

Package leaflet: Information for the patient

Fiasp® 100 units/mL Penfill solution for injection in cartridge insulin aspart

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

- 1 What Fiasp® is and what it is used for
- 2 What you need to know before you use Fiasp®
- 3 How to use Fiasp®
- 4 Possible side effects
- 5 How to store Fiasp®
- 6 Contents of the pack and other information

1. What Fiasp® is and what it is used for

Fiasp® is a mealtime insulin with a fast-acting blood sugar lowering effect. Fiasp® is a solution for injection containing insulin aspart and is used to treat diabetes mellitus in adults, adolescents and children aged 1 year and above. Diabetes is a disease where your body does not produce enough insulin to control the level of blood sugar. Treatment with Fiasp® helps to prevent complications from your diabetes.

Fiasp® should be injected up to 2 minutes before the start of the meal, with an option to inject up to 20 minutes after starting the meal.

This medicine has its maximum effect between 1 and 3 hours after the injection and the effect lasts for 3 to 5 hours.

This medicine should normally be used in combination with intermediate-acting or long-acting insulin preparations.

2. What you need to know before you use Fiasp®

Do not use Fiasp®

- ▶ if you are allergic to insulin aspart, or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Fiasp®. Be especially aware of the following:

- Low blood sugar (hypoglycaemia) - If your blood sugar is too low, follow the guidance for low blood sugar in section 4 'Possible side effects'. Fiasp® starts to lower blood sugar faster

compared to other mealtime insulins. If hypoglycaemia occurs, you may experience it earlier after an injection with Fiasp®.

- High blood sugar (hyperglycaemia) - If your blood sugar is too high, follow the guidance for high blood sugar in section 4 'Possible side effects'.
- Switching from other insulin medicinal products - The insulin dose may need to be changed if you switch from another insulin.
- Pioglitazone used together with insulin - This may increase the risk of heart failure, see under 'Other medicines and Fiasp®' below.
- 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.

If you have poor eyesight, please see section 3 'How to use Fiasp®'.

Some conditions and activities can affect how much insulin you need. Talk to your doctor:

- if you have trouble with your kidneys or liver, or with your adrenal, pituitary or thyroid glands.
- if you exercise more than usual or if you want to change your usual diet, as this may affect your blood sugar level.
- if you are ill, carry on taking your insulin and talk to your doctor.

When using Fiasp® it is strongly recommended that the name and batch number of each package is recorded in order to maintain a record of the batches used.

Skin changes at the injection site

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 section 3 'How to use Fiasp®'). Tell your doctor if you notice any skin changes at the injection site. Tell your doctor if you are currently injecting into these affected areas before you start injecting in a different area. Your doctor may tell you to check your blood sugar more closely, and to adjust your insulin or your other antidiabetic medications dose.

Children and adolescents

This medicine is not recommended for use in children below the age of 1 year.

Other medicines and Fiasp®

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Some medicines affect your blood sugar level - this may mean your insulin dose has to change.

Listed below are the most common medicines which may affect your insulin treatment.

Your blood sugar level may fall (hypoglycaemia) if you take:

- other medicines for diabetes (oral and injectable)
- sulphonamides - for infections
- anabolic steroids - such as testosterone
- beta-blockers - for e.g., high blood pressure or angina. They may make it harder to recognise the warning signs of low blood sugar (see section 4 'Warning signs of low blood sugar')
- acetylsalicylic acid (and other salicylates) - for pain and mild fever
- monoamine oxidase (MAO) inhibitors - for depression
- angiotensin converting enzyme (ACE) inhibitors - for some heart problems or high blood pressure.

Your blood sugar level may rise (hyperglycaemia) if you take:

- danazol - for endometriosis

- oral contraceptives (birth control pills)
- thyroid hormones - for thyroid problems
- growth hormone - for growth hormone deficiency
- glucocorticoids such as 'cortisone' - for inflammation
- sympathomimetics such as epinephrine (adrenaline), salbutamol or terbutaline - for asthma
- thiazides - for high blood pressure or if your body is keeping too much water (water retention).

Octreotide and lanreotide - used to treat a rare condition involving too much growth hormone (acromegaly). They may increase or decrease your blood sugar level.

Pioglitazone - oral antidiabetic medicine used to treat type 2 diabetes. Some patients with long-standing type 2 diabetes and heart disease or previous stroke who were treated with pioglitazone and insulin developed heart failure. Tell your doctor immediately if you have signs of heart failure such as unusual shortness of breath, rapid increase in weight or localised swelling (oedema).

If any of the above applies to you (or you are not sure), talk to your doctor or pharmacist.

Fiasp® with alcohol

If you drink alcohol, your need for insulin may change as your blood sugar level may either rise or fall. You should therefore monitor your blood sugar level more often than usual.

