

# Protaphane<sup>®</sup> InnoLet<sup>®</sup> Mixtard<sup>®</sup> 30/70 InnoLet<sup>®</sup>

Human insulin (rys)

## Consumer Medicine Information

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This leaflet answers some common questions about human insulin InnoLet<sup>®</sup>. It does not contain all the available information. It does not take the place of talking to your doctor 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 or pharmacist.**

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

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### What human insulin is used for

The human insulin in InnoLet 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. Human insulin lowers your blood sugar level after injection.

Each of the following human insulins is available in InnoLet, a compact pre-filled insulin delivery device able to deliver 1-50 units in increments of 1 unit:

*Protaphane<sup>®</sup>* is Isophane Insulin Injection. It is a neutral suspension of isophane human insulin (rys). When shaken gently, the liquid appears white and cloudy.

*Mixtard<sup>®</sup> 30/70* is Biphasic Isophane Insulin Injection. It is a pre-mixed neutral suspension of human insulin (rys) consisting of neutral insulin injection (30%) and isophane insulin injection (70%). When shaken gently, the liquid appears white and cloudy.

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

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

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### Before you use InnoLet<sup>®</sup>

#### **When you must not use it**

#### **Do not use InnoLet if:**

- you have very low blood sugar levels (hypoglycaemia). See section “If you use too much (overdose)”

- you are allergic to human insulin or any of the ingredients listed under each type of insulin in the “Ingredients” section of this leaflet
- it is after the expiry date (“Expiry”) printed on the label and carton
- the packaging is torn, shows signs of tampering or does not look quite right
- you think it has been frozen or exposed to excessive heat
- the insulin in your Protaphane or Mixtard 30/70 InnoLet does not become white and uniformly cloudy when shaken

#### **Before you start to use it**

#### **Tell your doctor if you:**

- are pregnant or planning to become pregnant
- are breast-feeding or planning to breast-feed
- plan to have surgery
- think you may have allergies to human insulin or any of the ingredients listed under each insulin type in the “Ingredients” section of this leaflet

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

- kidney problems
- liver problems
- gastrointestinal problems

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

## **Taking other medicines**

Your dose of insulin may need to change if you take other medicines. You should tell your doctor if you are currently taking any medicines, especially the following:

- oral hypoglycaemic agents - used for the treatment of non-insulin dependent diabetes (type 2 diabetes)
- monoamine oxidase inhibitors (MAOI) - used for the treatment of depression
- non-selective beta-blocking agents - used for the treatment of certain heart conditions and high blood pressure
- alpha-blocking agents - used for the treatment of high blood pressure and to relieve difficulty in passing urine caused by an enlarged prostate
- angiotensin converting enzyme (ACE) inhibitors - used for the treatment of 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 and glucocorticoids (except topical administration) – used to treat inflammatory conditions
- oral contraceptives (“the pill”) - used for birth control
- thiazides, frusemide or ethacrynic acid - used for the treatment of high blood pressure or fluid retention (oedema)
- thyroid hormones - used for the treatment of malfunction of the thyroid gland
- sympathomimetics - used for the treatment of asthma
- sulphonamides – used to treat bacterial infections

Or other specific medicines including:

- danazol - used to treat certain female conditions
- oxymetholone – used to treat certain blood disorders
- octreotide - used to treat gastrointestinal endocrine tumours
- diazoxide - used for the treatment of high blood pressure
- nicotinic acid - used for the treatment of high cholesterol levels in the blood
- asparaginase - used to treat leukaemia and lymph gland tumours
- quinine – used for the prevention of malaria and the relief of muscle cramps
- quinidine – used for the control of heart problems
- growth hormone – used to treat persons with growth hormone deficiency

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

## **Immediately before you use it**

**Make sure that:**

- the insulin in your Protaphane or Mixtard 30/70 InnoLet looks uniformly white and cloudy
- your InnoLet is not damaged

InnoLet is for use by you alone to avoid the risk of passing on diseases.

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## **Using InnoLet®**

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### **How to use InnoLet®**

**Carefully follow the advice from your doctor and your diabetes team regarding type**

**of insulin, dosage and time of administration, blood sugar monitoring, diet and exercise in order to achieve good control of your diabetes.**

Your doctor may also want you to use another insulin.

