A guide for **adults/adolescents**

Fiasp®
fast-acting insulin aspart

Supporting you with your Fiasp® treatment

This booklet is intended for UK-based adults and adolescents who have been prescribed Fiasp® (fast-acting insulin aspart)

Information on warnings and precautions for Fiasp® can be found on pages 6–9 of this booklet.
Information on possible side effects for Fiasp® can be found on pages 13–18 of this booklet.


This is not a real patient and is for illustrative purposes only.

Please refer to the Package Leaflet: Information for the patient found in the product carton for:

- Further information on Fiasp®
- Further information on how to use Fiasp®
- A full list of side effects, warnings and precautions

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Reporting side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at https://yellowcard.mhra.gov.uk/ ↗ or search for MHRA Yellow Card in the Google Play or Apple App Store. Side effects should also be reported to Novo Nordisk Limited (Telephone Novo Nordisk Customer Care Centre 0800 023 2573). Calls may be monitored for training purposes. By reporting side effects, you can help provide more information on the safety of this medicine.

This material has been produced and funded by Novo Nordisk for UK-based adult and adolescent patients who have already been prescribed Fiasp®. This information does not replace the Package Leaflet: Information for the patient, which you are advised to read in full. It is not intended as a substitute for clinical advice provided by your healthcare professional. Please contact your healthcare professional if you have any questions about your treatment and for clinical advice. This material is designed to be viewed digitally. It contains hyperlinks which are viewable online only.

This booklet has been made with you in mind, to help support you throughout your insulin treatment.

It will give you:

- Information about Fiasp®
- An explanation of how Fiasp® works
- Some things to remember when injecting your daily Fiasp® doses

If there are any words in this booklet that are new or difficult to understand, please look at the section at the back called '**Useful words to know**'.

This is not a real patient and is for illustrative purposes only.

Contents

Why have you been prescribed Fiasp®?

Having diabetes means that managing your blood sugar level is very important.

You and your healthcare professional have decided that Fiasp® is the appropriate kind of insulin to help you do this. This medicine should normally be used in combination with intermediate-acting or long-acting insulin preparations.

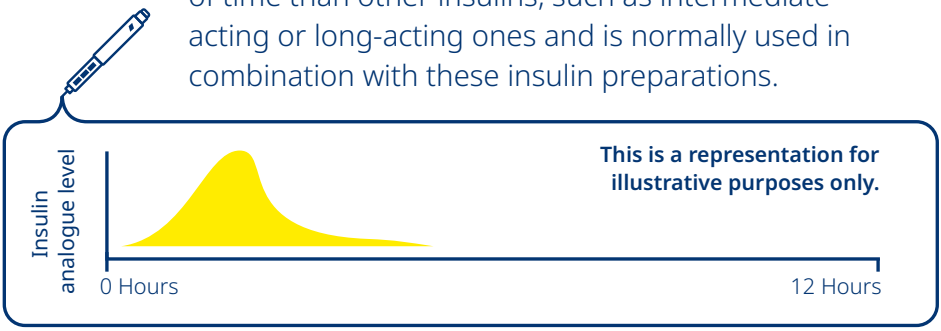
More information on what is covered in the rest of this booklet can be found in the **Package Leaflet: Information for the patient** enclosed with your medication. Please take the time to read through this in full. If you still have any questions or queries, please speak with your healthcare professional.

How Fiasp® works

In people without diabetes, the body releases insulin after meals to help control the rise in blood sugar levels.

People with type 1 diabetes are unable to produce any or very little insulin to help control blood sugar levels. In people with type 2 diabetes, the body prevents the insulin it makes from working correctly. The body may make some insulin, but not enough. Many people with type 2 diabetes may eventually need to inject insulin. Injecting insulin is a way to replace the insulin that your body needs.

Fiasp® is a mealtime (fast-acting) insulin, also known as a "bolus" insulin, which helps the body regulate blood sugar levels. It works for a shorter length of time than other insulins, such as intermediate-acting or long-acting ones and is normally used in combination with these insulin preparations.



The image above shows how Fiasp® acts quickly to help lower blood sugar levels after mealtimes. The maximum effect is between 1 and 3 hours after injection and the effect lasts for 3 to 5 hours.

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

Please refer to the Package Leaflet: Information for the patient found in the product carton in full for further information on Fiasp®.

What you need to know before you use Fiasp®

Please refer to the Package Leaflet: Information for the patient found in the product carton for a full list of warnings and precautions.

