Regulatory Operations

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NovoRapid® FlexPen®

100 U/ml solution for injection in pre-filled pen.

Qualitative and quantitative composition
1 ml of the solution contains 100 U of insulin aspart* (equivalent to 3.5 mg).
1 pre-filled pen contains 3 ml equivalent to 300 U.
*Insulin aspart is produced by recombinant DNA technology in *Saccharomyces cerevisiae*.

Pharmaceutical form
Clear, colourless, aqueous solution for injection in pre-filled pen. FlexPen®.

Therapeutic indications
Treatment of diabetes mellitus in adults, adolescents and children aged 1 year and above.

Posology
NovoRapid® is a rapid-acting insulin analogue. NovoRapid® dosage is individual and determined 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. Blood glucose monitoring and insulin dose adjustment are recommended to achieve optimal glycaemic control.
The individual insulin requirement in adults and children is usually between 0.5 and 1.0 U/kg/day. In a basal-bolus treatment regimen, 50–70% of this requirement may be provided by NovoRapid® and the remainder by intermediate-acting or long-acting insulin. Adjustment of dosage may be necessary if patients undertake increased physical activity, change their usual diet or during concomitant illness.
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.
Due to the shorter duration, NovoRapid® has a lower risk of causing nocturnal hypoglycaemic episodes.

Special populations
As with all insulin products, in elderly patients and 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 and adolescents aged 1 year and above in preference to soluble human insulin when a rapid onset of action might be beneficial, for example, in the timing of the injections in relation to meals. The safety and efficacy of NovoRapid® in children below 1 year of age have not been established. No data are available.

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.

Method of administration
NovoRapid® is administered subcutaneously by injection in the abdominal wall, the thigh, the upper arm, the deltoid region or the gluteal region. Injection sites should always be rotated within the same region in order to reduce the risk of lipodystrophy. As with all insulin products, subcutaneous injection in the abdominal wall ensures a faster absorption than other injection sites.
The duration of action will vary according to the dose, injection site, blood flow, temperature and level of physical activity.
However, the faster onset of action compared to soluble human insulin is maintained regardless of injection site.
NovoRapid® FlexPen® is a pre-filled pen designed to be used with NovoFine® or NovoTwist® disposable needles up to a length of 8 mm.
NovoRapid® FlexPen® is colour-coded and accompanied by a package leaflet with detailed instructions for use to be followed.
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.

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When used with an insulin infusion pump, NovoRapid® should not be mixed with any other insulin products.
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 delivery method available in case of pump system failure.

Intravenous use:
If necessary, NovoRapid® can be administered intravenously by physicians or other healthcare staff if applicable.
For intravenous use, infusion systems 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 including 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 infusion bag. Monitoring of blood glucose is necessary during insulin infusion.

Contraindications
Hypersensitivity to the active substance or any of the excipients.

Special warnings and precautions for use
Before travelling between different time zones, the patient should seek the doctor's advice since this may mean that the patient has to take the insulin and meals at different times.

Hyperglycaemia
Inadequate dosing or discontinuation of treatment, especially in type 1 diabetes, may lead to hyperglycaemia and diabetic ketoacidosis.

Hypoglycaemia
Omission of a meal or unplanned, strenuous physical exercise may lead to hypoglycaemia.
Especially in children, care should be taken to match insulin doses (especially in basal-bolus regimens) with food intake, physical activities and current blood glucose level in order to minimise the risk of 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. Usual warning symptoms may disappear in patients with longstanding diabetes.
A consequence of the pharmacodynamics of rapid-acting insulin analogues is that if hypoglycaemia occurs, it may occur earlier after an injection when compared to soluble human insulin.
Since NovoRapid® should be administered in immediate relation to a meal, the rapid onset of action should be considered in patients with concomitant diseases or medication where a delayed absorption of food might be expected.
Concomitant illness, especially infections and feverish conditions, usually increases the patient's insulin requirements. Concomitant diseases of 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 become less pronounced than those experienced with their previous insulin.

Transfer from other insulin products
Transferring a patient to another type or brand (e.g. strength or manufacturer) of insulin should be done under strict medical supervision and may require a change in dosage or number of daily injections from that used with their usual insulin products. If an adjustment is needed, it may occur with the first dose or during the first few weeks or months.