## **Changing to human insulin**

An adjustment in dosage may be necessary when a switch is made from beef insulin to human insulin. If an adjustment is needed, it may occur with the first dose or during the first several weeks or months. **Do not change dosage or preparation except on your doctor's advice.**

A few patients have reported that after being transferred to human insulin, the early warning symptoms for hypoglycaemia (low blood glucose) were less pronounced than they were with animal source insulins. The character and intensity of these warning symptoms may also change during periods of tight blood glucose control, for instance during intensified insulin treatment.

## **When to use it**

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

## **How much to use**

Your doctor will tell you how much insulin to inject each time.

## **How to use it**

- InnoLet devices are designed to be used with NovoFine® S needles.
- Make sure you are using the correct type and strength of insulin. Carefully follow the instructions on how to use your InnoLet.

- Do not use the residual scale to measure your dose of insulin (see “Instructions For Use”).
- Prime InnoLet before each injection until a drop of insulin appears at the tip of the needle. Do not use InnoLet if you have to prime it **more** than 6 times before the first injection (see “Instructions For Use”).
- You should inject human insulin under the skin (subcutaneous injection) as shown to you by your doctor or diabetes educator.
- 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 educator.
- Protaphane and Mixtard 30/70 InnoLet are suitable for intramuscular administration in emergency under medical supervision only. Discard InnoLet after emergency use.
- Take care not to drop or knock InnoLet.

When using InnoLet the colour of the push button is specific for the insulin preparation.

Insulin can either be clear (insulin solution) or cloudy (insulin suspension). Treatment with long-acting cloudy insulin may be supplemented by short-acting clear insulin given separately in accordance with your doctor’s advice.

**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 human insulin unless your doctor tells you to.**

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

Your blood sugar level may become too low (hypoglycaemia). This can also happen if you miss a meal or exercise more than usual.

The first **symptoms of hypoglycaemia** can come on suddenly. They may include: cold sweat, cool pale skin, fatigue, nervousness or tremor, anxious feeling, unusual tiredness and weakness, confusion, difficulty in concentration, excessive hunger, temporary vision changes, headache, nausea or rapid heart beat.

### ***What to do in case of hypoglycaemia***

If you experience any of the symptoms mentioned above you should immediately take sugary food or drink e.g. lollies, biscuits or fruit juice. **So always carry one of these with you.**

**Tell your relatives, friends and close workmates that you have diabetes and how they can help you if you get a severe hypoglycaemic reaction. Make sure they know you should not be given anything to eat or drink if you are unconscious because you could choke.**

If you are unconscious, you should be turned on your side and your relatives, friends or workmates should get medical help immediately.

An injection of the hormone glucagon may speed up recovery from unconsciousness. This can be given by a relative or friend who has been instructed in its use. If glucagon is used, sugary food or drink should be given by mouth as soon as you are conscious again. If you do not feel better after this, you should contact

your doctor, diabetes educator or the closest hospital. If you do not respond to glucagon treatment, you will have to be treated in a hospital.

**See your doctor if you have had repeated hypoglycaemic reactions or one reaction which led to unconsciousness, as your insulin dose may need to be changed.**

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

### ***If you forget to use it***

If you realise you have missed a dose you should check your blood sugar level. If you repeatedly use less insulin than you need, your blood sugar level may become unusually high (hyperglycaemia). This can also happen if you are sick or if you eat much more than usual.

The **symptoms of unusually high blood sugar levels** will appear gradually. They include: increased urination, thirst, loss of appetite, nausea, vomiting, drowsiness (fatigue), flushed dry skin, dry mouth and acetone breath.

### ***What to do in case of hyperglycaemia***

If you recognise any of the symptoms mentioned above, you should check your blood sugar level and test your urine for ketones as soon as possible. These symptoms may indicate that you have a condition called ketoacidosis.

**Contact your doctor immediately as this condition is critical and if untreated may result in coma and death.**

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## While you are using InnoLet®

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### **Things you must do**

**Make sure that you tell every doctor or health care professional who is treating you that you have diabetes and are using insulin.** If your child has diabetes it is important to tell their carers.

