

Protaphane[®] NovoLet[®] 3mL

Human insulin (rys)

Consumer Medicine Information

What is in this leaflet

What Protaphane[®] is used for .1

Before you use Protaphane[®] NovoLet[®]1

Using Protaphane[®] NovoLet[®] .2

While you are using Protaphane[®] NovoLet[®]3

Things to be careful of.....4

Things that may help your condition4

Side effects4

Storage.....5

Product Description.....5

Instructions For Use.....6

This leaflet answers some common questions about Protaphane[®] NovoLet[®] 3mL. 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 Protaphane 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.

What Protaphane[®] is used for

The human insulin, or “Protaphane”, in Protaphane NovoLet 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.

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

Protaphane lowers your blood sugar level after injection. The duration of action will vary according to the dose, injection site, blood flow, temperature and level of physical activity.

NovoLet 3mL is a pre-filled, dial-a-dose insulin delivery device able to deliver 2-78 units.

Ask your doctor if you have any questions about why Protaphane NovoLet has been prescribed for you.

Before you use Protaphane[®] NovoLet[®]

When you must not use it

Do not use Protaphane NovoLet 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 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 NovoLet 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 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 Protaphane NovoLet.

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 NovoLet looks uniformly white and cloudy
- your NovoLet is not damaged

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

Using Protaphane[®] NovoLet[®]

How to use Protaphane[®] NovoLet[®]

Carefully follow the advice from your doctor and your diabetes team regarding 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.

How much to use

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

How to use it

- Protaphane NovoLet is designed to be used with NovoFine[®] needles.
- Make sure you are using the correct type and strength of insulin. Carefully follow the instructions on how to use Protaphane NovoLet.
- Do not use the insulin level indicator to measure your dose of insulin (see “Instructions For Use”).
- Prime Protaphane NovoLet before each injection until a drop of insulin appears at the tip of the needle. Do not use Protaphane NovoLet if you have to prime it **more** than 6

times before the first injection (see “Instructions For Use”).

- You should inject Protaphane under the skin (subcutaneous injection) as shown to you by your doctor or diabetes educator.
- The best place to inject Protaphane is in the thigh.
- You will feel the effect more quickly if the insulin is injected into your abdomen; however, you can also inject into your thigh, buttock or upper arm.
- Remember to change your injection site regularly as shown to you by your doctor or diabetes educator.
- Protaphane NovoLet is suitable for intramuscular administration in emergency under medical supervision only. Discard NovoLet after emergency use.
- Take care not to drop or knock your Protaphane NovoLet.

Insulin can either be clear (insulin solution) or cloudy (insulin suspension). Treatment with long-acting cloudy insulin such as Protaphane 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 Protaphane NovoLet.

How long to use it

Do not stop using Protaphane NovoLet unless your doctor tells you to.

If you use too much (overdose)

Your blood sugar 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 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 test your blood sugar level and 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.

While you are using Protaphane® NovoLet®

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 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 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 Protaphane NovoLet to anyone else, even if they have the same condition as you.

Do not use Protaphane NovoLet to treat any other complaints.

Do not stop using Protaphane NovoLet without checking with your doctor.

Things to be careful of

When you are drinking alcohol

Be careful when you drink alcohol. Alcohol (including beer and wine) may lead to low blood sugar (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.**

Things that may help your condition

People with diabetes should lead a healthy lifestyle.

Diet

Insulin is essential to keep the blood sugar 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.

Side effects

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

Protaphane NovoLet 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 Protaphane NovoLet.

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

Storage

Protaphane NovoLet 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 Protaphane NovoLet from light by keeping the insulin delivery devices in the carton when not in use.**

The Protaphane NovoLet **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. **Discard Protaphane NovoLet after 4 weeks even if there is still some insulin left in it.**

Protaphane NovoLet must not be frozen, or exposed to heat or direct sunlight.

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

Never use Protaphane NovoLet if the suspension does not become white and uniformly cloudy after shaking.

Keep out of the reach of children.

Product Description

What it looks like

Protaphane is a white, cloudy suspension for subcutaneous injection. Protaphane NovoLet 3mL is a glass cartridge contained in an insulin delivery device.

Ingredients

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.

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.

Manufacturer

Protaphane NovoLet 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 15 October 2003

Protaphane NovoLet 3mL:
AUST R 56247

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

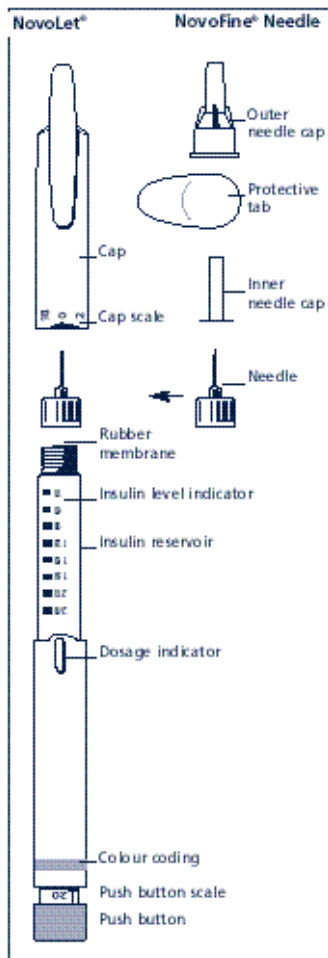
www.novonordisk.com.au

Protaphane[®] NovoLet[®] 3mL

Human insulin (rys)

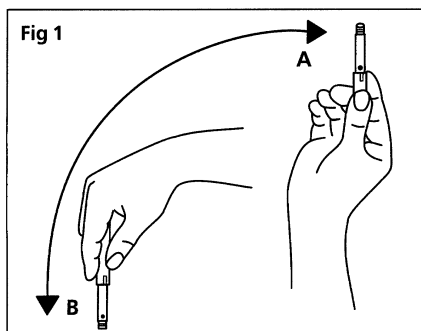
Instructions For Use

Read the following instructions carefully in order to correctly prepare your Protaphane[®] NovoLet[®].