Injection site reactions
As with any insulin therapy, injection site reactions may occur and include pain, redness, hives, inflammation, bruising, swelling and itching. Continuous rotation of the injection site within a given area reduces the risk of developing these reactions. Reactions usually resolve in a few days to a few weeks. On rare occasions, injection site reactions 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.

Avoidance of accidental mix-ups/medication errors
Patients must be instructed to always check the insulin label before each injection to avoid accidental mix-ups between NovoRapid® and other insulin products.

Insulin antibodies
Insulin administration may cause insulin antibodies to form. In rare cases, the presence of such insulin antibodies may necessitate adjustment of the insulin dose in order to correct a tendency to hyper- or hypoglycaemia.

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

The following substances may reduce the patient's insulin requirements:
Oral antidiabetic products, monoamine oxidase inhibitors (MAOIs), beta-blockers, angiotensin converting enzyme (ACE) inhibitors, salicylates, anabolic steroids and sulfonamides.

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

Beta-blocking agents may mask the symptoms of hypoglycaemia.
Octreotide/lanreotide may either increase or decrease the insulin requirements.
Alcohol may intensify or reduce the hypoglycaemic effect of insulin.

Pregnancy
NovoRapid® (insulin aspart) can be used in pregnancy. Data from two randomised controlled clinical trials do not indicate any adverse effect of insulin aspart on pregnancy or on the health of the foetus/newborn when compared to soluble human insulin (see *Pharmacodynamic properties*).
Intensified blood glucose control and monitoring of pregnant women with diabetes are 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 normally return rapidly to pre-pregnancy values.

Lactation
There are no restrictions on treatment with NovoRapid® during breast-feeding. 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 to avoid hypoglycaemia while 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.

Undesirable effects
a. Summary of the safety profile

Adverse reactions observed in patients using NovoRapid® are mainly due to the pharmacologic effect of insulin.
The most frequently reported adverse reaction during treatment is hypoglycaemia. The frequencies of hypoglycaemia vary with patient population, dose regimens and level of glycaemic control, please see section c below.
At the beginning of the insulin treatment, refraction anomalies, oedema and injection site reactions (pain, redness, hives, inflammation, bruising, swelling and itching at the injection site) may occur. These reactions are usually of transitory nature. Fast improvement in blood glucose control may be associated with acute painful neuropathy, which is usually reversible.
Intensification of insulin therapy with abrupt improvement in glycaemic control may be associated with temporary worsening of diabetic retinopathy, while long-term improved glycaemic control decreases the risk of progression of diabetic retinopathy.

b. Tabulated list of adverse reactions

Adverse reactions listed below are based on clinical trial data and classified according to MedDRA System Organ Class. Frequency categories are defined according to the following convention: Very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1,000 to < 1/100); rare (≥ 1/10,000 to < 1/1,000); very rare (< 1/10,000); not known (cannot be estimated from the available data).

Immune system disorders	Uncommon – Urticaria, rash, eruptions
	Very rare – Anaphylactic reactions*
Metabolism and nutrition disorders	Very common – Hypoglycaemia*
Nervous system disorders	Rare – Peripheral neuropathy (painful neuropathy)
Eye disorders	Uncommon – Refraction disorders
	Uncommon – Diabetic retinopathy
Skin and subcutaneous tissue disorders	Uncommon – Lipodystrophy*
General disorders and administration site conditions	Uncommon – Injection site reactions
	Uncommon – Oedema

* see section c

c. Description of selected adverse reactions

Anaphylactic reactions
The occurrence of generalised hypersensitivity reactions (including generalised skin rash, itching, sweating, gastrointestinal upset, angioneurotic oedema, difficulties in breathing, palpitation and reduction in blood pressure) is very rare but can potentially be life threatening.

Hypoglycaemia
The most frequently reported adverse reaction is hypoglycaemia. 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. The symptoms of hypoglycaemia usually occur suddenly. They may include cold sweats, cool pale skin, fatigue, nervousness or tremor, anxiousness, unusual tiredness or weakness, confusion, difficulty in concentration, drowsiness, excessive hunger, vision changes, headache, nausea and palpitation.
In clinical trials, the frequency of hypoglycaemia varied with patient population, dose regimens and level of glycaemic control. During clinical trials the overall rates of hypoglycaemia did not differ between patients treated with insulin aspart compared to human insulin.

Lipodystrophy
Lipodystrophy is reported as uncommon. Lipodystrophy may occur at the injection site.

