NovoRapid® FlexPen®

100 U/ml
Solution for injection in a pre-filled pen

Qualitative and quantitative composition

Insulin aspart*..... 100 U/ml
*produced by recombinant DNA technology in *Saccharomyces cerevisiae*.
One unit of insulin aspart corresponds to 6 nmol, 0.035 mg salt-free anhydrous insulin aspart.
1 pre-filled pen contains 300 U.

Pharmaceutical form

Solution for injection. Clear, colourless, aqueous, solution.

Clinical particulars

Therapeutic indications

Treatment of patients with diabetes mellitus

Posology and method of administration

NovoRapid® has a faster onset and a shorter duration of action than soluble human insulin. Due to the faster onset of action, NovoRapid® should generally be given immediately before a meal. When necessary, NovoRapid® can be given soon after a meal.

Dosage

Dosage of NovoRapid® is individual and determined on the basis of the physician's advice in accordance with the needs of the patient. It should normally be used in combination with intermediate-acting or long-acting insulin given at least once a day. The individual insulin requirement in adults and children is usually between 0.5 and 1.0 U/kg/day. In a meal-related treatment 50 – 70% of this requirement may be provided by NovoRapid® and the remainder by intermediate-acting or long-acting insulin. No studies have been performed in children under the age of 2 years.

Special populations

As with all insulin products, in elderly patients with renal or hepatic impairment, glucose monitoring should be intensified and the insulin aspart dosage adjusted on an individual basis.

Paediatric population

NovoRapid® can be used in children in preference to soluble human insulin when a rapid onset of action might beneficial. For example, in timing of the injections in relation to meals.

Transfer from other insulin products

When transferring from other insulin products, adjustment of the NovoRapid® dose and the dose of the basal insulin may be necessary

Administration

NovoRapid® is administered subcutaneously in the abdominal wall, the thigh, the deltoid region or the gluteal region. Injection sites should be rotated within the same region. When injected subcutaneously into the abdominal wall, the onset of action will occur within 10 – 20 minutes of

injection. The maximum effect is exerted between 1 and 3 hours after the injection. The duration of action is 3 to 5 hours.

As with all insulins, the duration of action will vary according to the dose, injection site, blood flow, temperature and level of physical activity. As with all insulins, subcutaneous injection in the abdominal wall ensures a faster absorption than other injection sites. However, the faster onset of action compared to soluble human insulin is maintained regardless of injection site. If necessary, NovoRapid® may also be administered intravenously which should be carried out by health care professionals.

Continuous Subcutaneous Insulin Infusion (CSII)
NovoRapid® may be used for Continuous Subcutaneous Insulin Infusion (CSII) in pump systems suitable for insulin infusion. CSII should be administered in the abdominal wall. Infusion sites should be rotated. When used with an insulin infusion pump, NovoRapid® should not be mixed with any other insulin.

Patients using CSII should be comprehensively instructed in the use of the pump system and use the correct reservoir and tubing for the pump. The infusion set (tubing and cannula) should be changed in accordance with the instructions in the product information supplied with the infusion set. Patients administering NovoRapid® by CSII must have alternative insulin available in case of pump system failure. Renal or hepatic impairment may reduce the patient's insulin requirements.

Intravenous use
If necessary, NovoRapid® can be administered intravenously by health care professionals. For intravenous use, infusion system with NovoRapid® 100 U/ml at concentrations from 0.05 U/ml to 1.0 U/ml insulin aspart in the infusion fluids 0.9% sodium chloride, 5% dextrose or 10% dextrose inclusive 40 mmol/l potassium chloride using polypropylene infusion bags are stable at room temperature for 24 hours. Although stable over time, a certain amount of insulin will be initially adsorbed to the material of the infusion bag. Monitoring of blood glucose is necessary during insulin infusion.

Contraindications
Hypoglycaemia. Hypersensitivity to insulin aspart or to any of the excipients.

Special warnings and special precautions for use
Hyperglycaemia
Inadequate dosing or discontinuation of treatment, especially in type 1 diabetes, may lead to hyperglycaemia and diabetic ketoacidosis. Usually, the first symptoms of hyperglycaemia develop gradually over a period of hours or day. The include thirst, increased frequency of urination, nausea, vomiting, drowsiness, flushed dry skin, dry mouth, loss of appetite as well as acetone odour of breath. In type 1 diabetes, untreated hyperglycaemic events eventually lead to diabetic ketoacidosis, which is potentially lethal.

