

# Fiasp® FlexTouch®

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor, diabetes education nurse, or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

### 1. Why am I using Fiasp® FlexTouch®?

Fiasp® contains the active ingredient insulin aspart. Insulin aspart is a rapid-acting insulin used to treat diabetes mellitus in adults, adolescents and children aged 1 year and above.

For more information, see Section [1. Why am I using Fiasp®?](#) in the full CMI.

### 2. What should I know before I use Fiasp® FlexTouch®?

Do not use if you have ever had an allergic reaction to insulin aspart or any of the ingredients listed at the end of the CMI.

**Talk to your doctor or pharmacist if you have any other medical conditions (especially kidney, liver or gland problems), take any other medicines, or are pregnant or plan to become pregnant or are breast-feeding.**

For more information, see Section [2. What should I know before I use Fiasp® FlexTouch®?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Fiasp® and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Fiasp® FlexTouch®?

- Use at the start of a meal (with an option to use up to 20 minutes after starting a meal). Inject into the abdomen, thighs, or upper arms.
- Change your injection site regularly. Carefully follow the advice on how to inject under the skin.

Detailed instructions can be found in Section [4. How do I use Fiasp®?](#) and [8. Instructions for use](#) and in the full CMI.

### 5. What should I know while using Fiasp® FlexTouch®?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist, pharmacist or diabetes education nurse you visit that you have diabetes and are using insulin.</li><li>• Tell your doctor if you often have hypos (low blood sugar levels).</li><li>• Always carry some sugary food or fruit juice with you.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using your medicine unless your doctor tells you to.</li><li>• Do not use the medicine if you think it has been frozen or exposed to excessive heat.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• 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.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Alcohol may mask the symptoms of hypos. If you drink alcohol, your need for insulin may change.</li><li>• Careful monitoring is recommended.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store Fiasp® FlexTouch® <i>that is not being used</i> between 2°C and 8°C in a refrigerator (not in or too near the freezer section or cooling element).</li><li>• You can keep the Fiasp® FlexTouch® <i>that you are using</i>, or that you are carrying as a spare, <b>either</b> at room temperature (not above 30°C) or in a refrigerator (2°C to 8°C), for up to 4 weeks.</li></ul>

For more information, see Section [5. What should I know while using Fiasp®?](#) in the full CMI.

### 6. Are there any side effects?

The most common side effect when using insulin is low blood sugar levels (a hypo). Tell your relatives, friends, close workmates, teachers or carers that you have diabetes. It is important that they can recognise the signs and symptoms of a hypo.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



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. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

# Fiasp<sup>®</sup> FlexTouch<sup>®</sup>

Active ingredient(s): *Insulin aspart*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Fiasp<sup>®</sup> FlexTouch<sup>®</sup>. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Fiasp<sup>®</sup> FlexTouch<sup>®</sup>.**

Where to find information in this leaflet:

- [1. Why am I using Fiasp<sup>®</sup>?](#)
- [2. What should I know before I use Fiasp<sup>®</sup>?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Fiasp<sup>®</sup> FlexTouch<sup>®</sup>?](#)
- [5. What should I know while using Fiasp<sup>®</sup> FlexTouch<sup>®</sup>?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using Fiasp<sup>®</sup>?

The insulin aspart, or “Fiasp<sup>®</sup>”, in Fiasp<sup>®</sup> FlexTouch<sup>®</sup> is a fast-acting insulin.

Fiasp<sup>®</sup> is used to treat diabetes mellitus in adults, adolescents and children aged 1 year and above.

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<sup>®</sup> lowers your blood sugar level after injection. When injected under your skin, Fiasp<sup>®</sup> has a faster onset of action than NovoRapid<sup>®</sup>. Fiasp<sup>®</sup> 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<sup>®</sup> 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.

FlexTouch<sup>®</sup> is a pre-filled dial-a-dose insulin pen able to deliver from 1 to 80 units of Fiasp<sup>®</sup> in one injection in steps of 1 unit.

Fiasp<sup>®</sup> is not addictive.

Fiasp<sup>®</sup> FlexTouch<sup>®</sup> is available only with a doctor’s prescription.