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. This medicine can be used during pregnancy; however your insulin dose may need to be changed during pregnancy and after delivery. Careful control of your diabetes is needed in pregnancy. Avoiding low blood sugar (hypoglycaemia) is particularly important for the health of your baby.

There are no restrictions on treatment with Fiasp® during breast-feeding.

Driving and using machines

Having low blood sugar can affect your ability to drive or use any tools or machines. If your blood sugar is low, your ability to concentrate or react might be affected. This could be dangerous to yourself or others. Ask your doctor whether you can drive if:

- ▶ you often get low blood sugar
- ▶ you find it hard to recognise low blood sugar.

Important information about some of the ingredients of Fiasp®

This medicine contains less than 1 mmol sodium (23 mg) per dose. This means that this medicine is essentially 'sodium-free'.

3. How to use Fiasp®

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

If you are blind or have poor eyesight and cannot read the dose counter on the pen, do not use this insulin medicinal product without any help. Get help from a person with good eyesight who is trained to use the pen.

When to use Fiasp®

Fiasp® is a mealtime insulin.

Adults: Fiasp® should be injected right before (0-2 minutes) the start of the meal, with an option to inject up to 20 minutes after starting the meal.

Children: Fiasp® should be injected right before (0-2 minutes) the start of the meal, with the possibility to inject up to 20 minutes after starting the meal in situations, when there is uncertainty about how the child will eat. Ask your doctor for advice on these situations.

This medicine has its maximum effect between 1 and 3 hours after the injection and the effect lasts for 3 to 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, check with your doctor, pharmacist or nurse first as a change in diet may alter your need for insulin.

When using other medicines, ask your doctor if your treatment needs to be adjusted.

Dose adjustment for type 2 diabetes

The daily dose 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.

Mealtime or bedtime blood sugar		Dose adjustment
mmol/L	mg/dL	
less than 4.0	less than 71	Reduce dose by 1 unit
4.0–6.0	71–108	No dose adjustment
more than 6.0	more than 108	Increase dose by 1 unit

Use in elderly patients (65 years or older)

This medicine can be used in elderly patients. 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.

Injecting Fiasp®

This medicine is only suitable for injection under the skin (subcutaneous injection) from a reusable pen.

Before you use Fiasp® for the first time, your doctor or nurse will show you how to use it. Speak to your doctor if you need to inject your insulin by another method.

Where to inject

- ▶ The best places to inject are the front of your waist (abdomen) or upper arms.
- ▶ Do not inject into a vein or muscle.
- ▶ Change the place within the area where you inject each day to reduce the risk of developing changes under the skin (see section 4).

Do not use Fiasp®

- ▶ if the cartridge or the reusable pen you are using is damaged. Take it back to your supplier. See your reusable pen manual for further instructions.
- ▶ if the cartridge has not been stored correctly (see section 5 ‘How to store Fiasp®’).
- ▶ if the insulin does not appear clear (e.g., cloudy) and colourless.

How to inject Fiasp®

- ▶ Read the manual that comes with your reusable pen.
- ▶ Check the name and strength on the label of the cartridge (Penfill®) to make sure it is Fiasp®.
- ▶ Always use a new needle for each injection to prevent contamination.
- ▶ Needles must not be shared.

If you use more Fiasp® than you should

If you use too much insulin your blood sugar may get too low (hypoglycaemia), see advice in section 4 under ‘Low blood sugar’.

If you forget to use Fiasp®

If you forget to use your insulin your blood sugar may get too high (hyperglycaemia). See section 4 under ‘High blood sugar’.

Three simple steps that may help avoiding low or high blood sugar are:

- Always keep spare cartridges of Fiasp®.
- Always carry something to show you have diabetes.
- Always carry products containing sugar with you. See section 4 under ‘What to do if you get low blood sugar’.

If you stop using Fiasp®

Do not stop using your insulin without talking to your doctor. If you stop using your insulin this could lead to a very high blood sugar level (severe hyperglycaemia) and ketoacidosis (a condition with too much acid in the blood which is potentially life-threatening). See symptoms and advice in section 4 under ‘High blood sugar’.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Low blood sugar (hypoglycaemia) is very common with insulin treatment (may affect more than 1 in 10 people). It can be very serious. If your blood sugar level falls too much you may become unconscious. Serious hypoglycaemia may cause brain damage and may be life-threatening. If you have symptoms of low blood sugar, take actions **immediately** to increase your blood sugar level. See advice in ‘Low blood sugar’ below.

If you have a serious allergic reaction to insulin or any of the ingredients in Fiasp®, stop using this medicine and contact emergency medical service straight away.

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 heartbeat or feeling dizzy.