Hypoglycaemia
Ommision of a meal or unplanned, strenuous physical exercise may lead to hypoglycaemia. Hypoglycaemia may occur if the insulin dose is too high in relation to the insulin requirement. Patients, whose blood glucose control is greatly improved, e.g. by intensified insulin therapy, may experience a change in their usual warning symptoms of hypoglycaemia, and should be advised accordingly. A consequence of the pharmacodynamics of rapid acting insulin analogues is that if

hypoglycaemia occurs, it may occur earlier after an injection when compared with soluble human insulin.

NovoRapid® should be administered in immediate relation to a meal. The rapid onset of action should therefore be considered in patients with concomitant diseases or medication where a delayed absorption of food might be expected.

Concomitant illness, especially infections, usually increases the patient's insulin requirements. Concomitant disease in the kidney, liver or affecting the adrenal, pituitary or thyroid gland can require changes in the insulin dose.

When patients are transferred between different types of insulin products, the early warning symptoms of hypoglycaemia may change or become less pronounced than those experienced with their previous insulin.

Transfer from other insulin products
Transferring a patient to a new type or brand of insulin should be done under strict medical supervision. Changes in strength, brand, type, species (animal, human, human insulin analogue) and/or method of manufacture may result in a change in dosage. Adjustment of dosage may also be necessary if patients undertake increased physical activity or change their usual diet. Exercise immediately after a meal may increase the risk of hypoglycaemia. Patients taking NovoRapid® may require an increased number of daily injections or a change in dosage from that used with their usual insulins. If an adjustment is needed, it may occur with the first dose or during the first several weeks or months.

Injection site reactions
As with any insulin therapy, injection site reactions may occur and include pain, rednes, hives, inflammation, bruising, swelling and itching. Continuous rotation of the injections site within a given area may help to reduce or prevent these reactions. Reactions usually resolve in a few days to few weeks. On rare occasion, injections may require discontinuation of NovoRapid®.

Combination of thiazolidinediones and insulin medicinal products
Cases of congestive heart failure have been reported when thiazolidinediones were used in combination with insulin, especially in patients with risk factors for development of congestive heart failure. This should be kept in mind if treatment with the combination of thiazolidinediones and insulin medicinal products is considered. If the combination is used, patients should be observed for signs and symptoms of congestive heart failure, weight gain and oedema. Thiazolidinediones should be discontinued if any deterioration in cardiac symptoms occurs.

Interaction with other medicinal products and other forms of interaction
A number of medicinal products are known to interact with glucose metabolism.

The following substances may reduce the patient's insulin requirements:
Oral hypoglycaemic agents (OHAs), octreotide, monoamine oxidase inhibitors (MAOIs), non selective beta-adrenergic blocking agents, angiotensin converting enzyme (ACE) inhibitors, salicylates, alcohol, anabolic steroids and sulphonamides.

The following substances may increase the patient's insulin requirements:
Oral contraceptives, thiazides, glucocorticoids, thyroid hormones sympathomimetics and danazol.

Beta-blocking agents may mask the symptoms of hypoglycaemia.
Alcohol may intensify and prolong the hypoglycaemic effect of insulin.

Pregnancy

NovoRapid® (insulin aspart) can be used during pregnancy. Data from two randomised controlled clinical trials (322 + 27 exposed pregnancies) do not indicate any adverse effect of insulin aspart on pregnancy or on the health of the foetus/newborn when compared to insulin human (see *Pharmacodynamic properties*). Intensified blood glucose control and monitoring of pregnant women with diabetes (type 1 diabetes, type 2 diabetes or gestational diabetes) is recommended throughout pregnancy and when contemplating pregnancy. Insulin requirements usually fall in the first trimester and increase subsequently during the second and third trimesters. After delivery, insulin requirements return rapidly to pre-pregnancy values.

Lactation

There are no restrictions on treatment with NovoRapid® during lactation. Insulin treatment of the nursing mother presents no risk to the baby. However, the NovoRapid® dosage may need to be adjusted.