**Measure your blood sugar level regularly.**

### **When driving or operating machines**

For people with diabetes driving and operating heavy machinery is generally safe. However your ability to concentrate or react may be reduced if you have hypoglycaemia. Please keep this in mind in all situations where you might put yourself and others at risk (e.g. driving a car or operating machinery).

**Make sure that you have sugary food or drink easily available in the car or workplace. If practical, check your blood sugar level before driving or operating heavy machinery.**

You should contact your doctor if you have:

- frequent episodes of hypoglycaemia
- reduced or absent warning signs of hypoglycaemia

### **When you are sick**

Illness (especially with fever, infection, nausea or vomiting) may cause your insulin needs to change. Even if you are not eating you still require insulin. See your doctor or diabetes educator to develop an insulin plan for those times when you are sick.

If you have developed problems with your kidneys or your liver your doctor may lower your insulin dosage.

### **When you are pregnant or breast-feeding**

If you are pregnant or planning to become pregnant you should consult your doctor immediately to discuss the control of your diabetes and insulin requirements as these may change during pregnancy. Breast-feeding during insulin treatment should not harm your baby. Your insulin dosage and diet may need to change.

### **Things you must not do**

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

**Do not use InnoLet to treat any other complaints.**

**Do not stop using InnoLet without checking with your doctor.**

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## Things to be careful of

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### **When you are drinking alcohol**

**Be careful when you drink alcohol.** Alcohol (including beer and wine) may lead to low blood sugar levels (hypoglycaemia). The early warning symptoms of hypoglycaemia may not be noticed and go untreated if you have had too much alcohol. **Never drink alcohol on an empty stomach.**

### **When you are travelling**

The time differences within and between countries may mean that you have to take your insulin and meals at different times than usual. **Make sure you consult your doctor or diabetes team if you are planning to travel.**

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## Things that may help your condition

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People with diabetes should lead a healthy lifestyle.

### **Diet**

Insulin is essential to keep your blood sugar levels within acceptable limits. Regular meals and a balanced diet are important factors in the management of diabetes. It is important that you discuss a suitable diet plan with your doctor or diabetes team.

### **Smoking**

Smoking may increase the chance of complications with your diabetes.

Your doctor and diabetes team can give you information on healthy living for people with diabetes.

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## Side effects

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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.

### **Hypoglycaemia**

Human insulin may cause **hypoglycaemia** - see section "If you use too much (overdose)".

### **Allergy**

Some people may notice redness, swelling and itching at the site of injection (**local allergy**). Usually these symptoms disappear within a few weeks during continued use.

If the symptoms do not disappear, spread to other parts of your body or if you suddenly feel sick (i.e. sweating, vomiting, difficulty breathing, rapid heart beat, feeling dizzy) you should contact your doctor immediately. You may have a **general allergic reaction** which is rare but could be serious.

### **Other**

When you first start your insulin treatment you may get visual

problems or swollen hands and feet.

If you inject too often in the same site, this may result in skin changes (called lipodystrophy). To avoid this, you should change your injection site regularly as shown to you by your doctor or diabetes educator.

You should tell your doctor or pharmacist as soon as possible if you notice any side effects or do not feel well while you are using human insulin.

**Ask your doctor or pharmacist to answer any questions you have.**

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## Storage

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InnoLet that **are not being used** should be stored between 2°C and 8°C in a refrigerator (not too near the freezer section). **Protect the insulin in InnoLet from light by keeping the insulin delivery devices in the carton when not in use.**

The InnoLet **that you are using**, or that which 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 heat or direct sunlight.

**Never use InnoLet after the expiry date printed on the label and carton.**

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

**Keep out of the reach of children.**

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## Product Description

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### ***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 delivery device.

### ***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*<sup>®</sup> 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*<sup>®</sup> 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.

### ***Manufacturer***

InnoLet is made in Denmark and supplied in Australia by:

***Novo Nordisk Pharmaceuticals Pty Ltd***

A.B.N. 40 002 879 996  
Level 3  
21 Solent Circuit  
Baulkham Hills NSW 2153

This leaflet was prepared on 14 November 2003.

