

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

FIASP®

vial/Penfill®/FlexTouch®

insulin aspart injection

Solution, 100 U/mL, subcutaneous use

Read this carefully before you start taking **Fiasp®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Fiasp®**.

Serious Warnings and Precautions

- Low blood sugar is the most common adverse effect of insulin products, including Fiasp®.
- If low blood sugar or high blood sugar reactions are not treated, they can cause loss of consciousness, coma or even death.
- Blood sugar levels should be monitored for all patients with diabetes.
- Fiasp® should be injected up to 2 minutes before the start of the meal. When necessary, Fiasp® may be administered up to 20 minutes after starting the meal. (See 'How to take Fiasp®?')
- Accidental mix-up between Fiasp® and other insulin products have been reported. Always carefully check the insulin label before each injection to avoid mix-ups between insulin products.
- DO NOT dilute or mix Fiasp® with any other insulin products or solutions, except when given into your vein under medical supervision.
- Fiasp® should generally be used in a regimen with intermediate- or long-acting insulin (plus metformin for type 2 diabetes as recommended) or with insulin infusion pump therapy to maintain blood sugar levels.
- Only use Fiasp® if the solution looks water-clear and colourless.

What is Fiasp® used for?

- The treatment of adults and children 2 years and above with diabetes mellitus who require insulin for the control of high blood sugar.
- The treatment of type 2 diabetes patients generally used in combination with an intermediate- or long-acting insulin (plus metformin) for the control of high blood sugar.

How does Fiasp® work?

Fiasp® is a fast-acting mealtime insulin aspart formulation used to treat diabetes. Fiasp® will start to lower your blood sugar within 20 minutes after starting a meal. Due to this short action Fiasp® should normally be taken in combination with intermediate- or long-acting insulin preparation (plus metformin for type 2 diabetes as recommended).

What are the ingredients in Fiasp®?

Medicinal ingredients: The active ingredient in Fiasp® is insulin aspart.

Non-medicinal ingredients: Arginine (as L-arginine HCl), disodium-phosphate dihydrate, glycerol, metacresol, niacinamide (vitamin B₃), phenol, water for injections, and zinc (as zinc acetate). Hydrochloric acid and/or sodium hydroxide may be added for pH adjustment.

Fiasp® comes in the following dosage forms:

- Fiasp® 10 mL vial (1,000 units per 10 mL); Pack size: 1 vial of 10 mL
- Fiasp® Penfill® 3 mL cartridge (designed for use with Novo Nordisk Insulin Delivery Devices) (300 units per 3 mL); Pack size: 5 cartridges of 3 mL
- Fiasp® FlexTouch® 3 mL prefilled pen (300 units per 3 mL); Pack size: 5 pre-filled pens of 3 mL

Fiasp® 10 mL vial can be used for continuous infusion in a pump system.

Fiasp® is presented as a water-clear, colourless and aqueous solution for injection. Each mL contains 100 units of insulin aspart.

Fiasp® FlexTouch® and Fiasp® Penfill® in a Novo Nordisk Insulin Delivery Device is designed for use with NovoFine®, NovoFine® Plus and/or NovoTwist® needles as part of The All-In-One System®. Novo Nordisk cannot be held responsible for malfunctions occurring as a consequence of using Fiasp® with products that do not meet the same specifications or quality standards as NovoFine®, NovoFine® Plus and/or NovoTwist® needles.

Do not use Fiasp® if:

- You feel a low blood sugar coming on. (see *'What are possible side effects from using Fiasp®?'* for more about low blood sugar).
- You are allergic (hypersensitive) to insulin aspart, metacresol or any of the other ingredients in this insulin. Look out for the signs of an allergic reaction. (see *'What are possible side effects from using Fiasp®?'*).
- If the protective cap is loose or missing. Each vial has a protective, tamper proof plastic cap. If the cap is not in perfect condition when you get the vial, return the vial to your supplier.
- If the Penfill® cartridge or Novo Nordisk Insulin Delivery Device containing the cartridge is dropped, damaged or crushed; there is a risk of leakage of insulin.
- The FlexTouch® is dropped, damaged or crushed; there is a risk of leakage of insulin.
- The insulin has not been stored correctly or if it has been frozen. (see *'Storage'*)
- The insulin does not appear water-clear and colourless.
- Taking thiazolidinediones (class of oral antidiabetic drugs) together with insulin may increase risk of oedema and heart failure. Inform your doctor as soon as possible if you experience localised swelling (oedema) or signs of heart failure such as unusual shortness of breath.

