

Fiasp[®] 10 mL vial

Insulin aspart (rys)

Consumer Medicine Information

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This leaflet answers some common questions about Fiasp[®] 10 mL vial. It does not contain all the available information. It does not take the place of talking to your doctor, diabetes education nurse or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Fiasp[®] 10 mL vial against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor, diabetes education nurse or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Fiasp[®] 10 mL vial is used for

The insulin aspart, or “Fiasp[®]”, in Fiasp[®] 10 mL vial is a fast-acting insulin used to treat diabetes mellitus in adults. Diabetes mellitus is a condition where your pancreas does not produce enough insulin to control your blood sugar (glucose) level. Extra insulin is therefore needed.

There are two types of diabetes mellitus:

- type 1 diabetes

- type 2 diabetes

Patients with type 1 diabetes always require insulin to control their blood sugar levels.

Some patients with type 2 diabetes may also require insulin after initial treatment with diet, exercise and tablets.

Fiasp[®] lowers your blood sugar level after injection. When injected under your skin, Fiasp[®] has a faster onset of action than NovoRapid[®]. Fiasp[®] can be injected at the start of a meal, with an option to inject 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[®] should normally be used in combination with intermediate-acting or long-acting insulin preparations.

As with all insulins, the duration of action will vary according to the dose, injection site, blood flow, temperature and level of physical activity.

Fiasp[®] is not addictive.

Fiasp[®] 10 mL vial is available only with a doctor’s prescription.

Ask your doctor, diabetes education nurse or pharmacist if you have any questions about why Fiasp[®] 10 mL vial has been prescribed for you.

Before you use Fiasp[®] 10 mL vial

When you must not use it

Do not use Fiasp[®] 10 mL vial if you have an allergy to:

- any medicine containing insulin
- any of the ingredients listed in the “Ingredients” section of this leaflet.

Some of the symptoms of an allergic reaction may include:

- redness, swelling, rash and itching at the injection site

- rash, itching or hives on the skin
- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body

If you are not sure whether you should start using this medicine, talk to your doctor.

Do not use this medicine after the expiry date printed on the pack, or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- kidney problems
- liver problems
- adrenal, pituitary or thyroid gland problems

Tell your doctor if you are pregnant or plan to become pregnant.

Fiasp[®] 10 mL vial can be used during pregnancy. Pregnancy may make managing your diabetes more difficult. Insulin needs usually decrease during the first three months of pregnancy and increase during the last six months. Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are breast-feeding or plan to breast-feed.

Your doctor or pharmacist can discuss with you the risks and benefits involved. There are no restrictions on treatment with Fiasp[®] during breast-feeding.

Inform your doctor as soon as possible if you experience signs of heart failure such as unusual

shortness of breath or rapid increase in weight or localised swelling (oedema).

Some patients with long-standing type 2 diabetes mellitus and heart disease or previous stroke who are treated with thiazolidinediones in combination with insulin may develop heart failure.

Do not use Fiasp® in children or adolescents.

There is no experience with Fiasp® in children and adolescents under 18 years of age.

If you have not told your doctor about any of the above, tell them before you use Fiasp® 10 mL vial.

Taking other medicines

Your dose of insulin may need to change if you take other medicines. **Tell your doctor if you are currently taking any medicines, especially the following:**

- other medicines (oral and injectable) used for the treatment of diabetes
- monoamine oxidase inhibitors (MAOI) - used for the treatment of depression
- beta-blocking agents - used for the treatment of certain heart conditions and high blood pressure
- angiotensin converting enzyme (ACE) inhibitors - used for the treatment of certain heart conditions, high blood pressure or elevated protein/albumin in the urine
- salicylates e.g. aspirin - used to relieve pain and lower fever
- anabolic steroids – used to promote growth
- glucocorticoids (except when applied locally) – used to treat inflammatory conditions
- oral contraceptives (“the pill”) - used for birth control
- thiazides - used for the treatment of high blood pressure or fluid retention (oedema)
- thyroid hormones - used for the treatment of malfunction of the thyroid gland
- sympathomimetics - used for the treatment of asthma

- sulphonamides – used to treat bacterial infections

Or other specific medicines including:

- danazol - used to treat endometriosis, menorrhagia, fibrocystic breast disease and hereditary angioedema
- octreotide - used to treat gastrointestinal endocrine tumours and enlargement of parts of the body (e.g. hands, feet, head) caused by abnormal growth hormone levels
- lanreotide – used to treat enlargement of parts of the body (e.g. hands, feet, head) caused by abnormal hormone levels
- growth hormone – used to treat growth disorders

Tell your doctor about any other medicines that you are taking.