Allergic reactions such as generalised skin rash and facial swelling may occur. These are uncommon and may affect up to 1 in 100 people. See a doctor if the symptoms worsen or you see no improvement in a few weeks.

Skin changes at the injection site If you inject insulin at the same place, the fatty tissue may shrink (lipoatrophy) or thicken (lipohypertrophy) (*may affect up to 1 in 100 people*). Lumps under the skin

may also be caused by build-up of a protein called amyloid (cutaneous amyloidosis; how often this occurs is not known). 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.

Other side effects include:

Common (*may affect up to 1 in 10 people*)

Reaction at administration site: Local reactions at the place you inject yourself may occur. The signs may include: rash, redness, inflammation, bruising, irritation, pain 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.

General effects from insulin treatment including Fiasp®

► **Low blood sugar (hypoglycaemia)** (very common)

Low blood sugar may happen if you:

Drink alcohol; use too much insulin; exercise more than usual; eat too little or miss a meal.

Warning signs of low blood sugar – these may come on suddenly:

- headache
- slurred speech
- fast heartbeat
- cold sweat
- cool pale skin
- feeling sick
- feeling very hungry
- tremor or feeling nervous or worried
- feeling unusually tired, weak and sleepy
- feeling confused
- difficulty in concentrating
- short-lasting changes in your sight.

What to do if you get low blood sugar

- If you are conscious, treat your low blood sugar immediately with 15–20 g of fast-acting carbohydrate: eat glucose tablets or another high sugar snack, like fruit juice, sweets or biscuits (always carry glucose tablets or a high sugar snack, just in case).
- It is recommended that you retest your blood glucose levels after 15–20 minutes and re-treat if your blood glucose levels are still less than 4 mmol/L.
- Wait until the signs of low blood sugar have gone or when your blood sugar level has settled. Then carry on with your insulin treatment as usual.

What others need to do if you pass out

Tell everyone you spend time with that you have diabetes. Tell them what could happen if your blood sugar gets too low, including the risk of passing out.

Let them know that if you pass out, they must:

- turn you on your side to avoid choking
- get medical help straight away
- **not** give you any food or drink because you may choke.

You may recover more quickly from passing out with an injection of glucagon. This can only be given by someone who knows how to use it.

- If you are given glucagon you will need sugar or a sugary snack as soon as you come round.
- If you do not respond to a glucagon injection, you will have to be treated in a hospital.

If severe low blood sugar is not treated over time, it can cause brain damage. This can be short or long-lasting. It may even cause death.

Talk to your doctor if:

- ▶ your blood sugar got so low that you passed out
- ▶ you have been given an injection of glucagon
- ▶ you have had too low blood sugar a few times recently.

This is because the dosing or timing of your insulin injections, food or exercise may need to be changed.

- ▶ **High blood sugar (hyperglycaemia)** frequency not known (cannot be estimated from the available data)

High blood sugar may happen if you:

Eat more or exercise less than usual; drink alcohol; get an infection or a fever; have not used enough insulin; keep using less insulin than you need; forget to use your insulin or stop using insulin.

Warning signs of high blood sugar – these normally appear gradually:

- flushed skin
- dry skin
- feeling sleepy or tired
- dry mouth
- fruity (acetone) breath
- urinating more often
- feeling thirsty
- losing your appetite
- feeling or being sick (nausea or vomiting).

These may be signs of a very serious condition called ketoacidosis. This is a build-up of acid in the blood because the body is breaking down fat instead of sugar. If not treated, this could lead to diabetic coma and eventually death.

What to do if you get high blood sugar

- ▶ Test your blood sugar level.
- ▶ Give a correction dose of insulin if you have been taught how to do this.
- ▶ Test your urine for ketones.
- ▶ If you have ketones, seek medical help straight away.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

United Kingdom:

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland:

HPRA Pharmacovigilance

Website: www.hpra.ie

Malta:

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. *How to store Fiasp®*

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:

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

After first opening or if carried as a spare: 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.

Throw away the needle after each injection.

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.

6. *Contents of the pack and other information*

What Fiasp® contains

- The active substance is insulin aspart. 1 mL solution contains 100 units of insulin aspart. One cartridge contains 300 units of insulin aspart in 3 mL solution.
- The other ingredients are phenol, metacresol, glycerol, zinc acetate, disodium phosphate dihydrate, arginine hydrochloride, nicotinamide (vitamin B₃), hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment) (see end of section 2 under 'Important information about some of the ingredients of Fiasp®') and water for injections.

What Fiasp® looks like and contents of the pack

Fiasp® is presented as a clear, colourless and aqueous solution for injection in cartridge.

Pack sizes of 5 and 10 cartridges of 3 mL. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency website:

<http://www.ema.europa.eu>.

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