you are not sure what to do, talk to your doctor, diabetes education nurse or pharmacist.

Do not use a double dose of your insulin.

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to.

Otherwise, use it as soon as you remember and then go back to using it as you would normally.

Your blood sugar levels may become high (hyperglycaemia) if you:

- miss doses of insulin or use less insulin than you need
- have uncontrolled diabetes
- exercise less than usual
- eat more carbohydrates than usual
- are ill or stressed

High blood sugar levels over a long period of time can lead to too much acid in the blood (diabetic ketoacidosis).

Contact your doctor immediately if your blood sugar level is high or you recognise any of the following symptoms.

Symptoms of mild to moderate hyperglycaemia include:

- drowsy feeling
- flushed face
- thirst, loss of appetite

- fruity odour on the breath
- blurred vision
- passing larger amounts of urine than usual
- getting up at night more often than usual to pass urine
- high levels of glucose and acetone in the urine

Symptoms of severe hyperglycaemia include:

- heavy breathing
- fast pulse
- nausea, vomiting
- dehydration
- loss of consciousness

Severe hyperglycaemia can lead to unconsciousness and in extreme cases death if untreated.

Discuss any worries you may have about this with your doctor, diabetes education nurse or pharmacist.

While you are using human insulin InnoLet®

Things you must do

Measure your blood sugar level regularly.

Make sure all friends, relatives, workmates or carers know that you have diabetes.

If your child has diabetes it is important to tell their carers.

Keep using your insulin even if you feel well.

It helps to control your condition, but does not cure it.

Tell your doctor if you often have hypos (low blood sugar levels).

Your doctor may need to adjust your insulin dose.

Always carry some sugary food or fruit juice with you.

If you experience any of the symptoms of a hypo, immediately eat some sugary food or have a sugary drink e.g. lollies, biscuits or fruit juice.

Tell your doctor if you have trouble recognising the symptoms of hypos.

Under certain conditions, the early warning signs of hypos can be different or less obvious. Your doctor may need to adjust your insulin dose.

Make sure that you tell every doctor, dentist, pharmacist or other health care professional who is treating you that you have diabetes and are using insulin.

Tell your doctor, diabetes education nurse or pharmacist if you are travelling.

Ask them for a letter explaining why you are taking injecting devices with you. Each country you visit will need to see this letter, so you should take several copies.

You may need to inject your insulin and eat your meals at different times because of time differences in and between countries.

You may not be able to get the same type of insulin in the country you are visiting.

Your doctor, diabetes education nurse or pharmacist can provide you with some helpful information.

Things you must not do

Do not stop using your medicine unless your doctor tells you to.

Do not use the medicine if you think it has been frozen or exposed to excessive heat.

It will not work as well.

Do not refill your InnoLet®.

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how the insulin affects you.

Tell your doctor if you drink alcohol.

Alcohol may mask the symptoms of hypos.

Tell your doctor if you are ill.

Illness, especially with nausea and vomiting, may cause your insulin needs to change. Even if you are not eating, you still require insulin. You and your doctor should design an insulin plan for those times when you are sick.

Tell your doctor if you are exercising more than usual.

Exercise may lower your need for insulin. Exercise may also speed up the effect of a dose of it, especially if the exercise involves the area of the injection site (e.g. the leg should not be used for injection prior to jogging or running).

Tell your doctor if your diet changes.

Changes in diet may cause your insulin needs to change.

Side effects

Tell your doctor, diabetes education nurse or pharmacist as soon as possible if you do not feel well while you are using human insulin.

Insulin helps most people for whom it is prescribed, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor, diabetes education nurse or pharmacist to answer any questions you may have.

The most common side effect when using insulin is low blood sugar levels (a hypo).

Tell your doctor if you notice any of the following and they worry you:

- hypos (mild to moderate)
- redness, swelling or itching at the injection site. Usually these symptoms disappear within a few weeks during continued use. If you have serious or continuing reactions, you may need to stop using your current insulin and use another insulin.
- a depression or thickening of the skin around the injection site (lipodystrophy)
- when you first start your insulin treatment you may get visual problems or swollen hands and feet

This list includes the more common side effects of your medicine. They are usually mild and short-lived.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital :

More severe symptoms of low blood sugar levels, including:

- disorientation
- seizures, fits or convulsions
- loss of consciousness

If a severe hypo is not treated, it can cause brain damage and death.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following :

- skin rashes over a large part of the body
- shortness of breath, wheezing
- swelling of the face, lips or tongue
- fast pulse
- sweating

This list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Ask your doctor, diabetes education nurse or pharmacist to answer any questions you have.