Do not refill a Fiasp® Penfill® cartridge.

If you are treated with Fiasp® Penfill® and another insulin in Penfill® cartridge, you should use two Novo Nordisk Insulin Delivery Devices, one for each type of insulin.

As a precautionary measure:

- Always carry a spare insulin delivery device with a Penfill® cartridge or FlexTouch® and new needles with you, in case of loss or damage.
- Always carry something to show you have diabetes.
- Always carry products containing sugar with you. See the section on *'Causes of low blood sugar (hypoglycemia): What to do if you get any of these signs'*.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Fiasp®. Talk about any health conditions or problems you may have, including if you:

- Have trouble with your adrenal, pituitary or thyroid glands, your doctor may decide to alter your insulin dose.
- Have an infection, fever or have had an operation you may need more insulin than usual.
- Suffer from diarrhea, vomiting or eat less than usual you may need less insulin than usual.
- Exercise more than usual or if you want to change your usual diet.
- Are ill: continue taking your insulin. Your need for insulin may change.
- Go abroad: travelling over time zones may affect your insulin needs and the timing of your injections. Consult your doctor if you are planning such travel.
- Are pregnant, or planning a pregnancy or are breastfeeding please contact your doctor for advice.
- Drive or use tools or machines: watch for signs of a hypoglycemia. Your ability to concentrate or to react will be less during a hypoglycemic reaction. 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). Never drive or use machinery if you feel a hypoglycemic reaction coming on.

Other warnings you should know about:

- The onset of effect for Fiasp® is twice as fast when compared to NovoRapid®. Therefore if low blood sugar occurs, you may experience it earlier after an injection.
- Hypokalemia (low potassium) is a possible side effect with all insulins. You might be more at risk if you are on potassium lowering drugs or losing potassium (e.g. diarrhea).
- Eye disorder - Fast improvements in blood sugar control may lead to a temporary worsening of diabetic eye disorder.
- Pain due to nerve damage - If your blood sugar level improves very fast, you may get nerve related pain, this is usually temporary.
- Swelling around your joints - When you first start using your medicine, your body may keep more water than it should. This causes swelling around your ankles and other joints. This is usually only short-lasting.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Fiasp®:

Some medicines affect the way glucose works in your body and this may influence your insulin dose. Listed below are the most common medicines, which may affect your insulin treatment. Tell your doctor, Diabetes Nurse Educator or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. In particular, you should tell your doctor if you are using any medicine as mentioned below that affects your blood sugar level.

If you take any of the medicines below, your blood sugar level may fall (hypoglycemia)

- Other medicines for the treatment of diabetes
- Medicines used to treat high blood pressure and/or heart problems, such as: angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blocking (ARB) agents, disopyramide

- Fibrates (medicine used for lowering high levels of blood fats)
- Monoamine oxidase inhibitors (MAOI) (medicines used to treat depression)
- Medicines used to relieve pain and lower fever, such as pentoxifylline, propoxyphene and salicylates
- Sulfonamide antibiotics (medicines used to treat infections)
- Somatostatin analogs, such as octreotide
- Fluoxetine

If you take any of the medicines below, your blood sugar level may rise (hyperglycemia)

- Atypical antipsychotics (e.g., olanzapine and clozapine)
- Hormones, such as: estrogens and/or progesterone (alone or as contraceptive pills), somatropin, thyroid hormones, glucagon.
- Corticosteroids (used to treat inflammation)
- Danazol (medicine acting on ovulation)
- Protease inhibitors (used to treat HIV infection)
- Diuretics (also called water pills), used to treat high blood pressure or fluid retention
- Isoniazid (used to treat tuberculosis)
- Some medicines used to treat asthma, such as albuterol, epinephrine, terbutaline
- Niacin and phenothiazines

If you take any of the medicines below, your blood sugar level may rise or fall

- High blood pressure medicines, such as: beta-blockers or clonidine
- Some medicines used to treat mental health problems, such as: lithium salts.
- Octreotide and lanreotide (used to treat a rare condition involving too much growth hormone (acromegaly))
- Alcohol (including wine and beer)
- A medicine used to treat some parasitic infections, called pentamidine. This may cause too low blood sugar which is sometimes followed by too high blood sugar.

