APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

PRODUCT NAME [strength, pharmaceutical form]

FIASP®, 100 U/ml, Solution for Injection

Read all of this leaflet carefully before you start using FIASP®

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or your pharmacist.

FIASP® has been prescribed for you personally and you should not share your FIASP® with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What FIASP is and what it is used for

FIASP® is a mealtime insulin, used to lower the high blood sugar level in adults, adolescents and children aged 1 year and above with diabetes mellitus (diabetes), can be used alone or in combination with other insulins or metformin.

2. What you need to know before you use FIASP

Do not use FIASP®:

- If you are allergic to insulin aspart or any of the other ingredients of FIASP® listed under heading “What FIASP® contains”

- Do not inject Fiasp® to children or adolescents, since there is no experience with Fiasp® in children and adolescents under 18 years of age.
- During episodes of hypoglycaemia

Warnings and precautions

Some conditions and activities can affect your need for insulin. Tell your doctor or healthcare professional before you administer FIASP®:

- if you have trouble 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 using your FIASP® and tell your doctor or other healthcare professional.

Low blood sugar (hypoglycaemia)

If your blood sugar is too low, follow the guidance for low blood sugar in section 'Possible side effects'. FIASP® has a faster onset of glucose lowering effect. If hypoglycaemia occurs, you may therefore experience it early after an injection.

High blood sugar (hyperglycaemia)

If your blood sugar is too high, follow the guidance for high blood sugar in section 'Possible side effects'.

Switching from other insulin products

The insulin dose may need to be changed if you switch from another type, brand or manufacturer of insulin.

If you have kidney or liver problems

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

Eye disorder

Fast improvements in blood sugar control may lead to a temporary worsening of diabetic eye disorder.

Pain due to nerve damage

If your blood sugar level improves very fast, you may get nerve related pain, this is usually transient.

Swelling around your joints

When you first start using your Fiasp®, your body may keep more water. This causes swelling around your ankles and other joints. This is usually only short-lasting.

Generalised hypersensitivity

Symptoms of generalised hypersensitivity may include generalised skin rash, itching, sweating, gastrointestinal upset, angio oedema, difficulties in breathing, palpitations and reduction in blood pressure. Generalised hypersensitivity reactions are potentially life-threatening.

Skin changes at the injection site

The injection site should be rotated to help prevent changes to the fatty tissue under the skin, such as skin thickening, skin shrinking or lumps under the skin. The insulin may not work very well if you inject into a lumpy, shrunken or thickened area (*see section 3 'How to use Fiasp®'*). Tell your doctor if you notice any skin changes at the injection site. Tell your doctor if you are currently injecting into these affected areas before you start injecting in a different area. Your doctor may tell you to check your blood sugar more closely, and to adjust your insulin or your other antidiabetic medications dose.

Use in elderly patients (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. Talk to your doctor about changes in your dose.

Children and adolescents

Fiasp® can be used in adolescents and children aged 1 year and above. There is no experience with the use of Fiasp® in children below the age of 1 year.

Other medicines and FIASP

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Some medicines affect your blood sugar level - this may mean your insulin dose has to change.

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

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

- other medicines for diabetes (oral and injectable)
- sulphonamides - for infections
- anabolic steroids - such as testosterone
- beta-blockers - for high blood pressure. They may make it harder to recognise the warning signs of too low blood sugar (see section ‘Warning signs of too low blood sugar’)
- acetylsalicylic acid (and other salicylates) - for pain and mild fever
- monoamine oxidase (MAO) inhibitors - for depression
- angiotensin converting enzyme (ACE) inhibitors, ARBs (Angiotensin Receptor Blockers) - used to treat certain heart conditions or high blood pressure
- GLP-1 receptor agonist – used to treated sugar diabetes

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

- danazol - for endometriosis
- oral contraceptives - birth control pills
- thyroid hormones - for thyroid problems

- growth hormone - for growth hormone deficiency
- glucocorticoids such as ‘cortisone’ - for inflammation
- sympathomimetics such as epinephrine (adrenaline), salbutamol or terbutaline - for asthma
- thiazides - for high blood pressure or if your body is keeping too much water (water retention).