Effects on ability to drive and use machines

The patient's ability to concentrate and react may be impaired as a result of hypoglycaemia. This may constitute a risk in situations where these abilities are of special importance (e.g. driving a car or operating machinery).

Patients should be advised to take precautions in order to avoid hypoglycaemia whilst driving, this is particularly important in those who have reduced or absent awareness of the warning signs of hypoglycaemia or have frequent episodes of hypoglycaemia. The advisability of driving should be considered in these circumstances.

Undesirable effects

Adverse drug reactions observed in patients using NovoRapid® are mainly dose-dependent and due to the pharmacologic effect of insulin. As for other insulin products, hypoglycaemia, in general is the most frequently occurring undesirable effect. It may occur if the insulin dose is too high in relation to the insulin requirement. Severe hypoglycaemia may lead to unconsciousness and/or convulsions and may result in temporary or permanent impairment of brain function or even death.

In clinical trials and during marketed use the frequency varies with patient population and dose regimens therefore no specific frequency can be presented. During clinical trials the overall rates of hypoglycaemia did not differ between patients treated with insulin aspart compared to human insulin.

Frequencies of adverse drug reactions from clinical trials, which by an overall judgement are considered related to NovoRapid® are listed below. The frequencies are defined as: Uncommon (>1/1,000, <1/100) and rare (>1/10,000, <1/1,000). Isolated spontaneous cases are presented as very rare defined as (<1/10,000).

Immune system disorders
Uncommon – Urticaria, rash, eruptions

Very rare – Anaphylactic reactions
Symptoms of generalised hypersensitivity may Include generalised skin rash, itching, sweating, gastrointestinal upset, angioneurotic oedema, difficulties in breathing, palpitation and reduction in blood pressure. Generalised hypersensitivity reactions are potentially life threatening.

Nervous system disorders
Rare – Peripheral neuropathy
Fast improvement in blood glucose control may be associated with a condition termed acute painful neuropathy, which is usually reversible.

Eye disorders
Uncommon – Refraction disorder
Refraction anomalies may occur upon initiation of insulin therapy. These symptoms are usually of transitory nature.

Uncommon – Diabetic retinopathy
Long-term improved glycaemic control decreases the risk of progression of diabetic retinopathy. However, intensification of insulin therapy with abrupt improvement in glycaemic control may be associated with worsening of diabetic retinopathy.

Skin and subcutaneous tissue disorders
Uncommon – Lipodystrophy
Lipodystrophy may occur at the injection site as a consequence of failure to rotate injection sites within an area.

Uncommon – Local hypersensitivity
Local hypersensitivity reactions (redness, swelling and itching at the injection site) may occur during treatment with insulin. These reactions are usually transitory and normally they disappear during continued treatment.

General disorders and administration site conditions
Uncommon – Oedema
Oedema may occur upon initiation of insulin therapy. These symptoms are usually of transitory nature.

Overdose
A specific overdose for insulin cannot be defined however hypoglycaemia may develop over sequential stages if too high doses relative to the patient's requirements are administered:
- Mild hypoglycaemic episodes can be treated by oral administration of glucose or sugary products. It is therefore recommended that the diabetic patient constantly carry sugar containing products
- Severe hypoglycaemic episodes, where the patient has become unconscious, can be treated by glucagon (0.5 to 1 mg) given intramuscularly or subcutaneously by a trained person, or glucose given intravenously by a medical professional. Glucose must also be given intravenously if the patient does not respond to glucagon within 10 to 15 minutes. Upon regaining consciousness, administration of oral carbohydrate is recommended for the patient in order to prevent relapse.

Pharmacological properties
Pharmacodynamic properties

Pharmacotherapeutic group: Insulins and analogues, fast-acting. ATC code A10AB05.

The blood glucose lowering effect of insulin occurs when the molecules facilitate the uptake of glucose by binding to insulin receptors on muscle and fat cells - and simultaneously inhibit the output of glucose from the liver.

NovoRapid® produces a more rapid onset of action compared to soluble human insulin, together with a lower glucose concentration, as assessed within the first four hours after a meal. NovoRapid® has a shorter duration of action compared to soluble human insulin after subcutaneous injection.