Some medicines may make it harder to recognize the warning signs of your blood sugar being too low (hypoglycemia). Such medicines include: beta-blockers medicines, clonidine, guanethidine, or reserpine.

Before using Fiasp®

- Check the label to make sure you have the right type of insulin.
- Remove the protective cap.
- Always check the Penfill® cartridge, including the rubber stopper (plunger). Don't use it if any damage is seen or if there is a gap between the rubber stopper and the white barcode label. Take it back to your supplier or call Novo Nordisk Canada at 1-800-465-4334 for assistance. See your Novo Nordisk Insulin Delivery Device manual for further instructions.
- Always use a new needle for each injection to prevent contamination.
- Do not share your Fiasp® Penfill® in a Novo Nordisk Insulin Delivery Device/FlexTouch® with another person, even if the needle is changed. Do not reuse or share needles with another person. You may give another person an infection or get an infection from them.
- The injection site should be rotated to help prevent changes to the fatty tissue under the skin, such as skin thickening, skin shrinking or lumps under the skin. The insulin may

not work very well if you inject into a lumpy, shrunken or thickened area (see 'How to use Fiasp®'). Tell your healthcare professional if you notice any skin changes at the injection site. Tell your healthcare professional if you are currently injecting into these affected areas before you start injecting in a different area. A sudden change of site may result in hypoglycemia. Your healthcare professional may tell you to check your blood sugar more closely, and to adjust your insulin or your other antidiabetic medications dose.

How to take Fiasp®:

Fiasp® is for injection under the skin (subcutaneously) or for continuous infusion in pumps. Administration in a pump will require a comprehensive instruction by your healthcare professional. Do not inject into a vein or muscle.

Always vary the site you inject within the same region, to avoid lumps (see '*What are possible side effects from using Fiasp®?*'). The best places to give yourself an injection are: the front of your thighs; the front of your waist (abdomen); or the upper arm. Your insulin will work more quickly if you inject around the waist.

You should always measure your blood glucose regularly.

Talk about your insulin needs with your doctor and Diabetes Nurse Educator. Do not change your insulin unless your doctor tells you to. Follow their advice carefully. This leaflet is a general guide only.

If your doctor has switched you from one type or brand of insulin to another, your dose may have to be adjusted by your doctor.

Due to the faster onset of action, Fiasp® should be injected up to 2 minutes before the start of a meal. When necessary, Fiasp® may be administered up to 20 minutes after starting a meal.

How to inject this insulin using a vial

- Draw into the syringe the same amount of air as the dose of insulin you are going to inject. Inject the air into the vial.
- Turn the vial and syringe upside down and draw the correct insulin dose into the syringe. Pull the needle out of the vial. Then expel the air from the syringe and check that the dose is correct.
- Inject the insulin under the skin. Use the injection technique advised by your doctor or Diabetes Nurse Educator.
- Discard needle after each injection.

For use in an insulin infusion pump system using a vial:

Follow the instructions and recommendations from your doctor regarding the use of Fiasp® in a pump. Before using Fiasp® in the pump system, you must have received a comprehensive instruction in the use and information about any actions to be taken in case of illness, too high or too low blood sugar or failure of the pump system. If you use Fiasp® from a vial in an infusion pump system it can be used for a maximum of 6 days.

Filling the pump using a vial:

- Fiasp® should never be diluted or mixed with any other insulin.

- Before inserting the needle, use soap and water to clean your hands and the skin where the needle is inserted to avoid any infection at the infusion site.
- When you fill a new reservoir, do not leave large air bubbles in either the syringe or the tubing.
- Changing of the infusion set (tubing and needle) must be done according to the instructions in the product information supplied with the infusion set.

To get the benefit of insulin infusion, and to detect possible malfunction of the insulin infusion pump, it is recommended that you measure your blood sugar level regularly.

What to do if the pump system fails

You should always have an alternative delivery method for your insulin available for injection under the skin (for example, a pen injector or syringes) in case the pump system fails.

How to inject this insulin using a Penfill® cartridge:

- Please read the manual that comes with your insulin delivery device.
- Inject the insulin under the skin. Use the injection technique advised by your doctor or Diabetes Nurse Educator and described in your Novo Nordisk Insulin Delivery Device Manual. Keep the needle under your skin for at least six seconds. Keep the push button fully depressed until the needle has been withdrawn. This will ensure correct delivery and limit possible flow of blood into the needle or insulin reservoir.
- After each injection discard the needle.