Australian Registration Numbers:

Protaphane InnoLet:  
AUST R 75223  
Mixtard 30/70 InnoLet:  
AUST R 75225

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# Protaphane<sup>®</sup> InnoLet<sup>®</sup> Mixtard<sup>®</sup> 30/70 InnoLet<sup>®</sup>

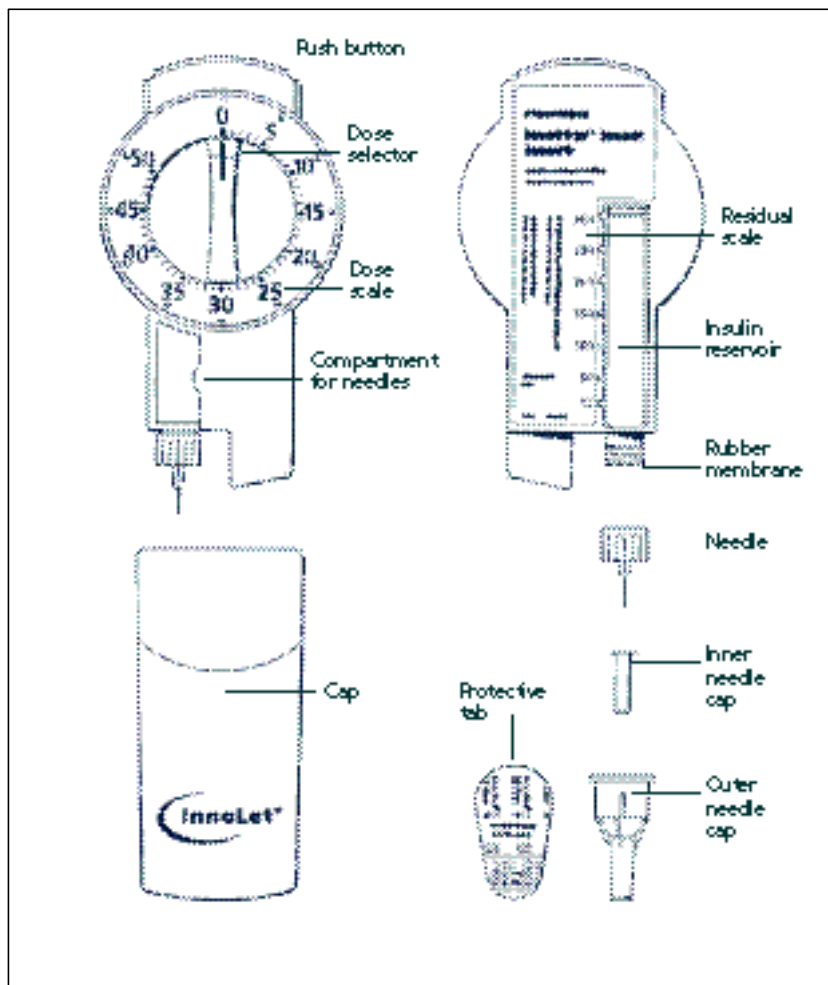
Human insulin (rys)

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## Instructions For Use

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Read the following instructions carefully in order to correctly prepare your InnoLet<sup>®</sup>.

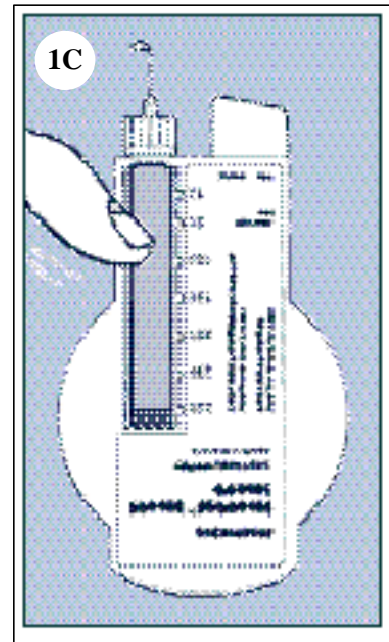
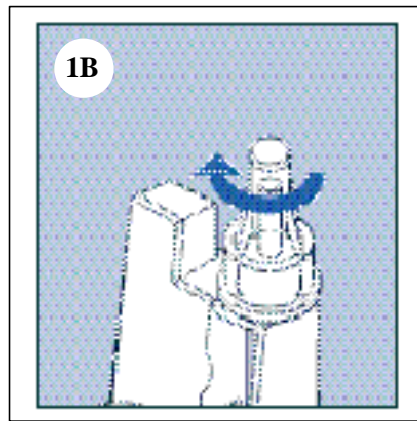
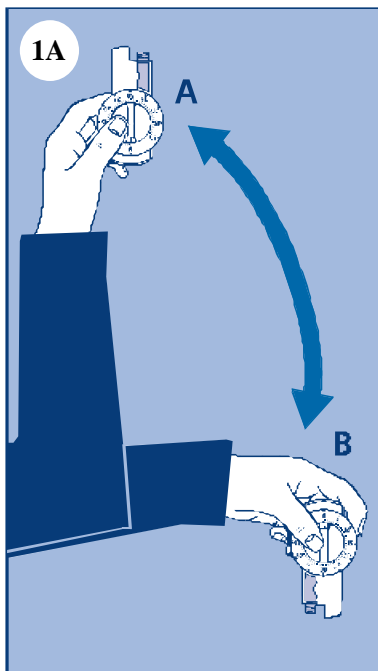