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 always carries sugar containing products.
- Severe hypoglycaemic episodes, where the patient has become unconscious, can be treated with glucagon (0.5 to 1 mg) given intramuscularly or subcutaneously by a trained person, or with glucose given intravenously by physicians or other healthcare staff if applicable. Glucose must 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 a relapse.

Pharmacodynamic properties
Pharmacotherapeutic group: Drugs used in diabetes. Insulins and analogues for injection, fast-acting. ATC code A10AB05.

Mechanism of action
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 to 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.
Insulin aspart is equipotent to soluble human insulin on a molar basis.

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 1,070 and 884 patients, respectively, NovoRapid® reduced glycated haemoglobin by 0.12 percentage points and by 0.15 percentage points compared to soluble human insulin; a difference of limited clinical significance.

Clinical trials in patients with type 1 diabetes have demonstrated a reduced risk of nocturnal hypoglycaemia with insulin aspart compared to soluble human insulin. The risk of daytime hypoglycaemia was not significantly increased.

Elderly: in a PK/PD trial the relative differences in the PD properties between insulin aspart and soluble human insulin in the elderly patients with type 2 diabetes were similar to those seen in healthy subjects and younger patients with diabetes.

Children and adolescents: when given to children, NovoRapid® showed similar long-term glucose control compared to soluble human insulin.
In clinical trials for children and adolescents aged 2 to 17, the pharmacodynamic profile of insulin aspart in children was similar to that seen in adults.

The efficacy and safety of NovoRapid® given as bolus insulin in combination with either insulin detemir or insulin degludec as basal insulin have been studied for up to 12 months in two randomised controlled clinical trials in adolescents and children aged 1 to less than 18 years (n=712). The trials included 167 children aged 1–5 years, 260 aged 6–11 and 285 aged 12–17. The observed improvements in HbA_{1c} and the safety profiles were comparable between all age groups.

Pregnancy: a clinical trial comparing safety and efficacy of insulin aspart vs. soluble human insulin in the treatment of pregnant women with type 1 diabetes (322 exposed pregnancies) 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. soluble human insulin showed similar safety profiles between treatments as well as a significant improvement in postprandial glucose control in the insulin aspart treated group.

Pharmacokinetic properties
In NovoRapid® substitution of 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 pmol/l was reached 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 C_{max} (352 ± 240 pmol/l) and later t_{max} (60 minutes). The intra-individual variability in time to maximum concentration is significantly less for NovoRapid® than for soluble human insulin, whereas the intra-individual variability in C_{max} for NovoRapid® is larger.

Children and adolescents: the pharmacokinetic and pharmacodynamic properties of NovoRapid® were investigated in children and adolescents with type 1 diabetes. Insulin aspart was rapidly absorbed in both age groups, with similar t_{max} as in adults. However, C_{max} 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 with type 2 diabetes were similar to those observed in healthy subjects and in younger patients with diabetes.
A decreased absorption rate was observed in elderly patients, resulting in a later t_{max} (82 minutes), whereas C_{max} was similar to that observed in younger patients with type 2 diabetes and slightly lower than in patients with type 1 diabetes.

Hepatic impairment: in patients with hepatic impairment, t_{max} was delayed to about 85 min. (50 min. in subjects with normal hepatic function) while AUC, C_{max} and CL/F were similar.

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, C_{max}, CL/F and t_{max} of insulin aspart was found. Data were limited in patients with moderate and severe renal impairment. Patients with renal failure necessitating dialysis treatment were not investigated.

Preclinical safety data
Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity or toxicity to reproduction.
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.

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

Incompatibilities
Substances added to NovoRapid® may cause degradation of insulin aspart.
This product must not be diluted or mixed with other products, except infusion fluids as described in section *Posology.*

Special precautions for storage
Before opening: Store in a refrigerator (2°C – 8°C). Keep away from the cooling element.
During use or when carried as a spare: Store below 30°C. Can be stored in a refrigerator (2°C – 8°C). Use within 4 weeks.
Do not freeze.
Keep the pen cap on NovoRapid® FlexPen® in order to protect from light.
NovoRapid® must be protected from excessive heat and light.
The expiry date is printed on the label and carton.

Nature and contents of container
3 ml solution in cartridge (type 1 glass) with a plunger (bromobutyl) and a rubber closure (bromobutyl/polyisoprene) contained in a pre-filled multidose disposable pen made of polypropylene in a carton.
Pack sizes of 1, 5 and 10 pre-filled pens. Not all pack sizes may be marketed.