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

Pioglitazone - oral anti-diabetic medicines used to treat type 2 diabetes
Some patients with long-standing type 2 diabetes and heart disease or previous stroke, who were treated with pioglitazone and insulin, experienced the development of heart failure. Inform your doctor immediately if you experience signs of heart failure such as unusual shortness of breath, rapid increase in weight or localised swelling (oedema).
If any of the above applies to you (or you are not sure), tell your doctor, pharmacist or other healthcare professional.

FIASP with food and drink and 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 breastfeeding:

Safety in pregnancy and lactation has not been established.
If you are pregnant, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before using FIASP®.

Your insulin dose may need to be changed during pregnancy and after delivery. Careful control of your diabetes is needed during pregnancy. Avoiding too low blood sugar (hypoglycaemia) is particularly important for the health of your baby.

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

Driving and using machines

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

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

FIASP contains sodium

FIASP® contains less than 1 mmol sodium (23 mg) per dose. This means that the medicine is essentially ‘sodium-free’.

HOW TO USE FIASP®

Do not share Fiasp® prescribed for you with any other person

Always use **FIASP®** exactly as your doctor has instructed you. You should check with your doctor, pharmacist if you are not sure.

When to inject FIASP®

FIASP® is a mealtime insulin.

FIASP® can be injected at the start of a meal or within 20 minutes after starting a meal.

A maximum effect occurs between 1 and 3 hours after the injection and the effect lasts for 3 - 5 hours.

FIASP® dose

Dose for type 1 and type 2 diabetes

Your doctor will decide together with you:

- how much FIASP® you will need at each meal
- when to check your blood sugar level and if you need a higher or lower dose.

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

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 (*mmol/ℓ*	**Dose adjustment (*Unit*)**
less than 4,0	-1
4,0 – 6,0	no adjustment
more than 6,0	+1

Injecting FIASP®

FIASP® is for injection under the skin (subcutaneous injection).

FlexTouch®:

Before you inject FIASP® for the first time, your doctor, pharmacist or other healthcare professional will show you how to use the pre-filled pen.

Penfill®:

Before you inject FIASP® for the first time, your doctor, pharmacist or other healthcare professional will show you how to administer your injection using a durable device.

Vial:

FIASP® is for injection under the skin (subcutaneous injection) or for continuous infusion in pumps. Administration in a pump will require a comprehensive instruction by your healthcare professional.

Where to inject

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

Do not use FIASP®

Discard all the pens, cartridges and or vials in which freezing has taken place.

FlexTouch®:

- if the pen is damaged or has not been stored correctly (see section 'How to store FIASP®').
- if the insulin does not appear clear and colourless.

Detailed instructions for use are provided in appendix 1.

Penfill®:

- if the cartridge or the delivery system you are using is damaged. Take it back to your supplier. See your delivery system manual for further instructions.
- if the cartridge has not been stored correctly (see section 'How to store FIASP®')
- if the insulin does not appear clear and colourless.

Vial:

- if the protective cap on the vial is loose or missing. Each vial has a protective, tamper-proof plastic cap. If the vial is not in perfect condition when you get it, return the vial to your supplier.
- if the vial has not been stored correctly or has been frozen (see section 'How to store FIASP®').
- if the insulin does not appear clear and colourless.

How to inject FIASP®

Penfill®:

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 pen.

- Please also read the manual that comes with your insulin delivery system.
- Check the name and strength on the label of the cartridge (Penfill®) to make sure it is FIASP®
- Always use a new needle for each injection to prevent contamination.
- Needles must not be shared.

Three simple steps to avoid too low or too high blood sugar are:

FlexTouch®:

- Always keep a spare pen in case you lose your FlexTouch® or it gets damaged.