After using human insulin InnoLet®

Storage

InnoLet® that **are not being used** should be stored between 2°C and 8°C in the refrigerator (away from the cooling element). **Protect the insulin in InnoLet® from light by keeping the insulin pen in the carton when not in use.**

The InnoLet® that you are using, or that you are carrying as a spare, does not need to be kept in a refrigerator. You can use it up to 4 weeks after taking it out of the refrigerator if it is kept below 25°C. **Discard InnoLet® after 4 weeks even if there is still some insulin left in it.**

InnoLet® must not be frozen, or exposed to excessive heat or light.

Never use InnoLet® after the expiry date printed on the label and carton after 'Expiry.'

The expiry date refers to the last day of that month.

Never use Protaphane® or Mixtard® 30/70 InnoLet® if the suspension does not become uniformly white and cloudy after resuspending.

Keep out of the reach of children.

Disposal

Dispose of your used InnoLet® safely into a yellow plastic sharps container.

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product Description

What it looks like

Protaphane® and Mixtard® 30/70 are white, cloudy suspensions for subcutaneous injection. Protaphane® and Mixtard® 30/70 InnoLet® are 3mL glass cartridges contained in an insulin pen.

Ingredients

Human insulin (rys) is characterised by being identical to natural human insulin. The abbreviation "rys" indicates the method of genetic engineering used to manufacture the insulin.

Protaphane® is a neutral suspension of isophane human insulin (rys) 100 IU/mL. Also contains: glycerol, meta-cresol, phenol, dibasic sodium phosphate dihydrate, zinc chloride, protamine sulfate, water for injections. Hydrochloric acid and sodium hydroxide are used to adjust the pH.

Mixtard® 30/70 is a pre-mixed neutral suspension of human insulin (rys) 100 IU/mL, consisting of neutral insulin injection (30%) and isophane insulin injection (70%). Also contains: glycerol, meta-cresol, phenol, dibasic sodium phosphate dihydrate, zinc chloride, protamine sulfate, water for injections. Hydrochloric acid and sodium hydroxide are used to adjust the pH.

Sponsor

InnoLet® is supplied in Australia by:

Novo Nordisk Pharmaceuticals Pty Ltd

Level 3

21 Solent Circuit

Baulkham Hills NSW 2153

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Australian Registration Numbers:

Protaphane® InnoLet®:

AUST R 169633

Mixtard® 30/70 InnoLet®:

AUST R 169628

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Further information

For further information call the NovoCare® Customer Care Centre on 1800 668 626.

www.novonordisk.com.au

You can also get more information about diabetes and insulin from Diabetes Australia:

- freecall helpline 1300 136 588

www.diabetesaustralia.com.au

Instructions For Use

Please read the following instructions carefully before using your human insulin InnoLet®.

Introduction

Human insulin 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 of 8mm or shorter length.