How to inject this insulin FlexTouch®:

Detailed instructions for use are provided on the other side of this leaflet.

Usual dose:

When to use Fiasp®:

Fiasp® is a mealtime insulin. Fiasp® should be injected up to 2 minutes before the start of a meal. When necessary, Fiasp® may be administered up to 20 minutes after starting a meal. A maximum effect occurs between 1 and 3 hours after the injection and the effect lasts for 3-5 hours.

Fiasp® dose

Dose for type 1 and type 2 diabetes

Your doctor will decide together with you:

- How much Fiasp® you will need at each meal
- When to check your blood sugar level and if you need a higher or lower dose.

If you want to change your usual diet, first check with your doctor, Diabetes Nurse Educator or pharmacist as a change in diet may alter your need for insulin.

When using other medicines, ask your doctor or Diabetes Nurse Educator if your treatment needs to be adjusted.

Dose adjustment for type 2 diabetes

The dose each day for Fiasp® should be based on your blood sugar level at mealtimes and bedtime from the previous day.

- Before breakfast - dose should be adjusted according to the blood sugar level before lunch the previous day.
- Before lunch - dose should be adjusted according to the blood sugar level before dinner the previous day.
- Before dinner - dose should be adjusted according to the bedtime blood sugar level the previous day.

Dose adjustment	
Mealtime or bedtime plasma glucose	Dose adjustment
less than 4.0 mmol/L	Reduce dose by 1 unit
4.0 - 6.0 mmol/L	no adjustment
more than 6.0 mmol/L	Increase dose by 1 unit

Use in elderly patients (65 years or older)

Fiasp® can be used in geriatric patients but if you are geriatric you may need to check your blood sugar level more often. Talk to your doctor about changes in your dose.

If you have kidney or liver problems

If you have kidney or liver problems you may need to check your blood sugar level more often. Talk to your doctor about changes in your dose.

Overdose:

Causes of low blood sugar (hypoglycemia):

You get a hypoglycemia if your blood sugar gets too low.

This might happen:

- If you take too much insulin
- If you eat too little or miss a meal
- If you exercise more than usual
- If you drink alcohol

The warning signs of a hypoglycemia may come on suddenly and can include: cold sweat; cool pale skin; headache; slurred speech; fast heartbeat; feeling sick; feeling very hungry; temporary changes in vision; drowsiness; unusual tiredness and weakness; nervousness or tremor; feeling anxious; feeling confused; and difficulty concentrating.

What to do if you get any of these signs:

- Eat glucose tablets or a high sugar snack (sweets, biscuits, fruit juice), then rest. Don't take any insulin if you feel a hypoglycemia coming on.
- Measure your blood sugar if possible and rest. You may need to measure your blood sugar more than once.
- Wait until the signs of too low blood sugar have gone or when your blood sugar level has settled. Then carry on with your insulin as usual.

If severe hypoglycemia is not treated, it can cause brain damage (temporary or permanent) and even death.

If you have a hypoglycemia that makes you pass out, or if you get a lot of hypoglycemias, talk

to your doctor. The amount or timing of your insulin dose, the amount of food you eat or the amount of exercise you do, may need to be adjusted.

What others need to do if you pass out:

Tell your relatives, friends and close colleagues that if you pass out (become unconscious); they must turn you on your side and get medical help right away. They must not give you anything to eat or drink as it could choke you.

Using glucagon

You may recover more quickly from unconsciousness with an injection of the hormone glucagon given by someone who knows how to use it. If you are given glucagon you will need to eat glucose or a sugary snack as soon as you are conscious. If you do not respond to glucagon treatment, you will have to be treated in a hospital. Contact your doctor or hospital emergency after an injection of glucagon: you need to find the reason for your hypoglycemia in order to avoid getting more.

If you think you, or a person you are caring for, have taken too much Fiasp[®], contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Causes of high blood sugar (hyperglycemia):

You get a hyperglycemia if your blood sugar gets too high.

This might happen:

- If you forget to take or stop taking insulin
- If you keep taking less insulin than you need
- If you eat more than usual
- If you exercise less than usual
- If you drink alcohol
- If you get an infection or fever

The warning signs appear gradually. They include: increased urination; feeling thirsty; losing your appetite; feeling sick (nausea or vomiting); feeling drowsy or tired; flushed dry skin; a dry mouth and a fruity (acetone) smelling breath.