## 2. What should I know before I use Fiasp<sup>®</sup>?

### Warnings

Do not use Fiasp<sup>®</sup> if:

- you are allergic to a medicine containing insulin, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. 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.
- you are experiencing a low blood sugar level (a “hypo”) when the dose is due. If you have a lot of hypos discuss appropriate treatment with your doctor.
- the expiry date printed on the pack has passed, 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. The expiry date refers to the last day of that month.

Check with your doctor or pharmacist if you:

- have or have had any other medical conditions such as kidney or liver problems, adrenal, pituitary or thyroid gland problems
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breast-feeding

Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

Fiasp<sup>®</sup> 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.

Talk to your doctor or pharmacist if you are breast-feeding or intend to breast-feed.

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

### Heart disease or stroke history

- 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.

### Use in children

- **Do not use Fiasp® in children below the age of 1 year.** There is no experience with the use of Fiasp® in children below the age of 1 year. Ensure the correct length of needle is selected for use in children.

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines affect your blood sugar level. Your dose of insulin may need to change if you take other medicines.

#### Medicines that may **cause your blood sugar to fall** (hypoglycaemia):

- other medicines (oral and injectable) used for the treatment of diabetes
- sulphonamides – used to treat bacterial infections
- 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.

#### Medicines that may **cause your blood sugar to rise** (hyperglycaemia):

- 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
- growth hormone – used to treat growth disorders
- danazol – used to treat endometriosis, menorrhagia, fibrocystic breast disease and hereditary angioedema.

#### Medicines that may **cause your blood sugar to rise or fall**:

- 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.

**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.

## 4. How do I use Fiasp® FlexTouch®?

**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 who is trained to use Fiasp® FlexTouch®.

**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.

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

#### When to use Fiasp®

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.

<b>Mealtime or bedtime plasma glucose</b>	<b>Dose adjustment</b>
<i>mmol/L</i>	<i>Unit</i>
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 Fiasp®

- Fiasp® is for injection under the skin (subcutaneous injection). Before you use Fiasp® for the first time, your doctor or diabetes education nurse will show you how to use the pre-filled pen.
- Fiasp® may be injected into the front of the waist (abdomen), thighs or upper arms.
- Do not inject into a vein or muscle.
- 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® FlexTouch®:

- Check your Fiasp® FlexTouch® 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.
- **Read the instructions printed at the end of this leaflet carefully in order to prepare and handle your Fiasp® FlexTouch® correctly.**

### How long to use it

Do not stop using Fiasp® FlexTouch® unless your doctor tells you to.

### If you use too much Fiasp® (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, teachers 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, teacher 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 think that you have used too much Fiasp®, you may need urgent medical attention.

**You should immediately:**

- contact your doctor, or
- go to the Accident and Emergency department at your nearest hospital, or
- phone the Poisons Information Centre (**by calling 13 11 26**).

**You should do this even if there are no signs of discomfort or poisoning.**

**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.**

## 5. What should I know while using Fiasp®?

### Things you should do

**Measure your blood sugar level regularly.**

**Make sure all friends, relatives, workmates, teachers 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 sugary 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.

**Remind every doctor, dentist or pharmacist or other health professionals who are 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 should 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 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.**

**Do not share needles or pens.**

### Things to be careful of

**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.

### Tell your doctor if you notice any skin changes at the injection site.

If you inject insulin at the same place, the fatty tissue may shrink (lipoatrophy) or thicken (lipohypertrophy). Lumps under the skin may also be caused by build-up of a 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.

**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.

### Driving or using machines

**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.

### Drinking alcohol

**Tell your doctor or pharmacist 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.

### Looking after your medicine

- Store Fiasp® FlexTouch® **that is 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® FlexTouch® **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 - 8°C) for up to 4 weeks. **Discard Fiasp® FlexTouch® after 4 weeks even if there is still some Fiasp® left in it.**
- Protect the Fiasp® in Fiasp® FlexTouch® from light by always keeping the cap on the pen when not in use.
- Never use Fiasp® FlexTouch® 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® FlexTouch® if the solution is not clear and colourless.
- Keep out of the reach of children.