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

Preparing for injection

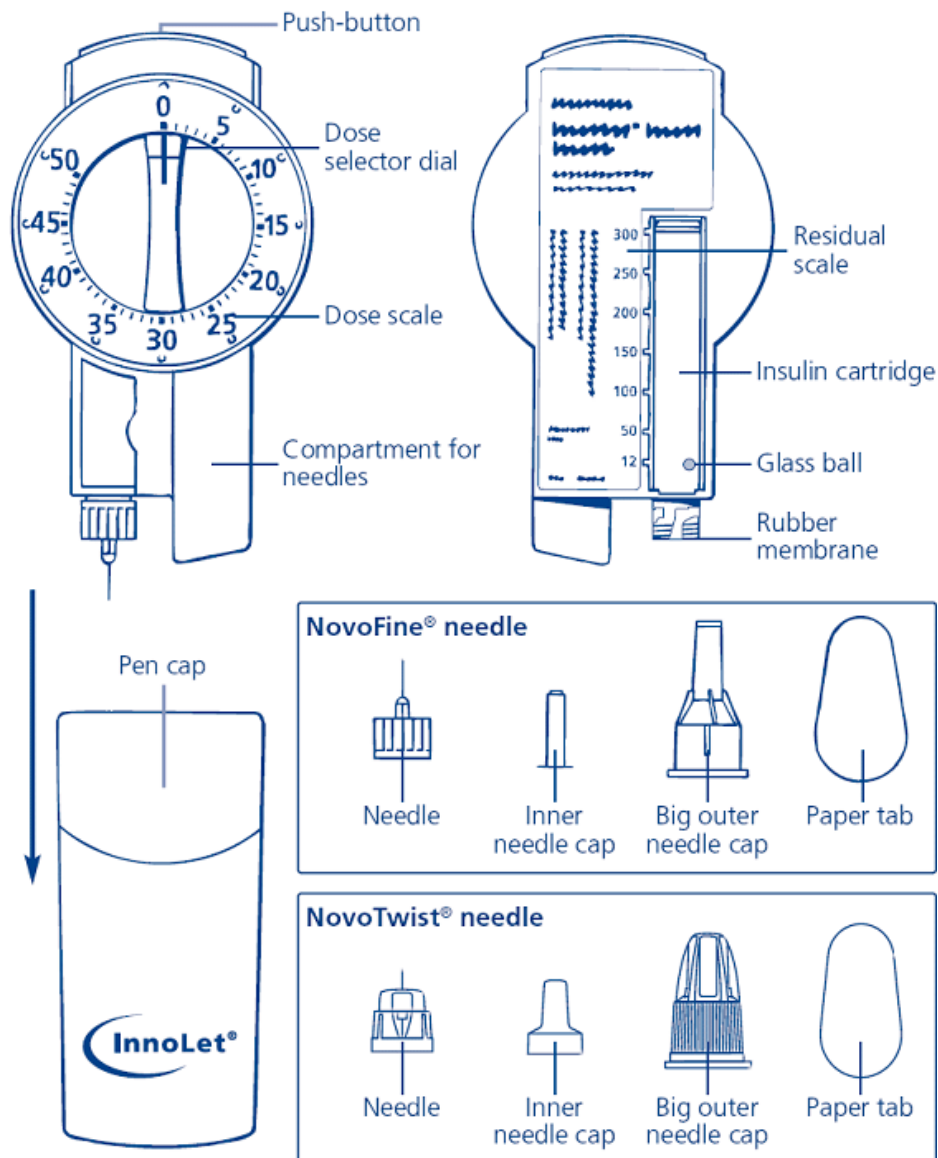
Check the label to make sure that your InnoLetCheck the label to make sure contains the correct type of insulin. Take off the pen cap (as shown by the arrow).

Resuspending is easier when the insulin has reached room temperature.

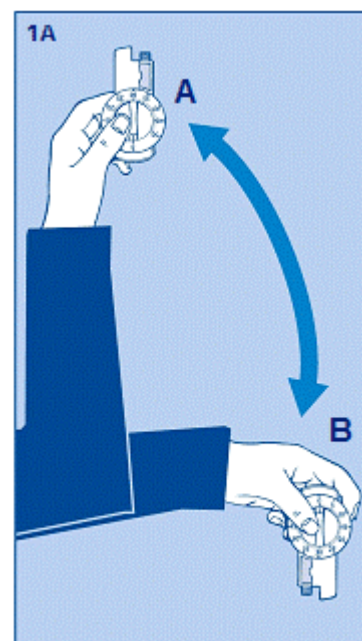
Resuspending the insulin

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.

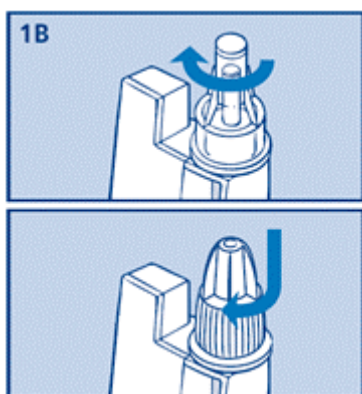


- **After resuspending the insulin, complete all of the following stages of injection without delay.**



Attaching the needle

- **Disinfect the rubber membrane** with a medicinal swab.
- **Always use a new needle** for each injection to prevent contamination.
- **Remove the paper tab** from a NovoFine® or NovoTwist® needle.
- If using a NovoFine® needle **screw the needle** onto your InnoLet® (picture 1B) so that it is straight and secure. If using a NovoTwist® needle, twist the needle onto your InnoLet® until a "click" is heard.



- **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.