When NovoRapid® is injected subcutaneously, the onset of action will occur within 10 – 20 minutes of injection. The maximum effect is exerted between 1 and 3 hours after injection. The duration of action is 3 to 5 hours.

Adults
Clinical trials in patients with type 1 diabetes have demonstrated a lower postprandial blood glucose with NovoRapid® compared to soluble human insulin. In two long-term open label trials in patients with type 1 diabetes comprising 1070 and 884 patients, respectively, NovoRapid® reduced glycosylated haemoglobin by 0.12 [95% C.I. 0.03; 0.22] percentage points and by 0.15 [95% C.I. 0.05; 0.26] percentage points compared to human insulin; a difference of doubtful clinical significance.

Elderly
A randomized, double blind cross over PK/PD trial comparing insulin aspart with soluble human insulin was performed in elderly patients with type 2 diabetes (19 patients aged 65 – 83 years, mean age 70 years). The relative differences in the pharmacodynamic properties (GIRmax, AUCGIR, 0 – 120 min) between insulin aspart and soluble human insulin in the elderly were similar to those seen in healthy subjects and in younger patients with diabetes.

Children and adolescents
A clinical trial comparing preprandial soluble human insulin with postprandial insulin aspart was performed in small children (26 patients aged 2 to less than 6 years), studied for 12 weeks,(among those four were younger than 4 years old)and a single dose PK/PD trial was performed in children (6 – 12 years) and adolescents (13 – 17 years). The pharmacodynamic profile of insulin aspart in children was similar to that seen in adults. Clinical trials in patients with type 1 diabetes have demonstrated a reduced risk of nocturnal hypoglycaemia with insulin aspart compared with soluble human insulin. The risk of daytime hypoglycaemia was not significantly increased.

Pregnancy
A clinical trial comparing safety and efficacy of insulin aspart vs. insulin human in the treatment of pregnant women with type 1 diabetes (322 exposed pregnancies (insulin aspart: 157; insulin human: 165)) did not indicate any adverse effect of insulin aspart on pregnancy or on the health of the foetus/newborn.

In addition the data from a clinical trial including 27 women with gestational diabetes randomised to treatment with insulin aspart vs. insulin human (insulin aspart: 14; insulin human: 13) showed similar safety profiles between treatments as well a significant improvement in postprandial glucose control in the insulin aspart treated group.

Pharmacokinetic properties

In NovoRapid® substitution of the amino acid proline with aspartic acid at position B28 reduces the tendency to form hexamers as observed with soluble human insulin. NovoRapid® is therefore more rapidly absorbed from the subcutaneous layer compared to soluble human insulin.

The time to maximum concentration is, on average, half of that for soluble human insulin. A mean maximum plasma concentration of 492 ± 256 pmol/l was reached 40 (interquartile range: 30 – 40) minutes after a subcutaneous dose of 0.15 U/kg bodyweight in type 1 diabetic patients. The insulin concentrations returned to baseline about 4 to 6 hours after dose. The absorption rate was somewhat slower in Type 2 diabetic patients, resulting in a lower Cmax (352 ± 240 pmol/l) and later tmax (60 (interquartile range: 50 – 90) minutes). The intraindividual variability in time to maximum concentration is significantly less for NovoRapid® than for soluble human insulin, whereas the intraindividual variability in Cmax for NovoRapid® is larger.

Children and adolescents

The pharmacokinetic and pharmacodynamic properties of NovoRapid® were investigated in children (6 – 12 years) and adolescents (13 – 17 years) with type 1 diabetes. Insulin aspart was rapidly absorbed in both age groups, with similar tmax as in adults. However, Cmax differed between the age groups, stressing the importance of the individual titration of NovoRapid®.

Elderly

The relative differences in pharmacokinetic properties between insulin aspart and soluble human insulin in elderly patients (65 – 83 years, mean age 70 years) with type 2 diabetes were similar to those observed in healthy subject and in younger patients with diabetes. A decreased observed in elderly subjects, resulting in a later tmax (82 (interquartile range: 60 – 120) minutes), whereas Cmax was similar to that observed in younger patients with type 2 diabetes and slightly lower than patients with type 1 diabetes.