Penfill®:

- Always keep spare pen and cartridges of FIASP®.

Vial:

- Always keep spare syringes and a spare vial of FIASP®.

FlexTouch®/Penfill®/Vial:

- Always carry something to show you are diabetic.
- Always carry products containing sugar with you. See section ‘What to do if you get too low blood sugar’.

If you inject more FIASP® than you should

If you inject too much insulin your blood sugar may get too low (hypoglycaemia), see advice in ‘Too low blood sugar’ under “Possible Side Effects”.

In the event of overdosage, please consult your doctor or pharmacist.

If neither is available, seek help at the nearest hospital or poison control center.

If you forget to inject FIASP or you inject inadequate dose of FIASP

If you forget to use your insulin your blood sugar may get too high (hyperglycaemia). See ‘Too high blood sugar’ under “*Possible Side Effects*”.

If you stop treatment with FIASP

Do not stop using your insulin without speaking to your doctor. If you stop using your insulin this could lead to a very high blood sugar level (severe hyperglycaemia) and ketoacidosis (a potentially life threatening condition with too much ketone bodies in the blood). See advice in section ‘Too high blood sugar’ under “Possible side effects”.

4. Possible side effects

Fiasp can cause side effects.

- *Serious allergic reactions:*

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

- the reactions 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.

- *Too low blood sugar*

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

Other side effects include:

Frequent

- *Reaction at administration site:*

Local reactions at the place you inject yourself may occur. The signs may include: rash, redness, inflammation, bruising and itching.

Skin reactions:

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

Less frequent

Skin changes at the injection site

If you inject Fiasp at the same place ~~F~~ fatty tissue under the skin may shrink (lipoatrophy) or get thicker (lipohypertrophy). 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. Changing where you inject each time may reduce the risk of developing these skin changes. If you notice these skin changes, tell your doctor, pharmacist or other healthcare professional. If you keep injecting at the same place, these reactions can become more severe and affect the amount of medicine your body gets from the pen.

- *Allergic reactions:*

Allergic reactions such as generalised skin rash and facial swelling may occur.
Stop using Fiasp® and see a doctor straight away if the reactions become serious. For more information see 'Serious allergic reaction' above.

Other possible side effects

- *Vision problem:*

When you first start Fiasp® treatment, it may disturb your vision (blurred vision), but the disturbance is usually temporary**.**

- Diabetic retinopathy (an eye disease related to diabetes, which can lead to loss of vision):

If you have diabetic retinopathy and your blood sugar level improves very fast, the retinopathy may get worse. Ask your doctor about this.

- *Painful neuropathy (pain due to nerve damage)*

If your blood sugar level improves very fast, you may get nerve related pain, this is called acute painful neuropathy and is usually transient.

- *Swollen joints*

When you start Fiasp® treatment, water retention may cause swelling around your ankles and other joints. Usually this soon disappears**.**

See a doctor if the above described side effects do not disappear after a few weeks, or if they spread throughout your body.

General effects from diabetes treatment

►*Too low blood sugar (hypoglycaemia)*

Too low blood sugar may happen if you:

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

Warning signs of too low blood sugar

These may come on suddenly:

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

What to do if you get too low blood sugar

- 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).
- Measure your blood sugar if possible and rest. You may need to measure your blood sugar more than once.
- Wait until the signs of too low blood sugar have gone or when your blood sugar level has settled. Then carry on with your insulin as usual.

What others need to do if you pass out

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

Let them know what to do if you pass out,

they must:

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

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

- If you are given glucagon you will need sugar or a sugary snack as soon as you come round.

- If you do not respond to a glucagon injection, you will have to be treated in a hospital.
- If severe low blood sugar is not treated over time, it can cause brain damage. This can be short or long-lasting. It may even cause death.

Tell your doctor if:

- your blood sugar got so low that you passed out
- you have used 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.