### Disposal of your medicine

- Dispose of used needles 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.

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date. The expiry date refers to the last day of that month.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

**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® FlexTouch®.**

### Common side effects

Less serious side effects	What to do
<p><b>The most common side effect when using insulin is low blood sugar levels (a hypo).</b></p> <ul style="list-style-type: none"><li>• Mild to moderate</li></ul> <p><b>Other effects:</b></p> <ul style="list-style-type: none"><li>• 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.</li><li>• more widespread signs of allergy on the skin such as eczema, rash, itching, hives or dermatitis</li><li>• a depression or thickening of the skin around the injection site (lipodystrophy).</li><li>• lumps under your skin (cutaneous amyloidosis).</li><li>• when you first start your insulin treatment you may get visual problems, nerve-related pain or swollen hands and feet.</li></ul>	<p><b>Speak to your doctor, diabetes education nurse or pharmacist if you have any of these less serious side effects and they worry you.</b></p> <p>They are usually mild and short-lived.</p>

## Serious side effects

Serious side effects	What to do
<p><b>Symptoms of severe low blood sugar levels:</b></p> <ul style="list-style-type: none"><li>• disorientation</li><li>• seizures, fits or convulsions</li><li>• loss of consciousness.</li></ul> <p>If a severe hypo is not treated, it can cause brain damage and death.</p> <p><b>Other effects:</b></p> <ul style="list-style-type: none"><li>• skin rashes over a large part of the body</li><li>• shortness of breath, wheezing</li><li>• swelling of the face, lips or tongue</li><li>• fast pulse</li><li>• sweating.</li></ul>	<p><b>Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of these serious side effects.</b></p> <p>You may need urgent medical attention or hospitalisation. These side effects are very rare.</p>

**Tell your doctor if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

## 7. Product details

### What Fiasp® contains

<b>Active ingredient (main ingredient)</b>	insulin aspart 100 units per mL (100 U/mL)
<b>Other ingredients (inactive ingredients)</b>	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.

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

**Do not take this medicine if you are allergic to any of these ingredients.**

## What Fiasp® looks like

Fiasp® is a clear, colourless solution for subcutaneous injection. Fiasp® FlexTouch® is a 3 mL pre-filled glass cartridge contained in a dial-a-dose insulin pen. Pack sizes of 1 and 5 pre-filled pens of 3 mL. (AUST R 275394)

Not all pack sizes may be marketed.

## Who distributes Fiasp®

Fiasp® FlexTouch® is supplied in Australia by:

### **Novo Nordisk Pharmaceuticals Pty Ltd**

Level 10  
118 Mount Street  
North Sydney NSW 2060  
Australia

Fiasp® FlexTouch® is supplied in New Zealand by:

### **Novo Nordisk Pharmaceuticals Ltd.**

11-19 Customs Street West  
Commercial Bay Tower, Level 18, Office 1834  
Auckland 1010  
New Zealand

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### **For further information:**

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

- [www.novonordisk.com.au](http://www.novonordisk.com.au)
- [www.novonordisk.co.nz](http://www.novonordisk.co.nz)

You can also get more information about diabetes and insulin from:

Diabetes Australia:

- freecall helpline 1300 136 588
- [www.diabetesaustralia.com.au](http://www.diabetesaustralia.com.au)

Diabetes New Zealand:

- [www.diabetes.org.nz](http://www.diabetes.org.nz)

This leaflet was prepared on 02 November 2021.

# Fiasp<sup>®</sup> FlexTouch<sup>®</sup>

Active ingredient(s): *Insulin aspart*

## 8. INSTRUCTIONS FOR USE

### Introduction

**Please read these instructions carefully** before using your Fiasp<sup>®</sup> FlexTouch<sup>®</sup> pre-filled pen. If you do not follow the instructions carefully, you may get too little or too much insulin, which can lead to a blood sugar level that is too high or too low.

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

Start by checking your pen to **make sure that it contains Fiasp<sup>®</sup> 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 who is trained to use the FlexTouch<sup>®</sup> pre-filled pen.