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 FlexPen®.

Produced by
Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd, Denmark

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 physicians or other healthcare staff if applicable. Never inject your insulin directly into a muscle (intramuscularly).
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 into the waist. You should measure your blood sugar regularly.

How to handle NovoRapid® FlexPen®
Read the included 'Instructions on how to use NovoRapid® solution for injection in FlexPen®' carefully. You must use the pen as described in the instructions on how to use NovoRapid®.

NovoRapid®, FlexPen®, NovoFine® and NovoTwist® are trademarks owned by Novo Nordisk A/S, Denmark.

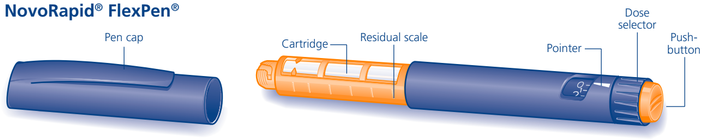
novo nordisk®

Instructions on how to use NovoRapid® solution for injection in FlexPen®

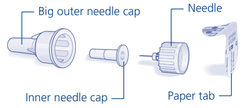
Read the following instructions carefully before using your FlexPen®. If you do not follow the instructions carefully, you may get too little or too much insulin, which can lead to too high or too low blood sugar level.

Your FlexPen® is a pre-filled 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.

NovoRapid® FlexPen®



Needle (example)



Caring for your pen

Your FlexPen® must be handled with care.
If it is dropped, damaged or crushed, there is a risk of insulin leakage. This may cause inaccurate dosing, which can lead to too high or too low blood sugar level.

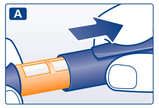
You can clean the exterior of your FlexPen® by wiping it with a medicinal swab. Do not soak it, wash or lubricate it as it may damage the pen.

Do not refill your FlexPen®.

Preparing your NovoRapid® FlexPen®

Check the name and coloured label of your pen to make sure that it contains the correct type of insulin. This is especially important if you take more than one type of insulin. If you take the wrong type of insulin, your blood sugar level may get too high or too low.

A Pull off the pen cap.



B Remove the paper 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.
Never try to put the inner needle cap back on the needle. You may stick yourself with the needle.

⚠ Always use a new needle for each injection. This reduces the risk of contamination, infection, leakage of insulin, blocked needles and inaccurate dosing.
⚠ Be careful not to bend or damage the needle before use.

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.

⚠ Always make sure that a drop appears at the needle tip before you inject. This makes sure that the insulin flows. If no drop appears, you will not inject any insulin, even though the dose selector may move. This may indicate a blocked or damaged needle.
⚠ Always check the flow before you inject. If you do not check the flow, you may get too little insulin or no insulin at all. This may lead to too high blood sugar level.

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.

⚠ Always use the dose selector and the pointer to see how many units you have selected before injecting the insulin.
⚠ Do not count the pen clicks. If you select and inject the wrong dose, your blood sugar level may get too high or too low. Do not use the residual scale, it only shows approximately how much insulin is left in your pen.

Further important information

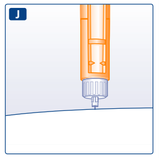
⚠ Caregivers must be very careful when handling used needles – to reduce the risk of needle sticks and cross-infection.
⚠ Dispose of your used FlexPen® carefully without the needle attached.
⚠ Never share your pen or your needles with other people. It might lead to cross-infection.
⚠ Never share your pen with other people. Your medicine might be harmful to their health.
⚠ Always keep your pen and needles out of sight and reach of others, especially children.

Making the injection

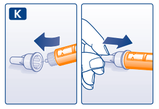
Insert the needle into your skin. Use the injection technique shown by your doctor or nurse.

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 and let the needle remain under the skin for at least 6 seconds. This will make sure you get the full dose.
Withdraw the needle from the skin, then release the pressure on the push-button.
Always make sure that the dose selector returns to 0 after the injection. If the dose selector stops before it returns to 0, the full dose has not been delivered, which may result in too high blood sugar level.



K Lead the needle into the big outer needle cap without touching it. 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. This reduces the risk of contamination, infection, leakage of insulin, blocked needles and inaccurate dosing.

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JRTC Quality Assurance	Jurate Clausen 1st Approver	2018/02/26 16:14:22