- *Too high blood sugar (hyperglycaemia)*

Too 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 without talking to your doctor.

Warning signs of too high blood sugar

These normally appear gradually:
Flushed, dry skin; feeling sleepy or tired; dry mouth, fruity (acetone) breath; urinating more often, feeling thirsty; losing your appetite, feeling or being sick (nausea or vomiting).
These may be signs of a very serious condition called ketoacidosis. This is a build-up of acid in the blood because the body is breaking down fat instead of sugar. If not treated, this could lead to diabetic coma and eventually death.
What to do if you get too high blood sugar:

- Test your blood sugar level
- Test your urine for ketones
- Get medical help straight away

Not all side effects reported for FIASP® are included in this leaflet. Should your general health worsen while using FIASP®, please consult your doctor, pharmacist or other health care professional for advice.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found on line under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of FIASP.

5. How to store FIASP®

Store all medicines out of reach of children.

Before first opening:

FIASP® vials, FlexTouch® and Penfill® not in use to be stored between 2 °C and 8 °C (in a refrigerator) for 30 months.

Keep away from the cooling element.

Do not freeze.

FlexTouch®:

Keep the cap on the pen in order to protect from light.

Vial/Penfill®:

Keep the vial/cartridge in the carton in order to protect from light.

After first opening or if carried as a spare:

FlexTouch®:

You can carry your FIASP® pre-filled pen (FlexTouch®) with you and keep it at room temperature (i.e. at or below 30 °C) or in a refrigerator (2°C to 8°C) for not more than 4 weeks (28 days). Always keep the cap on the pen when you are not using it in order to protect from light.

Penfill®:

Do not refrigerate. You can carry your FIASP® cartridge (Penfill®) with you and keep it at room temperature (i.e. at or below 30 °C) for not more than 4 weeks (28 days). Always keep the cartridge in the carton in order to protect from light.

Vial:

You can carry your FIASP® vial with you and keep it at room temperature (i.e. at or below 30 °C) or in a refrigerator (at 2 °C to 8 °C) for not more than 4 weeks (28 days). Always keep the vial in the carton in order to protect from light.

Do not use FIASP® after the expiry date which is stated on the FlexTouch®/Penfill®/vial label and carton, after 'EXP'. The expiry date refers to the last day of that month.
Discard any unused portion after after 4 weeks (28 days).
FIASP® exposed to temperatures higher than 37°C should be discarded.

FlexTouch®/Penfill®/Vial:

Do not throw FIASP® via wastewater or household waste. Ask your pharmacist how to throw away your FIASP® you no longer use.

6. Contents of the pack and other information

What FIASP® contains:

The active substance is insulin aspart. 1 ml contains 100 units of insulin aspart. One unit of insulin aspart corresponds to 6 nmol; 0,035 *mg* salt-free anhydrous insulin aspart.

The other ingredients are:

- The following preservatives are included - Phenol: 0,15 *%* m/v (1,50 *mg/ml*) and Metacresol: 0,172 *%* m/v (1,72 *mg/ml*)
- Glycerol

- Zinc acetate
- Disodium phosphate dihydrate
- Arginine hydrochloride
- Niacinamide (vitamin B3)
- Water for injections

What FIASP® looks like and contents of the pack

FIASP® is a sterile, clear, colourless, aqueous, neutral solution of insulin aspart (B28 Asp), free from visible particulate matter.

Inspect FIASP® to ensure the product is free from visible particulate matter prior to use.

FlexTouch®:

Fiasp® is presented as 3 ml solution (i.e. 300 units per 3 ml) for injection in a cartridge (type 1 colourless glass) with a (colour) plunger (halobutyl) and a (colour) stopper (halobutyl/polyisoprene) contained in a pre-filled multi-dose disposable pen made of polypropylene, polyoxymethylene, polycarbonate and acrylonitrile butadiene styrene. The pen(s) is/are packed in carton box.