Priming to expel air

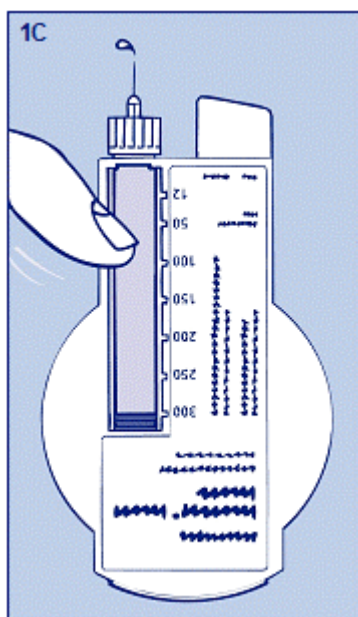
It is important to prime your InnoLet® prior to every injection. The priming procedure may highlight a malfunction with your InnoLet®. Priming also helps to remove air bubbles and would help indicate whether or not a needle is blocked. If problems are encountered during priming, use an alternative insulin delivery system, **DO NOT USE YOUR INNOLET®**, and contact your diabetes education nurse and/or Novo Nordisk.

To avoid injection of air and ensure proper dosing:

- **Dial 2 units** by turning the dose selector clockwise.

- **Hold InnoLet® 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 (picture 1C).
- **Keeping the needle upwards, press the push-button** and the dose selector returns to zero.
- **A drop of insulin must appear at the needle tip.** If not, change the needle and repeat the procedure no more than 6 times.

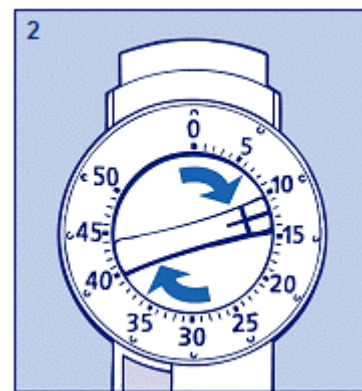
If a drop of insulin still does not appear, the pen is defective and must not be used.



Setting the dose

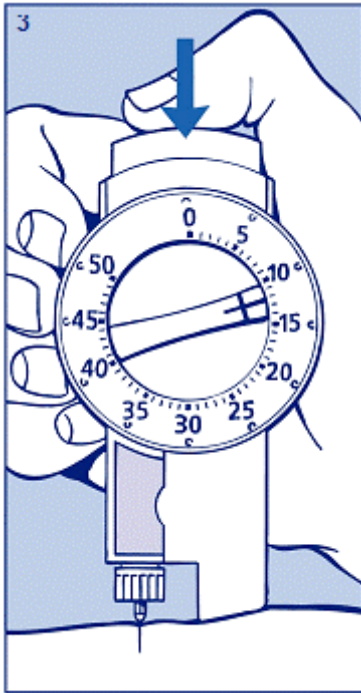
- **Always check that the push-button is fully depressed and the dose selector is set at zero.**
- **Dial the number of units required** by turning the dose selector clockwise (picture 2). Do not use the residual scale to measure your dose of insulin.
- **You will hear a click for every single unit dialled.** The dose can be corrected by turning the dial either way.

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



Injecting the insulin

- **Insert the needle into your skin.** Use the injection technique advised by your doctor or diabetes education nurse.
- **Deliver the dose by pressing the push-button fully down** (picture 3). You will hear clicks as the dose selector returns to zero. Turning the dial backwards does not deliver insulin. The push-button must be used.
- **After the injection, the needle must remain under the skin for at least 6 seconds** to ensure that the full dose has been delivered.
- **Make sure that you do not obstruct the dose selector while injecting**, as the dose selector must be allowed to return to zero when you press the push-button.
- **Remove the needle after each injection.**



Removing the needle

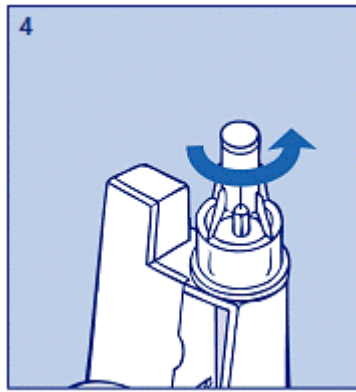
- **Replace the big outer needle cap carefully. Then remove the needle by unscrewing it (for NovoFine® needles) (picture 4), or with a twist (for NovoTwist® needles). Dispose of it carefully.**

Use a new needle for each injection.

Remove the needle after each injection and store InnoLet® without the needle attached. Otherwise, the liquid may leak out which can cause inaccurate dosing.

Health care professionals, relatives and other carers must follow general precautionary measures for removal and disposal of needles to eliminate the risk of unintended needle penetration.

Dispose of your used human insulin InnoLet® carefully with the needle removed.



Maintenance

Your human insulin InnoLet® is designed to work accurately and safely. It must be handled with care.

Do not refill your InnoLet®.

You can clean your human insulin InnoLet® by wiping it with a medicinal swab. Do not soak it, wash or lubricate it. This may damage the mechanism.