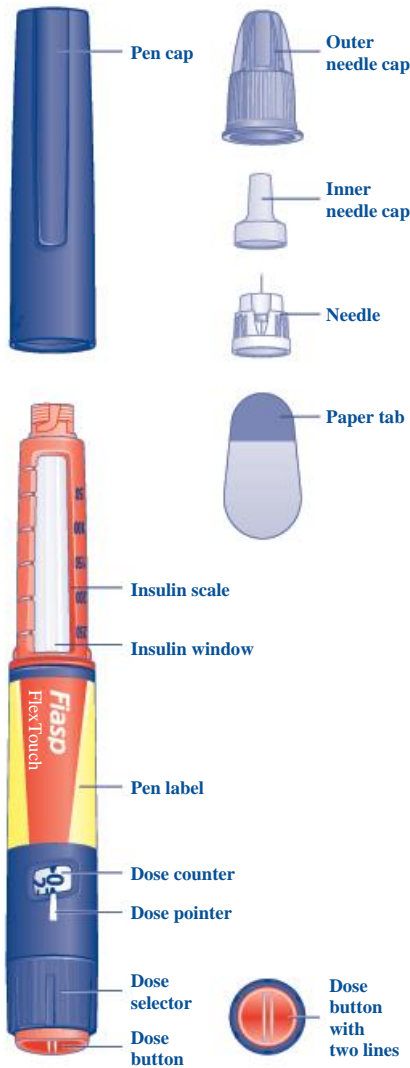
Your pen is a pre-filled dial-a-dose insulin pen containing 300 units of insulin. You can select a **maximum of 80 units per dose, in steps of 1 unit**. Your pen is designed to be used with NovoFine<sup>®</sup> or NovoFine<sup>®</sup> Plus single-use, disposable needles up to a length of 8 mm. Needles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

#### **Important information**

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



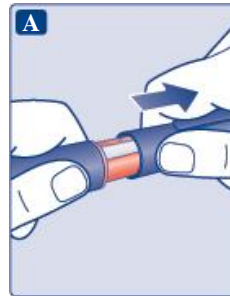
**Fiasp pre-filled pen and needle (example) (FlexTouch)**



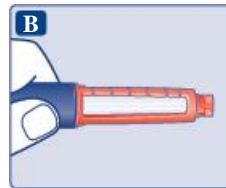
**1. Prepare your pen with a new needle**

- **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 use more than one type of insulin. If you inject the 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 **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.

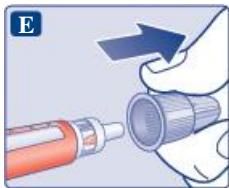


Ensure the correct length of needle is selected for use in children.

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



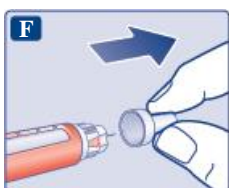
- Pull off the **outer** needle cap and **keep it for later**. You will need it after the injection, to safely remove the needle from the pen.



- 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 for 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 a blood sugar level that is too high.

### 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 diabetes education nurse.  
If you select an incorrect 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.

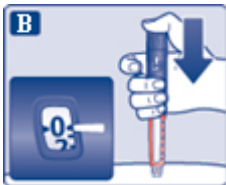
Do not use the insulin scale, it only shows approximately how much insulin is left in your pen.

#### 4. Inject your dose

- **Insert the needle into your skin as your doctor or diabetes education 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.



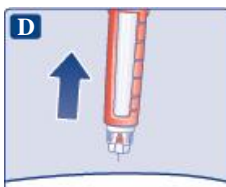
- **Press and hold down the dose button until the dose counter shows 0.**  
The 0 must line up with the dose pointer. You may then hear or feel a click.



- ▲ **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

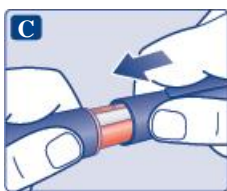
- **Lead the needle tip into the outer needle cap** on a flat surface without touching the needle or the outer cap.



- Once the needle is covered, **carefully push the outer needle cap completely on.**
- **Unscrew the needle** and dispose of it carefully.



- **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 a blood sugar level that is too high or too low.

### ▲ 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.
- 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.
- **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.

## 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.