The pen is blue when capped, with red dose button, on removal of the cap the pen consists of red cartridge holder with blue housing, labelled with red and yellow stripped label.

Pack sizes of:

- 1 x 3 ml FlexTouch (pre-filled pen)
- 5 X 3 ml FlexTouch (pre-filled pens)
- A multipack with 2 x (5 x 3 ml FlexTouch) pre-filled pens.
- 1 X 3 ml FlexTouch (pre-filled pen) including 7 NovoFine® Plus needles
- 1 X 3 ml FlexTouch (pre-filled pen) including 7 NovoFine® needles 1
- 1 X 3 ml FlexTouch (pre-filled pen) including 7 NovoTwist® needles

Not all pack sizes may be marketed

Vial:

Fiasp® is presented as 10 ml solution (i.e. 1000 units per 10 ml) for injection in a vial (type 1 colourless glass) closed with a halobutyl/polyisoprene (colour) rubber disc and a protective tamper-proof (colour) plastic cap. The vial(s) is/are packed in carton box.

Pack sizes of:

- 1 x 10 ml vial
- 5 x 10 ml vials
- A multipack with 5 x (1 x 10 ml) vials.

Not all pack sizes may be marketed

Penfill®:

Fiasp® is presented as 3 ml solution (i.e. 300 units per 3 ml) for injection in a cartridge (type 1 colourless glass), with a (colour) plunger (halobutyl) and a (colour) stopper (halobutyl/polyisoprene). The cartridge is packaged in press through blister pack made of aluminium foil and polyethylene terephthalate (PET). The blister is packed in a carton box.

Pack sizes of:

- 5 x 3 ml Penfill (cartridges)
- 10 x 3 ml Penfill (cartridges)

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Novo Nordisk (Pty) Ltd

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2196

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09 February 2022

Registration number

51/21.1/0733

Appendix 1 - Fiasp® FlexTouch® Instruction for use

Instructions on how to use Fiasp® FlexTouch®

Please read these instructions carefully before using your FlexTouch® pre-filled pen. If you do not follow the instructions carefully, you may get too little or too much insulin, which can lead to too high or too low blood sugar level.
Do not use the pen without proper training from your doctor or nurse.
Start by checking your pen to **make sure that it contains Fiasp® 100 units/ml,** then look at the illustrations below to get to know the different parts of your pen and needle.

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

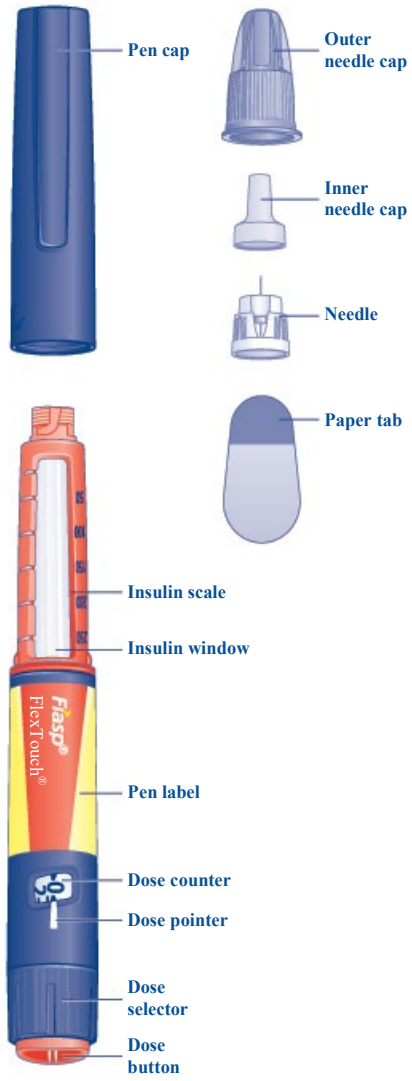
Your pen is a pre-filled dial-a-dose insulin pen containing 300 units of insulin. You can select a **maximum of 80 units per dose, in steps of 1 unit.** Your pen is designed to be used with NovoTwist®, NovoFine® or NovoFine® Plus single-use, disposable needles up to a length of 8 mm. Needles are not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