This is very important. Your doctor will advise you if it is all right to keep taking them or if you should stop taking them.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

How to use Fiasp® 10 mL vial

Your doctor, diabetes education nurse or pharmacist will have given you advice on how to use your medicine. Carefully follow all the directions.

They may differ from the information contained in this leaflet.

Any change in dose or type of insulin should be made cautiously and only under medical supervision.

If you change the type of insulin that you use, you may have to use more or less than before. This may happen with the first dose or over a period of time.

Fiasp® may be used for injection under the skin or for continuous infusion in a pump system. Fiasp® may also be injected into a vein under supervision by a doctor.

Before you use Fiasp® in a pump system you should receive comprehensive instructions from your doctor or diabetes education nurse about the use of the system, and what to do in case of illness, too high or too low blood sugar levels, or failure of the pump system.

If you do not understand the instructions, ask your doctor, diabetes education nurse or pharmacist for help.

When to use it

Fiasp® is a mealtime insulin. It can be injected at the start of a meal, with an option to inject up to 20 minutes after starting a meal.

How much to use

It is very important that you manage your diabetes carefully. Too much or too little insulin can cause serious effects.

Dose for type 1 and type 2 diabetes

Your doctor or diabetes education nurse 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.

Check with your doctor, diabetes education nurse or pharmacist first if you want to change your usual diet.

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 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.

Table 1 Dose adjustment	
Mealtime or bedtime plasma glucose	Dose adjustment
mmol/L	Unit
less than 4.0	-1
4.0 - 6.0	no adjustment
more than 6.0	+1

Talk to your doctor about changes in your dose if you are elderly (65 years' or older).

Fiasp® can be used in elderly patients but if you are elderly you may need to check your blood sugar level more often.

How to use it

- Fiasp® may be injected into the front of the waist (abdomen), thighs or upper arms.
- Remember to rotate your injection site regularly within the same region as shown to you by your doctor or diabetes education nurse.

Checking your Fiasp® 10 mL vial:

On first use of a new vial, check that the protective colour-coded, tamper-proof plastic cap is in place, and is not loose or missing.

Check your Fiasp® 10 mL vial before each preparation and injection. Make sure you are using the correct type of insulin.

Do not use this medicine if it is thickened, coloured, or has solid bits in it.

How to use Fiasp® 10 mL vial in a syringe

- You need to use U100 insulin syringes.
 - When you are using Fiasp® 10 mL vial you should use a new syringe for each injection.
1. Wash your hands.
 2. Draw a volume of air into the syringe that is equal to the dose of insulin to be injected.
 3. Put the needle through the rubber top of the vial and inject the air into the vial.
 4. Turn the vial and syringe upside down.
 5. Make sure that the tip of the needle is in the insulin and withdraw the correct dose into the syringe.
 6. Pull the needle out of the vial. Expel any air from the syringe and check that the dose is correct.
 7. If you need to put the syringe down, make sure that the needle does not touch anything.
 8. Inject Fiasp® under the skin (subcutaneous injection) as shown

to you by your doctor or diabetes education nurse.

9. Throw away the U100 syringe and needle after each injection.

How to use Fiasp® 10 mL vial in a subcutaneous infusion pump system

- Fiasp® may also be given under the skin by means of an insulin infusion pump. Use the type of pump system recommended by your doctor, and read and follow the instructions that accompany your pump.
- Fiasp® should never be diluted or mixed with any other insulin when used in a pump.
- Before inserting the needle, use soap and water to clean your hands and the skin where the needle is inserted so as to prevent infection at the infusion site.
- When you are filling a new syringe, be certain not to leave large air bubbles in either the syringe or the tubing.
- Change the infusion set (syringe and tubing) 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 pump, you should measure your blood sugar levels regularly.

What to do in case of infusion pump system failure

In case of infusion pump system failure, you should always carry a spare vial of Fiasp® and a U100 syringe, or an alternative insulin delivery system, for injection under the skin.

After you use it

- Do not refill your Fiasp® 10 mL vial.
- Health care professionals, relatives and other carers should follow general precautionary measures for removal and disposal of needles to eliminate the risk of needlestick injury.

How long to use it

Do not stop using Fiasp® 10 mL vial unless your doctor tells you to.

If you use too much (overdose) - Hypoglycaemia

Your blood sugar level may become too low (you may experience hypoglycaemia or a "hypo") if you:

- accidentally use too much of this medicine,
- have too much or unexpected exercise
- delay eating meals or snacks
- eat too little food
- are ill

The first symptoms of mild to moderate hypos can come on suddenly. They may include:

- cold sweat, cool pale skin
- fatigue, drowsiness, unusual tiredness and weakness
- nervousness, anxious feeling, tremor, rapid heart beat
- confusion, difficulty concentrating
- excessive hunger
- vision changes
- headache, nausea

Always carry some sugary food or fruit juice with you.