Do not use Fiasp®

- If you are allergic to insulin aspart, or any of the other ingredients of this medicine

Warnings and precautions

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

- Low blood sugar (hypoglycaemia). 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)
- Switching from other insulin medicinal products – your doctor may need to advise you on your insulin dose
- If your insulin treatment is being combined with pioglitazone (oral antidiabetic medicine used to treat type 2 diabetes) – tell your doctor as soon as possible if you get signs of heart failure such as unusual shortness of breath, rapid increase in weight or localised swelling caused by fluid retention (oedema)
- Eye disorder – fast improvements in blood sugar control may lead to a temporary worsening of diabetic eye disorder such as diabetic retinopathy
- 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

- Ensuring you use the right type of insulin – always check the insulin label before each injection to avoid accidental mix-ups between insulin products
- Insulin treatment can cause the body to produce antibodies to insulin (a substance that acts against insulin). However, only very rarely, this will require a change to your insulin dose

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
- If you are going abroad, travelling over time zones may affect your insulin needs and the timing of your injections

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. 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 medication's dose.

Please refer to the Package Leaflet: Information for the patient found in the product carton in full for further information on Fiasp®.

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)
- Sulfonamide antibiotics (used to treat infections)
- Anabolic steroids (such as testosterone)
- Beta-blockers (used to treat high blood pressure or angina)
- Salicylates (used to relieve pain and lower fever)
- Monoamine oxidase inhibitors (MAOI) (used to treat 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 (medicine acting on ovulation)
- 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.

Please refer to the Package Leaflet: Information for the patient found in the product carton in full for further information on Fiasp®.

If any of these apply 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. The amount of insulin you need usually falls during the first 3 months of pregnancy and increases for the remaining 6 months. Careful control of your diabetes is needed in pregnancy. Avoiding low blood sugar (hypoglycaemia) is particularly important for the health of your baby. After you have had your baby your insulin requirements will likely return to how much you needed before your pregnancy.

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, that is to say essentially 'sodium-free'.

Please refer to the Package Leaflet: Information for the patient found in the product carton in full for further information on Fiasp®.

How to use Fiasp®

Fiasp® is a mealtime insulin. **This means you should inject it right before** (0–2 minutes) the start of a meal with an option to inject 20 minutes after starting a meal.

You and your healthcare professional will decide how much Fiasp® you will need at each meal. You will also discuss when to check your blood sugar levels and whether you need a higher or lower dose.

Changing your usual diet and exercising more may have an effect on your need for insulin. If you want to do this, please check with your doctor, nurse, or pharmacist first.

It is important to remember to inject the right dose of Fiasp® at every mealtime.

If you **forget to inject a dose**, your blood sugar may get too high (this is known as hyperglycaemia). Please see page 18 of this booklet for more information on what to do if this happens.

If you **inject more Fiasp® than you should**, your blood sugar levels may get too low (this is known as hypoglycaemia). Please see page 16 of this booklet for more information on what to do if this happens.

Do not stop using your insulin without talking to a 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).

Please refer to the Package Leaflet: Information for the patient with your medication for details on how to use/inject Fiasp®.

Please refer to the Package Leaflet: Information for the patient found in the product carton in full for further information on Fiasp®.

Always use Fiasp® exactly as your doctor, nurse or pharmacist has told you to. If you are unsure, or have any questions, please check with them. Do not stop using insulin without talking to your doctor.

Things to do before injecting your dose

Your Fiasp® dose is given by an injection under the skin.

- Before you use Fiasp® for the first time, your doctor or nurse will show you how to use it
- Remember to check the label to make sure it is Fiasp®. This is especially important if you take more than one type of insulin
- Check the appearance of your insulin. Fiasp® should be clear and colourless
- Make sure you have your needles. These are packed separately to your insulin
- Always use a new needle for each injection to prevent contamination, infection and leakage of insulin. This will also prevent your needle becoming blocked, which could result in you receiving an incorrect dosage
- Needles and insulin pens must not be shared

Please refer to the Package Leaflet: Information for the patient found in the product carton in full for further information on Fiasp®.

Things to remember when injecting your dose

Fiasp® is only suitable for injection under the skin (subcutaneous injection). Being concerned about injections is normal. It is important to remember that you are not alone in this — many people are experiencing and feeling the same things.

Your healthcare professional will have advised you on the best places to inject your insulin. These can be the front of your waist (abdomen) or your upper arms.

Remember to change the place within the area where you inject each day. This can help reduce the chance of developing lumps and indentations under the skin.

Always keep a spare pen in case the one in use is lost or damaged.

Before you use Fiasp® for the first time, your healthcare professional will show you how to use it. Always follow the injection guidance given by your doctor, nurse, or pharmacist. Please refer to 'Tips' on page 20 for more information.

Please refer to the Package Leaflet: Information for the patient found in the product carton in full for further information on Fiasp®.

Possible side effects

Please refer to the Package Leaflet: Information for the patient found in the product carton for a full list of 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 action **immediately** to increase your blood sugar level.

If you have a serious allergic reaction (including an anaphylactic shock) to insulin or any of the ingredients in Fiasp®, (how often this occurs is not known), stop using this medicine and contact emergency medical services 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.

Please refer to the Package Leaflet: Information for the patient found in the product carton in full for further information on Fiasp®.

Skin changes at the injection site: If you inject insulin at the same place, the fatty tissue may shrink (lipoatrophy) or thicken (lipohypertrophy) (these are uncommon and 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.