These may be signs of a very serious condition called diabetic ketoacidosis (a condition with too much acid in the blood). If you don't treat it, this could lead to diabetic coma and death.

What to do if you get any of these signs: test your blood sugar level; test your urine for ketones if you can; then seek medical advice right away.

Causes of low potassium (hypokalemia)

If you take too much insulin, particularly when given intravenously, it might cause hypokalemia (low potassium). Hypokalemia must be corrected appropriately.

Missed Dose:

If you have missed a dose of Fiasp[®] or if you have not injected enough insulin, your blood sugar level may become too high (hyperglycemia). Check your blood sugar frequently. For information on the treatment of hyperglycemia, see *Causes of high blood sugar*

(*hyperglycemia*)' above.

Do not take a double dose to make up for a forgotten dose.

What are possible side effects from using Fiasp®?

These are not all the possible side effects you may feel when taking Fiasp®. If you experience any side effects not listed here, contact your healthcare professional.

The following side effects may be observed while taking Fiasp®:

- Very common (more than 1 out of 10 patients)
 - Low Blood Sugar (See section '*Causes of low blood sugar (hypoglycemia)*' above)
- Common (less than 1 out of 10 patients)
 - Reaction at administrations site
 - Skin reactions
- Uncommon
 - Changes under the skin where you use the injection (Lipodystrophy)
 - Allergic reactions
- Frequency not known
 - Lumps under the skin (Cutaneous Amyloidosis)

Reaction at administration site: Local reactions at the place you inject/infuse yourself may occur. The signs may include: rash, redness, inflammation, bruising and itching. The reactions usually disappear after a few days.

Skin reactions: Signs of allergy on the skin such as eczema, rash, itching, hives and dermatitis may occur.

Changes under the skin where you use the injection (lipodystrophy): Fatty tissue under the skin may shrink (lipoatrophy) or get thicker (lipohypertrophy). Changing where you inject each time may reduce the risk of developing these skin changes. If you notice these skin changes, tell your doctor or nurse. If you keep injecting in the same place, these reactions can become more severe and affect the amount of medicine your body gets.

Allergic reaction: If you have a serious allergic reaction to the insulin or any of the ingredients in Fiasp®, stop using Fiasp® and see a doctor straight away. The signs of a serious allergic reaction may include:

- Local reactions (e.g., rash, redness, and itching) spread to other parts of your body
- You suddenly feel unwell with sweating
- You start being sick (vomiting)
- You experience difficulty in breathing
- You experience rapid heart beat or feeling dizzy.

Cutaneous Amyloidosis: Lumps under the skin may also be caused by build-up of protein called amyloid (cutaneous amyloidosis). The insulin may not work very well if you inject into a lumpy, shrunken or thickened area. Change the injection site with each injection to help prevent these skin changes.

Serious side effects and what to do about them

Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY COMMON Hypoglycemia	√		√
COMMON Reaction at administration site		√	
Skin reactions		√	
RARE Changes under the skin where you use the injection (lipodystrophy)		√	
Allergic reaction			√
UNKNOWN Cutaneous Amyloidosis: lumps under skin		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton, after 'EXP'. The expiry date refers to the last day of that month.

Before first use:

[FlexTouch®] Store in the refrigerator (2°C to 8°C). Keep away from the freezing element. Do not freeze. Keep the cap on the pen in order to protect from light.

[Penfill®] Store in the refrigerator (2°C to 8°C). Keep away from the freezing element. Do not freeze. Keep the cartridge in the carton in order to protect from light.

[Vial] Store in the refrigerator (2°C to 8°C). Keep away from the freezing element. Do not freeze. Keep the vial in the carton in order to protect from light.

After first opening or if carried as a spare:

[FlexTouch®] You can carry your Fiasp® pre-filled pen (FlexTouch®) with you and keep it at room temperature (not above 30°C) or in a refrigerator (2°C to 8°C) for up to 4 weeks. Always keep the cap on the pen when you are not using it in order to protect from light.

[Penfill®] Do not refrigerate. You can carry your cartridge (Penfill®) with you and keep it at room temperature (not above 30°C) for up to 4 weeks. Always keep the cartridge in the carton in order to protect from light.

[FlexTouch®][Penfill®] Throw away the needle after each injection.