If you experience any of these symptoms of a hypo, immediately eat some sugary food or have a sugary drink, e.g. lollies, biscuits or fruit juice, and measure your blood sugar level.

Tell your relatives, friends, close workmates or carers that you have diabetes. It is important that they recognise the signs and symptoms of a hypo.

Make sure they know to give you some sugary food or fruit juice for mild to moderate symptoms of a hypo.

If you lose consciousness, make sure they know:

- **to turn you on your side and get medical help immediately.**
- **not to give you anything to eat or drink.**

This is because you could choke.

An injection of the hormone glucagon may speed up recovery from unconsciousness. This can be given by a relative, friend, workmate or carer who knows how to give it.

If glucagon is used, eat some sugary food or have a sugary drink as soon as you are conscious again.

If you do not feel better after this, contact your doctor, diabetes education nurse, or the closest hospital.

If you do not respond to glucagon treatment, you will require medical attention.

See your doctor if you keep having hypo reactions, or if you have ever become unconscious after using insulin.

Your insulin dose may need to be changed.

If a severe hypo is not treated, it can cause brain damage and even death.

If you miss a dose – Hyperglycaemia

If you forget your insulin dose, test your blood sugar level as soon as possible.

If you are not sure what to do, talk to your doctor, diabetes education nurse or pharmacist.

Do not use a double dose of your insulin.

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to.

Otherwise, use it as soon as you remember – *don't forget to eat some carbohydrate within 10 minutes of your injection* – and then go back to using it as you would normally.

Your blood sugar levels may become high (hyperglycaemia) if you:

- miss doses of insulin or use less insulin than you need
- have uncontrolled diabetes
- exercise less than usual
- eat more carbohydrates than usual
- are ill or stressed

High blood sugar levels over a long period of time can lead to too much acid in the blood (diabetic ketoacidosis).

Contact your doctor immediately if your blood sugar level is high or you recognise any of the following symptoms.

Symptoms of mild to moderate hyperglycaemia include:

- drowsy feeling
- flushed face
- thirst, loss of appetite
- fruity odour on the breath

- blurred vision
- passing larger amounts of urine than usual
- getting up at night more often than usual to pass urine
- high levels of glucose and acetone in the urine

Symptoms of severe hyperglycaemia include:

- heavy breathing
- fast pulse
- nausea, vomiting
- dehydration
- loss of consciousness

Severe hyperglycaemia can lead to unconsciousness and in extreme cases death if untreated.

Discuss any worries you may have about this with your doctor, diabetes education nurse or pharmacist.

While you are using Fiasp® 10 mL vial

Things you must do

Measure your blood sugar level regularly.

Make sure all friends, relatives, workmates or carers know that you have diabetes.

Keep using your insulin even if you feel well.

It helps to control your condition, but does not cure it.

Tell your doctor if you often have hypos (low blood sugar levels).

Your doctor may need to adjust your insulin dose.

Always carry some sugary food or fruit juice with you.

If you experience any of the symptoms of a hypo, immediately eat some sugary food or have a drink, e.g. lollies, biscuits or fruit juice.

Tell your doctor if you have trouble recognising the symptoms of hypos.

Under certain conditions, the early warning signs of hypos can be different or less obvious. Your doctor may need to adjust your insulin dose.

Make sure that you tell every doctor, dentist, pharmacist or other health care professional who is treating you

that you have diabetes and are using insulin.

Tell your doctor, diabetes education nurse or pharmacist if you are travelling.

Ask them for a letter explaining why you are taking injecting devices with you. Each country you visit will need to see this letter, so you should take several copies.

You may need to inject your insulin and eat your meals at different times because of time differences in and between countries.

You may not be able to get the same type of insulin in the country you are visiting.

Things you must not do

Do not stop using your medicine unless your doctor tells you to.

Do not use the medicine if you think it has been frozen or exposed to excessive heat.

It will not work as well.

Do not refill your Fiasp® 10 mL vial.

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how the insulin affects you.

If your blood sugar is low or high your concentration and ability to react might be affected, and therefore also your ability to drive or operate a machine. Bear in mind that you could endanger yourself or others. Please ask your doctor whether you can drive a car:

- if you have frequent hypos
- if you find it hard to recognise hypoglycaemia

Tell your doctor if you drink alcohol.

Alcohol may mask the symptoms of hypos. If you drink alcohol, your need for insulin may change as your blood sugar level may either rise or fall. Careful monitoring is recommended.