Hepatic impairment

A single dose pharmacokinetic study of insulin aspart was performed in 24 subjects with normal to severely impaired hepatic function. In subjects with hepatic impairment, absorption rate was decreased and more variable, resulting in delayed tmax from about 50 min in subjects with normal hepatic function to about 85 min in subjects with moderate and severe hepatic impairment. AUC, Cmax and CL/F were similar in subjects with reduced hepatic function compared with subjects with normal hepatic function.

Renal impairment

A single dose pharmacokinetic study of insulin aspart in 18 subjects with normal to severely impaired renal function was performed. No apparent effect of creatinine clearance values on AUC, Cmax, CL/F and tmax of insulin aspart was found. Data were limited in subjects with moderate and severe renal impairment. Subjects with renal failure necessitating dialysis treatment were not investigated.

Preclinical safety data

In *in vitro* tests, including binding to insulin and IGF-1 receptor sites and effects on cell growth, insulin aspart behaved in a manner that closely resembled human insulin. Studies also demonstrate that the dissociation of binding to the insulin receptor of insulin aspart is equivalent to

human insulin. Acute, one month and twelve months toxicity studies produced no toxicity findings of clinical relevance.

Pharmaceutical particulars

List of excipients

Glycerol, phenol, metacresol, zinc chloride, disodium phosphate dihydrate, sodium chloride, hydrochloric acid and/or sodium hydroxide (for pH adjustment), water for injections.

Incompatibilities

Substances added to the insulin may cause degradation of the insulin, e.g. if the medicinal product contains thiol or sulphites.

Shelf life

30 months

Special precautions for storage

Keep out of reach and sight of children. Store NovoRapid® FlexPen®, which is not in use in the original package between 2°C – 8°C in a refrigerator (not in or too near the freezer section or cooling element).
Do not freeze.

NovoRapid® FlexPen® in use or carried as a spare: can be kept at ambient temperature (not above 30°C) for up to 4 weeks, but any remainder must be discarded.
Do not refrigerate.

Keep the pen cap on when NovoRapid® FlexPen® is not in use in order to protect from light.
Do not use NovoRapid® FlexPen® after the expiry date stated on the label/carton.

Nature and contents of container

A glass (type 1) cartridge which contains a piston (bromobutyl rubber) and is closed with a disc (bromobutyl/polyisoprene rubber) containing 3 ml of solution in a multidose disposable pre-filled pen with a pen injector (plastic). Pack size of 5 pre-filled pens.

Special precautions for disposal and other handling

Needles and NovoRapid® FlexPen® must not be shared. The cartridge must not be refilled.
NovoRapid® must not be used if it does not appear clear and colourless or if it has been frozen.
The patient should be advised to discard the needle after each injection.

NovoRapid® may be used in an infusion pump system (CSII) as described in section *Method of administration*. Tubings in which the inner surface materials are made of polyethylene or polyolefin have been evaluated and found compatible with pump use.

In case of emergency in current NovoRapid® users (hospitalisation or insulin pen malfunction), NovoRapid® can be withdrawn with an U100 insulin syringe from the FlexPen®.

HARUS DENGAN RESEP DOKTER
Reg. No.: DKI1542000343A1

Manufactured by:
Novo Nordisk Produção Farmacêutica do Brasil Ltda.
Avenida C, 1413 Distrito Industrial, Minas Gerais 39404 004
Montes Claros – Brazil

Registered by:
PT Beta Pharmacon
Indonesia

Distributed by:
PT Anugrah Argon Medica
Indonesia

INSTRUCTIONS FOR USE FOR THE PATIENT

Do not use NovoRapid®

- **If you are allergic (hypersensitive)** to insulin aspart or any of the other ingredients in NovoRapid®.
- **If you suspect hypoglycaemia (low blood sugar)** is starting.
- **If FlexPen® is dropped, damaged or crushed.**
- **If it has not been stored correctly** or if it has been frozen.
- **If the insulin does not appear clear and colourless.**

Before using NovoRapid®

- **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 NovoRapid® FlexPen® must not be shared.**

Method of administration

NovoRapid® is for injection under the skin (subcutaneously) or for continuous infusion in a pump system. NovoRapid® may also be given directly into a vein (intravenously) by healthcare professionals. Never inject your insulin directly into a muscle (intramuscular).

