

Use of NovoLet®

Insulatard® NovoLet®

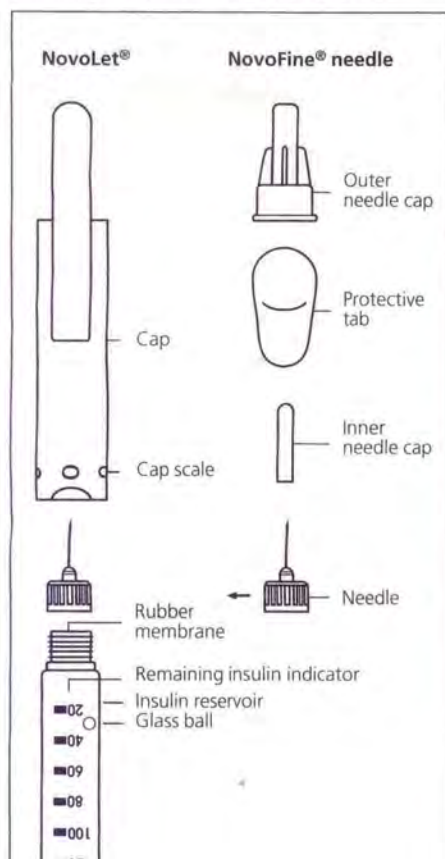
Isophane Insulin Injection
Biosynthetic Human Insulin
1.5 ml

100 iu/ml

NovoLet® is a pre-filled dial-a-dose insulin syringe able to deliver 2-58 units in increments of 2 units.

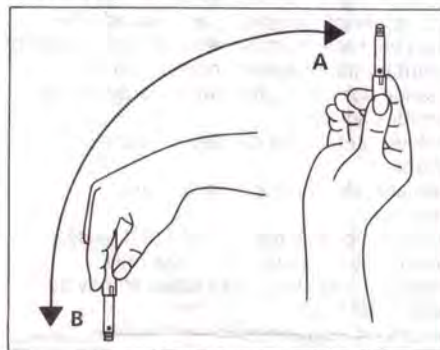
NovoLet pre-filled insulin syringes are specially designed for use with NovoFine® needles. Novo Nordisk A/S cannot be held responsible for malfunctions occurring as a consequence of using NovoLet in combination with products that do not meet the same specifications or quality standards as NovoFine needles. Insulatard®, NovoLet® and NovoFine® are trademarks owned by Novo Nordisk A/S, Denmark.

Please read these instructions carefully before using your NovoLet®



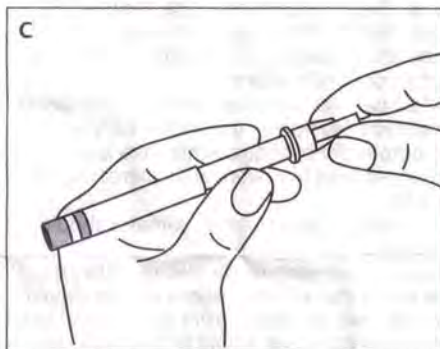
1. Preparing NovoLet

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



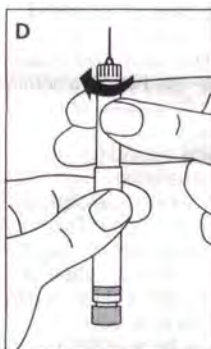
A. Turn NovoLet up and down between **A** and **B** so the glass ball is moved from one end of the reservoir to the other. Turn NovoLet up and down at least 10 times, until the liquid appears uniformly white and cloudy.

Disinfect the rubber membrane.

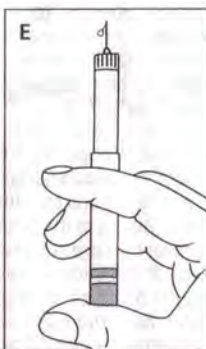


C. Remove the protective tab from a NovoFine needle and screw the needle onto NovoLet. Pull off the outer and inner needle cap. Small amounts of air may collect in the needle and reservoir during normal use.

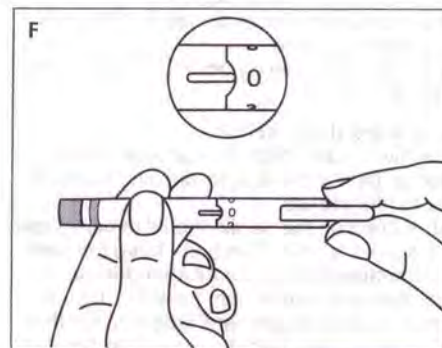
To avoid the injection of air:
Hold NovoLet with the needle upwards and tap the reservoir gently with the finger, so any air bubbles collect in the top of the reservoir.