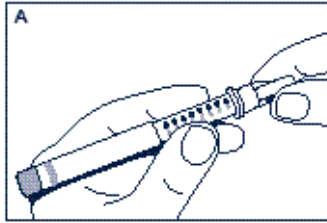
IMPORTANT

Before use, turn Protaphane NovoLet up and down between positions **A** and **B** - as shown in Figure 1 - so that the glass ball in the cartridge moves from one end to the other. *The movement must be performed at least 10 times until the liquid appears uniformly white and cloudy.*



1. Preparing Protaphane® NovoLet®

Check that NovoLet contains the correct type of insulin. Pull off the cap. Disinfect the rubber membrane with an alcohol swab prior to use.



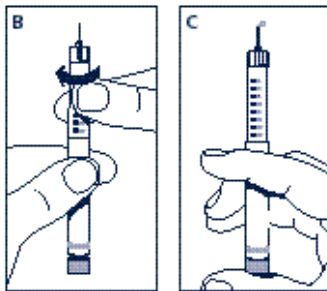
A. Remove the protective tab from a NovoFine needle and screw the needle onto Protaphane NovoLet securely. Pull off the outer and inner needle caps. Do not discard the outer needle cap unless you have a NovoFine needle remover available for use.

Priming Protaphane® NovoLet®

Always prime Protaphane NovoLet before each injection to ensure insulin flow. It is important that insulin appears at the tip of the needle before you make your injection. Otherwise you will not receive the full insulin dose.

How to prime your Protaphane® NovoLet®

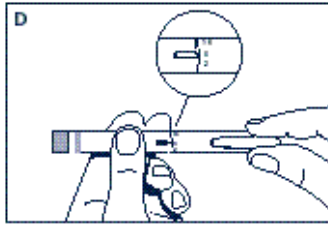
Hold Protaphane NovoLet with the needle upwards and tap the reservoir gently with your finger so that any air bubbles collect in the top of the reservoir.



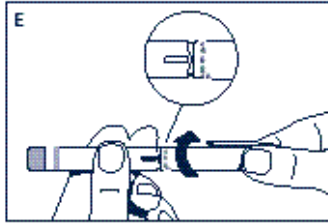
B. Whilst keeping the needle pointing upwards, turn the reservoir in the direction of the arrow until you feel one click.

C. With the needle still pointing upwards, press the push button fully in, and observe that a drop of insulin appears at the needle tip. If one does not appear, repeat the priming procedure until a drop of insulin is produced. Before the first use of Protaphane NovoLet you may need to perform the priming procedure **up to 6 times** to get a drop of insulin at the needle tip. (If you need to prime **more** than six times, do not use Protaphane NovoLet.) You may see some air bubbles in the insulin reservoir after this, but the air will not be injected.

2. Setting the dose



D. Replace the cap, so **0** is opposite the dosage indicator.

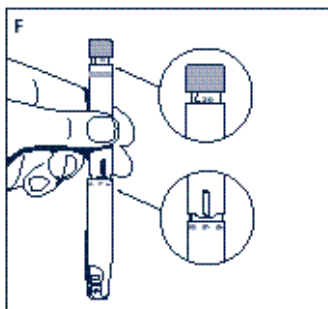


E. Hold Protaphane NovoLet horizontally and turn the cap in the direction of the arrow shown above to set the dose you want. Be careful not to put your hand over the push button when you dial the dose. If the button cannot rise freely, insulin will be pushed out of the needle.

The scale on the cap shows **0, 2, 4, 6, 8, 10, 12, 14, 16** and **18** units. For every click you feel when you turn the cap, 2 units have been set. As the cap is turned, the push button rises. The scale under the push button shows **20, 40** and **60** units. Every time you fully turn the cap, 20 extra units will be set.

Dosage examples

- How to select 8 units:
Turn the cap until **8** is opposite the dosage indicator.
- How to select 26 units:
Turn the cap 1 full turn so **0** is opposite the dosage indicator again. You have now selected 20 units. Continue turning until **6** is opposite the dosage indicator. The 20-line will show on the push button scale. Add the 6 from the dosage indicator to the 20 on the push button scale and you have selected 26 units (see F).



F. So, to check the dose set, add the figure on the cap opposite the dosage indicator to the highest figure revealed on the push button scale.

If you have set an incorrect dose, simply turn the cap forwards or backwards until the correct number of units has been set.

78 units is the maximum dose. If you try to set a higher dose, insulin will leak out of the needle and the dose will be incorrect. If you make this mistake, turn the cap back as far as you can until the push button is fully down and you can feel resistance. Then remove the cap and replace it with **0** opposite the dosage indicator. Now start again, remembering that 78 units is the maximum dose.

After the dose is set, remove the cap to make the injection.

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.
- 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 cap 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 insulin level indicator to measure how much insulin is left; however, you must not use the indicator to set or choose your dose

Note: 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 Protaphane NovoLet.

Dispose of your used (empty) Protaphane NovoLet carefully, with the needle removed.

4. After you use Protaphane[®] NovoLet[®]

After the injection, attach either a NovoFine needle remover or the outer needle cap, and unscrew the needle. Discard it carefully. If you do not remove it, temperature changes may cause liquid to leak out of the insulin reservoir.

Replace the cap with **0** opposite the dosage indicator.

Do not refill Protaphane NovoLet.