Patient organisations, such as Diabetes UK, often have helpful information that can support you.

Please refer to the Package Leaflet: Information for the patient found in the product carton in full for further information on Fiasp®.

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


Feeling unusually tired, weak and sleepy


Headaches


Slurred speech


Fast heartbeat


Cold sweat


Cool pale skin


Feeling sick (nausea)


Feeling very hungry


Tremors or feeling nervous, or worried


Difficulty concentrating or feeling confused


Short-lasting changes in vision

Please refer to the Package Leaflet: Information for the patient found in the product carton in full for further information on Fiasp®.

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 sugar levels after 15–20 minutes and re-treat if your blood sugar 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

Please refer to the Package Leaflet: Information for the patient found in the product carton in full for further information on Fiasp®.

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)

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

Please refer to the Package Leaflet: Information for the patient found in the product carton in full for further information on Fiasp®.

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 the package leaflet. You can also report side effects directly via the Yellow Card Scheme at https://yellowcard.mhra.gov.uk/ ↗ or search for MHRA Yellow Card in the Google Play or Apple App Store. Side effects should also be reported to Novo Nordisk Limited (Telephone Novo Nordisk Customer Care Centre 0800 023 2573). Calls may be monitored for training purposes. By reporting side effects, you can help provide more information on the safety of this medicine.

Please refer to the Package Leaflet: Information for the patient found in the product carton in full for further information on Fiasp®.

Storage

- Make sure your Fiasp® insulin is kept out of the sight and reach of children
- Do not use your insulin after its expiry date. The date stated refers to the last day of that month
- Keep your insulin in the refrigerator at 2–8°C until first use. Keep it away from the freezing element
- Do not freeze your insulin
- Depending on your injecting device, you may not need to keep your insulin in the fridge after the first use. Please refer to your Package Leaflet: Information for the patient enclosed with your medication for specific storage instructions, including how to protect it from light

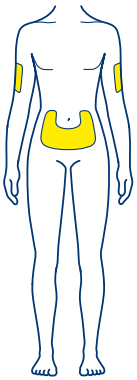
Always dispose of the needle immediately after each injection using a sharps bin. Never store your pen with the needle attached. Keep your sharps bin in a safe place so it's not a risk to other people and is out of the sight and reach of children. Sharps bins must not be disposed of in household waste. Discuss with your healthcare professional the procedure for disposing of sharps bins in your area.

Please refer to the Package Leaflet: Information for the patient found in the product carton in full for further information on Fiasp®.

Tips

Here are some things to remember when injecting your dose:

- When injecting under the skin, make sure there is no air trapped in the needle. Please see your injectable device instructions for more information
- Do not directly inject into a vein or muscle
- Your healthcare professional will have advised you on the best places to inject your insulin. These can be the front of your waist (abdomen) or your upper arms
- Remember to change the place within the area where you inject each day. This can help reduce the chance of developing lumps and indentations under the skin
- Tell your healthcare professional if you notice any skin changes



When injecting your dose:

- Insert the needle into your skin as described by your doctor or nurse. Be sure you can see the dose counter when doing this
- Press and hold down the dose button, watching as the dose counter returns to 0
- Continue to press the dose button while keeping the needle under your skin for at least 6 seconds
- After 6 seconds, remove the needle from your skin and then release the dose button

Please refer to the Package Leaflet: Information for the patient found in the product carton in full for further information on Fiasp®.

Useful words to know

Term	Description
Anaphylaxis	A life-threatening reaction that happens very quickly and needs treatment straight away. It usually affects the airways, breathing and circulation.
Bolus insulin	A bolus insulin is fast-acting, unlike a basal insulin which is long-acting. This means bolus insulin helps lower blood glucose levels after mealtimes.
Blood glucose	The measurement of how much glucose is in your blood.
Glucose	The main type of sugar in the blood. It is also the major energy source for the body.
Hyperglycaemia	When your blood glucose levels are too high.
Hypoglycaemia	When your blood glucose levels are too low (below 4 mmol/l).
Insulin	A hormone produced by an organ in the body called the pancreas. It helps regulate the amount of glucose in your blood.
Lipoatrophy	If you inject insulin at the same place, the fatty tissue may shrink. This can be avoided by rotating the injection site.
Lipohypertrophy	If you inject insulin at the same place, the fatty tissue may thicken. This can be avoided by rotating the injection site.

If you need more information

If you have any questions or need anything explaining further, please contact your doctor, nurse or local pharmacist. They will be able to support you with any queries you may have and, if necessary, advise you on who to contact for more information.

www.novonordisk.co.uk ↗
Novo Nordisk have been working in diabetes since 1923. To find out more about our work, please visit our website.

circular FOR zero

We are adopting a circular mindset, designing products that can be recycled or re-used, reshaping our business to minimise consumption and waste, and working with suppliers who share our ambition. We call this Circular for Zero.

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