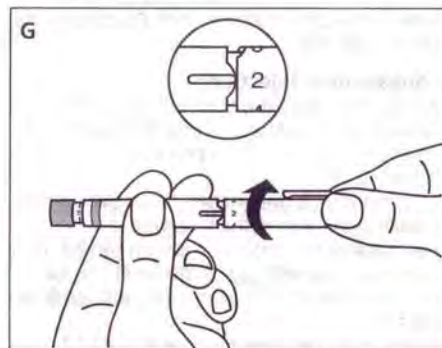
D. Keeping NovoLet with the needle upwards, turn the reservoir in the direction of the arrow until you feel one click.



2. Setting the Dose



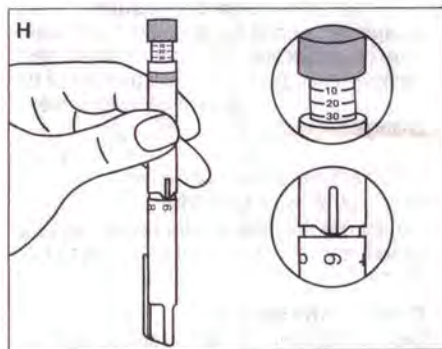
F. Replace the cap, so **0** is opposite the dosage indicator.



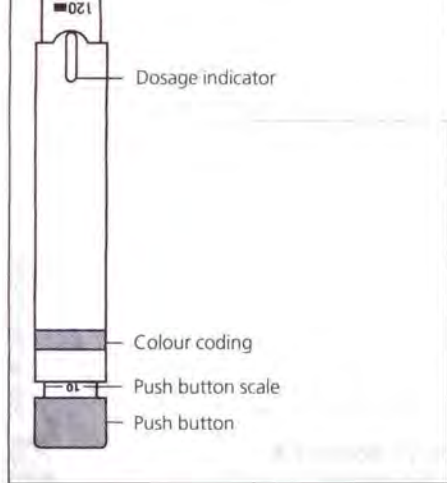
G. Hold NovoLet horizontally and turn the cap in the direction of the arrow to set the required dose.

Be careful not to put your hand over the push button when dialling the dose. If the button is not allowed to rise freely, insulin will be pushed out of the needle.

The scale on the cap shows **0, 2, 4, 6** and **8** 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 **10, 20, 30, 40** and **50** units. Every time you fully turn the cap, 10 units will be set.



H. 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.



E. Still with the needle upwards, press the push button fully home, and see if a drop of insulin appears at the needle tip. If not, repeat the procedure until a drop of insulin is seen at the needle tip. Before the first use of NovoLet you may need to perform **up to** 6 air-shots to get a droplet of insulin at the needle tip. If you need to make **more** than 6 air-shots, do not use NovoLet. Some air may remain in the insulin reservoir after this, but it will not be injected.

Dosage Examples

- 8 units:
Turn the cap until **8** is opposite the dosage indicator.
- 36 units:
Turn the cap 3 full turns so **0** is opposite the dosage indicator again. The 30-line will show on the push button scale. Continue turning until **6** is opposite the dosage indicator (see **H**).

If you have set a wrong dose, simply turn the cap forwards or backwards until the right number of units has been set.

58 units is the maximum dose. If you attempt to set a higher dose, excess insulin will be expelled from the needle and the dose will be wrong.

If you set more than 58 units, turn the cap back as far as you can until the push button is fully home and resistance is felt.

Then remove the cap and replace it with **0** opposite the dosage indicator. Now start again, remembering that 58 units is the maximum dose.

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

3. Making the Injection

Use the injection technique advised by your doctor. Deliver the dose by pressing the push button fully home.

After injection the needle should remain under the skin for at least 6 seconds. Keep the push button fully depressed until after the needle has been withdrawn from the skin. This will ensure correct delivery and limit possible flow of blood or other body fluids into the needle or insulin reservoir.

After injection the outer needle cap is replaced, the needle is unscrewed and carefully discarded. The cap is replaced with **0** opposite the dosage indicator.

4. Subsequent Injections

Always check that the push button is fully home. If not, turn the cap until the push button is completely down. Then proceed as stated under 1-3.

You cannot set a dose greater than the number of units remaining in the reservoir.

The indicator for remaining insulin can be used to estimate the amount of insulin still to be used. The indicator must not be used for dose selection.