[Vial] You can carry your Fiasp® vial with you and keep it at room temperature (not above 30°C) or in a refrigerator (2°C to 8°C) for up to 4 weeks (including the time it has been stored inside of a pump reservoir). Always keep the vial in the carton in order to protect from light.

When used in an insulin infusion pump system:

Fiasp® inside of the pump reservoir should be replaced:

- At least every 6 days, or according to the instructions in the product information supplied with the infusion set, whichever is shorter, or
- After being exposed to temperatures above 37°C

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

If you want more information about Fiasp®:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.novonordisk.ca, or by calling 1-800-465-4334.

This leaflet was prepared by Novo Nordisk Canada Inc.

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Instructions on how to use Fiasp® FlexTouch®

Please read these instructions carefully before using your FlexTouch® pre-filled pen. 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.

Do not use the pen without proper training from your doctor or nurse.

Start by checking your pen to **make sure that it contains Fiasp® 100 units/mL**, then look at the illustrations below to get to know the different parts of your pen and needle.

If you are blind or have poor eyesight and cannot read the dose counter on the pen, do not use this pen without help. Get help from a person with good eyesight that is trained to use the FlexTouch® pre-filled pen.

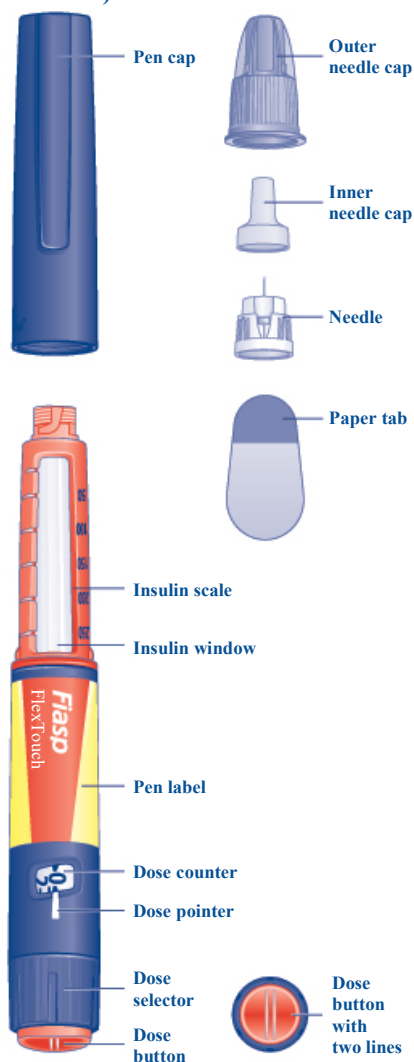
Your pen is a pre-filled dial-a-dose insulin pen containing 300 units of insulin. You can select a **maximum of 80 units per dose, in steps of 1 unit**. Your pen is designed to be used with NovoTwist®, NovoFine® or NovoFine® Plus single-use, disposable needles up to a length of 8 mm. Needles are not included in the pack.

Important information

Pay special attention to these notes as they are important for correct use of the pen.

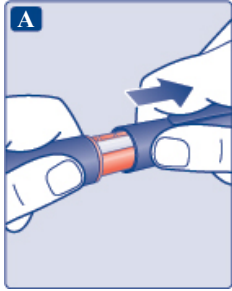
Fiasp® Pre-filled pen and needle (example) (FlexTouch®)

Fiasp pre-filled pen and needle (example) (FlexTouch)

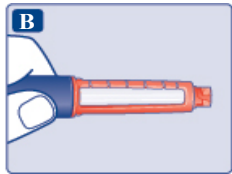


1 Prepare your pen with a new needle

- **Check the name and strength on the label** of your pen, to make sure that it contains Fiasp® 100 units/mL. This is especially important if you take more than one type of insulin. If you take a wrong type of insulin, your blood sugar level may get too high or too low.
- **Pull off the pen cap.**



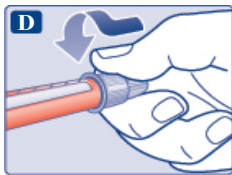
- **Check that the insulin in your pen is water-clear** and colourless. Look through the insulin window. If the insulin looks cloudy, do not use the pen.



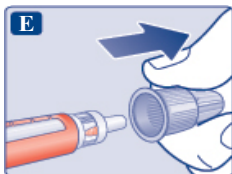
- **Take a new needle** and tear off the paper tab.