Always vary the sites you inject within the same region to reduce the risk of developing lumps or skin pitting. The best places to give yourself an injection are: the front of your waist (abdomen); the upper arm or the front of your thighs. The insulin will work more quickly if injected around the waist. You should measure your blood sugar regularly.

How to handle NovoRapid® FlexPen®

Read the included NovoRapid® FlexPen® INSTRUCTIONS FOR USE carefully. You must use the pen as described in the Instructions for Use.

Based on approvable letter date: 20 November 2015

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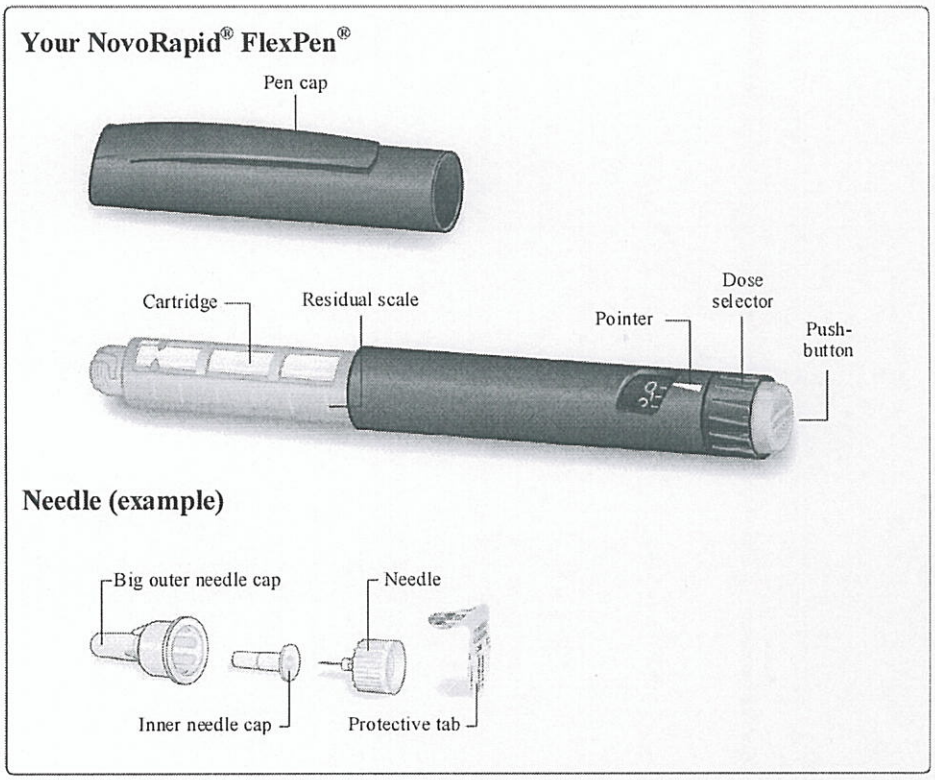
NovoRapid® solution for injection in pre-filled pen. FlexPen® INSTRUCTIONS FOR USE FOR THE PATIENT

Please read the following instructions carefully before using your NovoRapid® FlexPen®.

Your FlexPen® is a unique dial-a-dose insulin pen. You can select doses from 1 to 60 units in increments of 1 unit. FlexPen® 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 FlexPen® is lost or damaged.



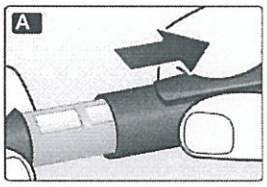
Maintenance
Your FlexPen® is designed to work accurately and safely. It must be handled with care.
If it is dropped or crushed, there is a risk of damage and leakage of insulin.

You can clean the exterior of your FlexPen® by wiping it with a medicinal swab. Do not soak it, wash or lubricate it as it may damage the pen.

Do not refill your FlexPen®.

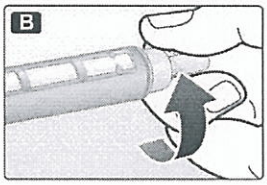
Preparing your NovoRapid® FlexPen®

Check the label to make sure that your FlexPen® contains the correct type of insulin.
A
Pull off the pen cap.