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 your dose is less than 12 units - and the reservoir is nearly empty - first dial up to 12 (to check that 12 units are left) and then set the desired dose. If 12 cannot be dialled, change to a new NovoLet. Discard the used NovoLet carefully, without the needle attached.

5. Important

- Expel air before each injection, until a drop of insulin appears at the needle tip. If you need to make **more** than 6 air-shots before the first injection, do not use NovoLet.
- When using **longer-acting insulin (suspension)**, the needle must be removed after each injection. If it is not removed, temperature changes may expel liquid out of the needle, and the insulin concentration may change.
- Care should be taken not to drop the syringe or subject it to impact or misuse.
- Keep out of reach of children.
- Do not use the indicator for remaining insulin to measure the amount of insulin to be injected.

6. Product Information

Insulatard NovoLet is a neutral suspension of biosynthetic human insulin consisting of isophane insulin.

Biosynthetic human insulin is manufactured by recombinant DNA technology using yeast cells as the production organism. It is characterized by being identical to human insulin and of monocomponent purity.

Action profile after subcutaneous injection (approximate figures): onset 1½ hour, maximum effect: between 4 th and 12 th hour, duration of action: 24 hours.

adjustments in therapy should be made under the guidance of your doctor. For patients currently controlled on porcine monocomponent or other highly purified human or porcine insulins, no dosage change is anticipated other than the routine adjustments made in order to maintain stable diabetic control. Do not change dosage or preparation except on your doctor's advice.

Follow carefully the directions for use of NovoLet.

Insulatard NovoLet is for subcutaneous injection.

To avoid possible transmission of disease, NovoLet is for single person use only.

Treatment with Insulatard NovoLet may be supplemented by short acting insulin in accordance with your doctor's advice.

Precautions

An insulin reaction (hypoglycaemia) may occur if you take too much insulin, miss meals, or exercise more than usual.

The first symptoms of an insulin reaction can come on suddenly and may include a cold sweat, rapid heart beat, nervousness or shakiness. These symptoms may be abolished by immediately taking sugar or a sugar sweetened product. Therefore, always carry a few sugar lumps or sweets with you.

A few patients have reported that after being transferred to human insulin, the early warning symptoms for hypoglycaemia were less pronounced than they were with animal-source insulin.

Your relatives and close work-mates should know that you are a diabetic and how to help if you get a severe insulin reaction. They must be aware that an unconscious person should not be given anything to eat or drink (as choking is possible), but should be turned on his side and medical assistance sought immediately. Recovery from unconsciousness may be hastened by the injection of glucagon, which can be given by a relative or friend who has been instructed in its use. If glucagon is used, sugar or glucose should be given by mouth as soon as consciousness has been regained. In the event of an insulin overdose, in addition to glucagon, glucose may be given intravenously by your doctor.

Consult your doctor if you have experienced repeated insulin reactions, or one leading to unconsciousness, since a change in insulin dosage may be necessary. If severe hypoglycaemia is not treated, it can cause temporary or permanent brain damage, and death.

Diabetic ketoacidosis means a condition in which the blood sugar is usually very high. This is a very serious condition, which may develop if you take less insulin than you need. This may be due to increased insulin demand during illness or infection, neglect of diet, omission of insulin doses or the injection of a smaller insulin dose than that prescribed by your doctor. A developing ketoacidosis will be revealed by urine tests which show large amounts of sugar and ketones. The symptoms of thirst, large urine volumes, loss of appetite, fatigue, dry skin and deep and rapid breathing come on gradually, usually over a period of some hours or days. If you recognize these symptoms, consult your doctor immediately. If such symptoms are not treated, they can cause diabetic coma and death.

Insulatard NovoLet which does not become completely homogeneous (uniform) when agitated should not be used.

Never use insulin after expiry date.

Insulatard NovoLet in use should not be kept refrigerated.

Indication

Diabetes mellitus.

Dosage and Administration

Follow the instructions from your doctor concerning type of insulin, dose and time of injection. Make sure that you have got the type and strength of insulin prescribed by your doctor.

When a switch is made from mixed species (porcine/bovine) or bovine insulin a dosage adjustment may be required dependent upon dosage, purity, species and formulation of the insulin(s) currently administered.

Variations in glycaemic control may occur and

Interactions

A number of drugs are known to influence insulin requirement. Therefore, if you are taking any other medication, please consult your doctor.

7. Storage

Insulatard NovoLet **not** in use should be stored between 2° and 8° C, preferably in a refrigerator (not too near the freezing compartment). Insulatard NovoLet can be used or carried with you as a spare for up to one month. They must not be exposed to sunlight or extreme temperatures.

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