Tell your doctor if you are ill.

Illness, especially with nausea and vomiting, may cause your insulin needs to change. Even if you are not eating, you still require insulin. You and your doctor should design an insulin plan for those times when you are sick.

Tell your doctor if you are exercising more than usual.

Exercise may lower your need for this medicine. Exercise may also speed up the effect of a dose of it, especially if the exercise involves the area of the injection site (e.g. the thigh should not be used for injection prior to jogging or running).

Tell your doctor if your diet changes.

Changes in diet may cause your insulin needs to change.

Side effects

Ask your doctor or pharmacist to answer any questions you have. Tell your doctor, diabetes education nurse or pharmacist as soon as possible if you do not feel well while you are using Fiasp® 10 mL vial.

This medicine helps most people for whom it is prescribed, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor, diabetes education nurse or pharmacist to answer any questions you may have.

The most common side effect when using insulin is low blood sugar levels (a hypo).

Tell your doctor if you notice any of the following and they worry you:

- hypos (mild to moderate)
- rash, redness, inflammation, bruising or itching at the injection site. Usually these symptoms disappear within a few weeks during continued use. If you have serious or continuing reactions,

you may need to stop using Fiasp® and use another insulin.

- more widespread signs of allergy on the skin such as eczema, rash, itching, hives or dermatitis
- a depression or thickening of the skin around the injection site (lipodystrophy)
- when you first start your insulin treatment you may get visual problems, nerve-related pain or swollen hands and feet

This list includes the more common side effects of your medicine. They are usually mild and short-lived.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

More severe symptoms of low blood sugar levels, including:

- disorientation
- seizures, fits or convulsions
- loss of consciousness.

If a severe hypo is not treated, it can cause brain damage and death.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- skin rashes over a large part of the body
- shortness of breath, wheezing
- swelling of the face, lips or tongue
- fast pulse
- sweating

This list includes very serious allergic reaction side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Ask your doctor, diabetes education nurse or pharmacist to answer any questions you have.

After using Fiasp® 10 mL vial

Storage

Store Fiasp® 10 mL vials *that are not being used* between 2°C and 8°C in a refrigerator (not in or too near the freezer section or cooling element).

You can carry the Fiasp® 10 mL vial *that you are using*, or that you are carrying as a spare, with you. You can keep it at room temperature (not above 30°C) or in a refrigerator (2°C to 8°C) for up to 4 weeks.

Protect the Fiasp® in Fiasp® 10 mL vial from light by keeping the vial in its carton when not in use.

Never use Fiasp® 10 mL vial after the expiry date printed on the label and carton after 'EXP.'

The expiry date refers to the last day of that month.

Never use Fiasp® 10 mL vial if the solution is not clear and colourless.

Keep out of the reach of children.

Disposal

Dispose of used needles and syringes safely into a yellow plastic sharps container.

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product Description

What it looks like and contents of the pack

Fiasp® is a clear, colourless solution for subcutaneous injection/infusion. Fiasp® 10 mL vial is a 10 mL glass vial designed to be used either with U100 insulin syringes or in insulin infusion pump systems. Pack size of 1 vial.

Ingredients

Fiasp® contains insulin aspart (rys) 100 units per mL (100 U/mL) as the active ingredient. Each vial contains 1000 units (U) of insulin aspart in 10 mL solution for injection.

The abbreviation "rys" indicates the method of genetic engineering used to manufacture this insulin.

The other ingredients are phenol, metacresol, glycerol, zinc acetate,

dibasic sodium phosphate dihydrate, arginine hydrochloride, nicotinamide (also known as niacinamide or vitamin B3), hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment) and water for injections.

- www.diabetes.org.nz

Fiasp[®] contains less than 1 mmol sodium (23 mg) per dose. This means that the medicine is essentially 'sodium-free.'

Sponsor

Fiasp[®] 10 mL vial is supplied in Australia by:

Novo Nordisk Pharmaceuticals Pty Ltd.,
Level 3, 21 Solent Circuit,
Baulkham Hills, NSW 2153,
Australia.

Fiasp[®] 10 mL vial is supplied in New Zealand by:

Novo Nordisk Pharmaceuticals Ltd.
58 Richard Pearse Drive
Airport Oaks
Mangere
New Zealand.

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Further Information

For further information call the NovoCare[®] Customer Care Centre on 1800 668 626 (Australia) or 0800 733 737 (NZ).

- www.novonordisk.com.au
- www.novonordisk.co.nz

You can also get more information about diabetes and insulin from Diabetes Australia and Diabetes New Zealand:

- freecall helpline 1300 136 588 (Australia)
- www.diabetesaustralia.com.au