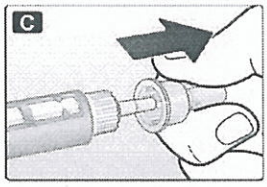


B
Remove the protective tab from a new disposable needle.

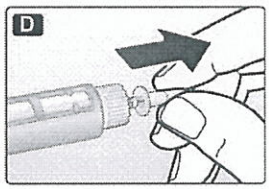
Screw the needle straight and tightly onto your FlexPen®.



C
Pull off the big outer needle cap and keep it for later.



D
Pull off the inner needle cap and dispose of it.

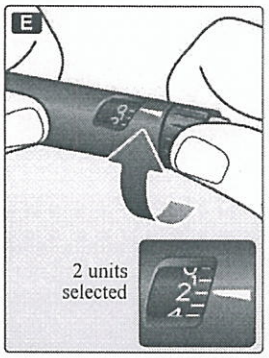


⚠ Always use a new needle for each injection to prevent contamination.
⚠ Be careful not to bend or damage the needle before use.
⚠ To reduce the risk of unexpected needle sticks, never put the inner needle cap back on when you have removed it from the needle.

Checking the insulin flow

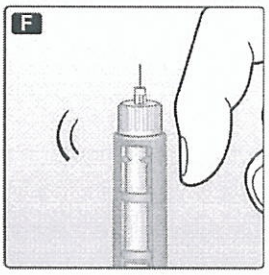
Prior to each injection small amounts of air may collect in the cartridge during normal use. To avoid injection of air and ensure proper dosing:

E
Turn the dose selector to select 2 units.



F

Hold your FlexPen® 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.

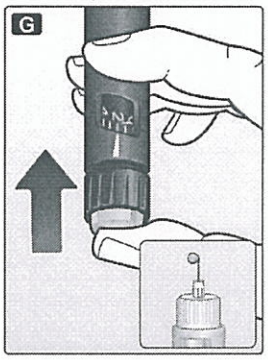


G

Keeping the needle upwards, press the push-button all the way in. The dose selector returns to 0.

A drop of insulin should 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 you must use a new one.



Selecting your dose

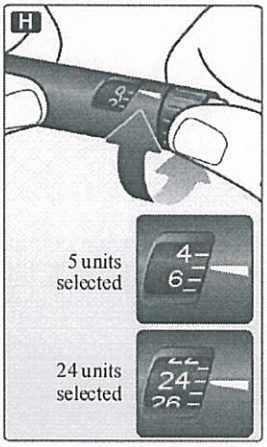
Check that the dose selector is set at 0.

H

Turn the dose selector to select the number of units you need to inject.

The dose can be corrected either up or down by turning the dose selector in either direction until the correct dose lines up with the pointer. When turning the dose selector, be careful not to push the push-button as insulin will come out.

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



⚠ Do not use the residual scale to measure your dose of insulin.

Making the injection

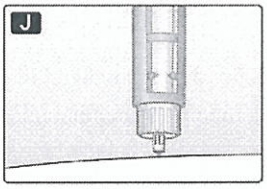
Insert the needle into your skin. Use the injection technique shown by your doctor or nurse.

I
Inject the dose by pressing the push-button all the way in until 0 lines up with the pointer. Be careful only to push the push-button when injecting.

Turning the dose selector will not inject insulin.

J
Keep the push-button fully depressed after the injection until the needle has been withdrawn from the skin.

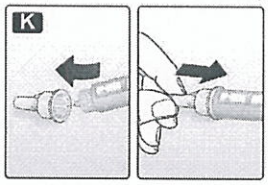
The needle must remain under the skin for at least 6 seconds. This will ensure that the full dose has been injected.



K

Lead the needle into the big outer needle cap without touching the big outer needle cap. When the needle is covered, carefully push the big outer needle cap completely on and then unscrew the needle.

Dispose of it carefully and put the pen cap back on.



- ⚠ Always remove the needle after each injection and store your FlexPen® without the needle attached. Otherwise the liquid may leak out which can cause inaccurate dosing.
- ⚠ Caregivers should be most careful when handling used needles to avoid needle sticks.
- ⚠ Dispose of the used FlexPen® carefully without the needle attached.
- ⚠ Needles and NovoRapid® FlexPen® must not be shared.