### 1. Preparing InnoLet<sup>®</sup>

Check that InnoLet contains the correct type of insulin. Pull off the cap.

#### 1A. Resuspending the insulin

Before using InnoLet the first time and before every injection: Turn InnoLet slowly up and down between positions **A** and **B** - as shown in Figure 1A - so that the glass ball inside the reservoir moves from one end to the other. *Do this at least 10 times until the liquid appears uniformly white and cloudy.* (For any injection there must be at least 12 units left in the reservoir to give the glass ball space to move when shaking the insulin. If there are less than 12 units left, InnoLet must not be used.) Now complete all of the following stages of injection without delay.



### 1B. Attaching the needle

Disinfect the rubber membrane with an alcohol swab prior to use. Remove the protective tab from a NovoFine® S needle and screw the needle securely onto InnoLet – as shown in Figure 1B. Pull off the outer and inner needle caps. You may wish to store the outer needle cap in the compartment for needles.

### 1C. Priming InnoLet®

Small amounts of air may collect in the needle and reservoir during normal use. To avoid injection of air:

Dial 2 units by turning the dose selector clockwise.

Hold InnoLet with the needle upwards and tap the reservoir gently with your finger a few times to make any air bubbles collect at the top of the reservoir.

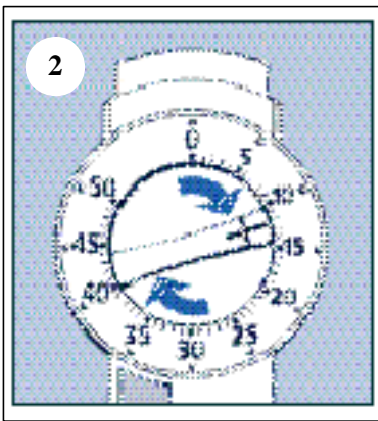
Whilst keeping the needle pointing upwards, fully depress the push button and the dose selector returns to zero. A drop of insulin should appear at the needle tip - as shown in Figure 1C. If one does not appear, repeat the priming procedure **up to 6 times**. If a drop of insulin still does not appear, the device must not be used.

Some air may remain in the insulin reservoir after priming but it will not be injected.

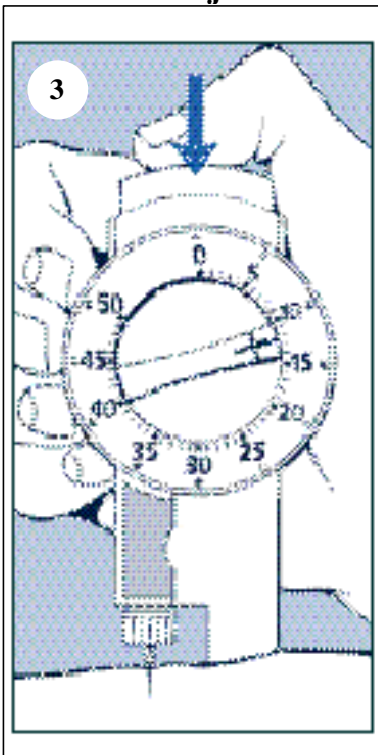
## 2. Setting the dose

To set the dose always check that the push button is fully depressed and the dose selector is set to zero. Dial the number of units required by turning the dose selector clockwise - as shown in Figure 2. You will hear a click for every single unit dialled.