- **Push the needle straight onto the pen. Turn until it is on tight.**



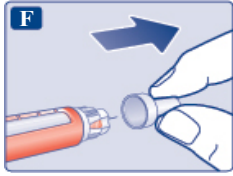
- **Pull off the outer needle cap and keep it for later.** You will need it after the injection, to safely remove the needle from the pen.



- **Pull off the inner needle cap and throw it away.** If you try to put it back on, you may accidentally stick yourself with the needle.

A drop of insulin may appear at the needle tip. This is normal, but you must still check the insulin flow.

Do not attach a new needle to your pen until you are ready to take your injection.

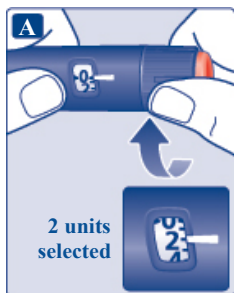


- ⚠ **Always use a new needle for each injection.**
This reduces the risk of contamination, infection, leakage of insulin, blocked needles and inaccurate dosing.

- ⚠ **Never use a bent or damaged needle.**

2 Check the insulin flow

- **Always check the insulin flow before you start.**
This helps you to ensure that you get your full insulin dose.
- Turn the dose selector to **select 2 units. Make sure the dose counter shows 2.**



- Hold the pen with the needle pointing up.
Tap the top of the pen gently a few times to let any air bubbles rise to the top.



- **Press and hold in the dose button** until the dose counter returns to 0.
The 0 must line up with the dose pointer.
A drop of insulin should appear at the needle tip.



A small air bubble may remain at the needle tip, but it will not be injected.

If no drop appears, repeat steps 2A to 2C up to 6 times. If there is still no drop, change the needle and repeat steps 2A to 2C once more.

If a drop of insulin still does not appear, dispose of the pen and use a new one.

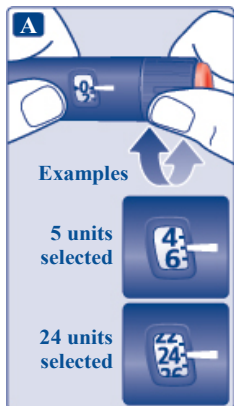
- ⚠ **Always make sure that a drop appears** at the needle tip before you inject. This makes sure that the insulin flows.
If no drop appears, you will **not** inject any insulin, even though the dose counter may move. This may indicate a blocked or damaged needle.
- ⚠ **Always check the flow before you 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.

3 Select your dose

- **Make sure the dose counter shows 0 before you start.**
The 0 must line up with the dose pointer.
- **Turn the dose selector to select the dose you need**, as directed by your doctor or nurse.

If you select a wrong dose, you can turn the dose selector forwards or backwards to the correct dose.

The pen can dial up to a maximum of 80 units.



The dose selector changes the number of units. Only the dose counter and dose pointer will show how many units you select per dose.

You can select up to 80 units per dose. When your pen contains less than 80 units, the dose counter stops at the number of units left.

The dose selector clicks differently when turned forwards, backwards or past the number of units left. Do not count the pen clicks.

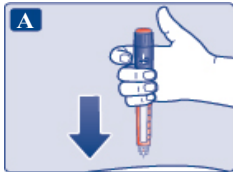
⚠ Always use the dose counter and the dose pointer to see how many units you have selected before injecting the insulin.

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 insulin scale, it only shows approximately how much insulin is left in your pen.

4 Inject your dose

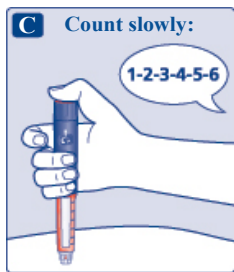
- **Insert the needle into your skin** as your doctor or nurse has shown you.
- **Make sure you can see the dose counter.**
Do not touch the dose counter with your fingers. This could interrupt the injection.



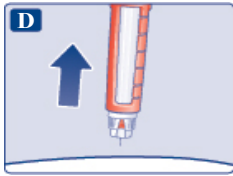
- **Press and hold down the dose button until the dose counter shows 0.**
The 0 must line up with the dose pointer. You may then hear or feel a click.



- **Keep the needle in your skin after** the dose counter has returned to 0 and **count slowly to 6.**
- If the needle is removed earlier, you may see a stream of insulin coming from the needle tip. If so, the full dose will not be delivered, and you should increase the frequency of checking your blood sugar level.