As the dose selector is turned, the push button rises. If you have set an incorrect dose, simply turn the dial forwards or backwards until the correct number of units has been set. **50 units is the maximum dose.**



### 3. How to inject



- Pinch your skin between two fingers, push the needle into the skin fold and inject the insulin under the skin by pressing the push button fully down - as shown in Figure 3.
- After the injection, leave the needle under the skin for at least 6 seconds. Keep the push button fully pushed down until you remove the needle from the skin. This will ensure complete delivery of the dose and will also mean that there is less risk of blood or other body fluids flowing back into the needle or insulin reservoir.
- If blood appears after the needle has been withdrawn, press the injection site lightly with a finger.

Do not inject cloudy insulins into a vein.

#### Subsequent injections

Always check that the push button is fully down. If it is not, turn the dose selector until the push button is completely down. Then proceed as described in sections 1 to 3.

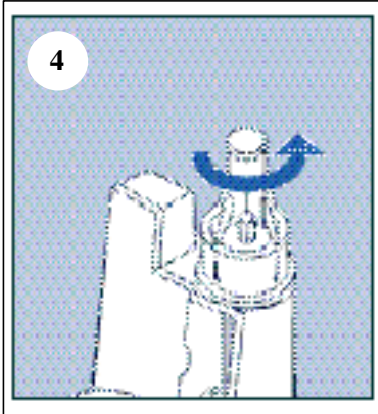
When depressing the push button you may hear a clicking sound. Do not rely on this clicking sound as a means of determining or confirming your dose.

Remember that:

- you cannot set a dose greater than the number of units left in the reservoir
- you can use the residual scale to measure how much insulin is left. You must not use the residual scale to set or choose your dose

Note: For the cloudy insulins, when you make any injection there must be at least 12 units left in the reservoir to give the glass ball space to move when you shake your insulin. If your dose is less than 12 units, and the reservoir is almost empty, first dial up to 12 (to check that 12 units are left) and then set the dose you need. If you cannot dial up to 12, change to a new InnoLet insulin delivery device.

#### 4. After you use InnoLet®

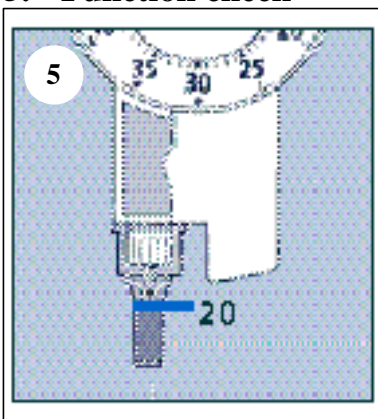


After the injection, attach either a NovoFine needle remover or – as shown in Figure 4 - the outer needle cap, and unscrew the needle. Discard it carefully. Health care professionals, relatives and other carers should follow general precautionary procedures for removal and disposal of needles to eliminate the risk of needlestick injury.

Replace the cap. Do not refill InnoLet.

When you are using InnoLet you should remove the needle after each injection. If you do not remove it, temperature changes may cause liquid to leak out of the insulin reservoir. It is important to use a new needle for each injection.

#### 5. Function check



If you think that your InnoLet is not working properly, follow this procedure:

- Screw on a new NovoFine S needle
- Prime InnoLet as described in section 1C “Priming InnoLet”
- Attach the outer needle cap
- Dispense 20 units of insulin into the needle cap

The insulin will fill the lower part of the cap - as shown in Figure 5. If InnoLet has released too much or too little insulin, repeat the test. If it happens again, contact your supplier and do not use your InnoLet. Dispose of your used InnoLet carefully with the needle removed.

## **6. Maintenance**

Your InnoLet is designed to work accurately and safely. It should be handled with care. Avoid situations where InnoLet can be damaged.

You can clean your InnoLet by wiping it with cotton wool moistened with alcohol. Do not soak it in alcohol or wash or lubricate it. This may damage the mechanism.