- **Remove the needle from your skin.** If blood appears at the injection site, press lightly. Do not rub the area.



You may see a drop of insulin at the needle tip after injecting. This is normal and does not affect your dose.

- ⚠ **Always watch the dose counter to know how many units you inject.** Hold the dose button down until the dose counter shows 0. If the dose counter does not return to 0, the full dose has not been delivered, which may lead to too high blood sugar level.

How to identify a blocked or damaged needle?

- If 0 does not appear in the dose counter after continuously pressing the dose button, you may have used a blocked or damaged needle.
- In this case - you have **not** received **any** medicine - even though the dose counter has moved from the original dose that you have set.

How to handle a blocked needle?

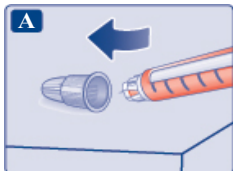
Remove the needle as described in section 5 and repeat all steps starting with section 1: Prepare your pen with a new needle. Make sure you select the full dose you need.

Never touch the dose counter when you inject.

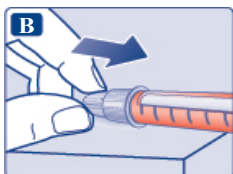
This can interrupt the injection.

5 After your injection

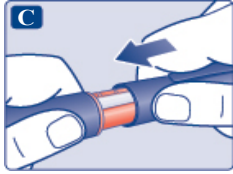
- **Lead the needle tip into the outer needle cap** on a flat surface without touching the needle or the outer cap.



- Once the needle is covered, **carefully push the outer needle cap completely on.**
- **Unscrew the needle** and dispose of it carefully, as instructed by your doctor, nurse, pharmacist or local authorities.



- **Put the pen cap on** your pen after each use to protect the insulin from light.



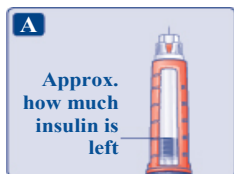
Always dispose of the needle after each injection. This reduces the risk of contamination, infection, leakage of insulin, blocked needles and inaccurate dosing. If the needle is blocked, you will **not** inject any insulin.

When the pen is empty, throw it away **without** a needle on as instructed by your doctor, nurse, pharmacist or local authorities.

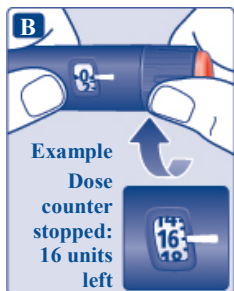
- ⚠ **Never try to put the inner needle cap back on the needle.** You may stick yourself with the needle.
- ⚠ **Always remove the needle from your pen after each injection** and store your pen without the needle attached. This reduces the risk of contamination, infection, leakage of insulin, blocked needles and inaccurate dosing.

6 How much insulin is left?

- The **insulin scale** shows you **approximately** how much insulin is left in your pen.



- **To see precisely how much insulin is left**, use the dose counter:
Turn the dose selector until the **dose counter stops**.
If it shows 80, **at least 80** units are left in your pen.
If it shows **less than 80**, the number shown is the number of units left in your pen.



- Turn the dose selector back until the dose counter shows 0.
- If you need more insulin than the units left in your pen, you can split your dose between two pens.

- ⚠ **Be very careful to calculate correctly if splitting your dose.**

If in doubt, take the full dose with a new pen. If you split the dose wrong, you will inject too little or too much insulin, which can lead to too high or too low blood sugar level.

 **Further important information**

- **Always keep your pen with you.**
- **Always carry an extra pen and new needles** with you, in case of loss or damage.
- Always keep your pen and needles **out of sight and reach of others**, especially children.
- **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.
- Caregivers must **be very careful when handling used needles** – to reduce the risk of needle injury and cross-infection.

Caring for your pen

Treat your pen with care. Rough handling or misuse may cause inaccurate dosing, which can lead to too high or too low blood sugar level.

- **Do not leave the pen in a car** or other place where it can get too hot or too cold.
- **Do not expose your pen to dust, dirt or liquid.**
- **Do not wash, soak or lubricate your pen.** If necessary, clean it with mild detergent on a moistened cloth.
- **Do not drop your pen** or knock it against hard surfaces.
If you drop it or suspect a problem, attach a new needle and check the insulin flow before you inject.
- **Do not try to refill your pen.** Once empty, it must be disposed of.
- **Do not try to repair your pen** or pull it apart.