⚠ **Important information**

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

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

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



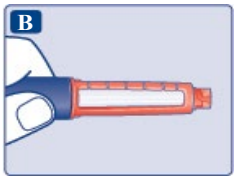
1. Prepare your pen with a new needle

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

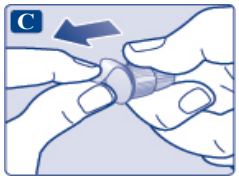
- **Pull off the pen cap.**



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



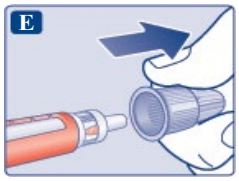
- **Take a new needle** and tear off the paper tab.



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



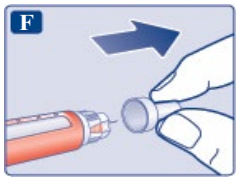
- **Pull off the outer needle cap and keep it for later.** You will need it after the injection, to safely remove the needle from the pen.



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

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

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



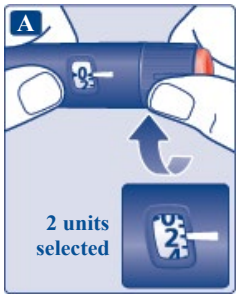
⚠ **Always use a new needle for each injection.**
This reduces the risk of contamination, infection, leakage of insulin, blocked needles and inaccurate dosing.

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

2. Check the insulin flow

- **Always check the insulin flow before you start.**
  This helps you to ensure that you get your full insulin dose.

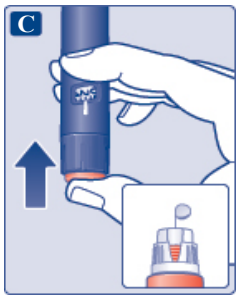
- Turn the dose selector to **select 2 units. Make sure the dose counter shows 2.**



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



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



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

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

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

⚠ **Always make sure that a drop appears** at the needle tip before you inject. This makes sure that the insulin flows.

If no drop appears, you will **not** inject any insulin, even though the dose counter may move. This may indicate a blocked or damaged needle.

⚠ **Always check the flow before you inject.** If you do not check the flow, you may get too little insulin or no insulin at all. This may lead to too high blood sugar level.

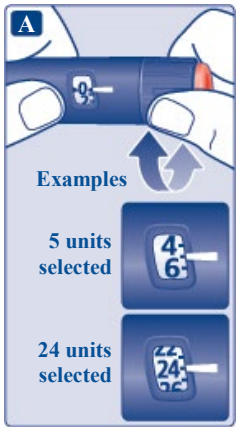
3. Select your dose

- **Make sure the dose counter shows 0 before you start.**
  The 0 must line up with the dose pointer.

- **Turn the dose selector to select the dose you need,** as directed by your doctor or nurse.

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

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



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

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

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

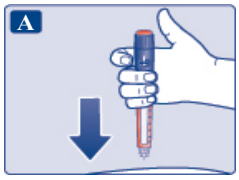
⚠ **Always use the dose counter and the dose pointer to see how many units you have selected before injecting the insulin.**
Do not count the pen clicks. If you select and inject the wrong dose, your blood sugar level may get too high or too low.

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

4. Inject your dose

- **Insert the needle into your skin** as your doctor or nurse has shown you.

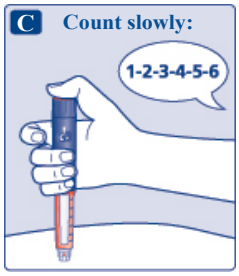
- **Make sure you can see the dose counter.**
  Do not touch the dose counter with your fingers. This could interrupt the injection.



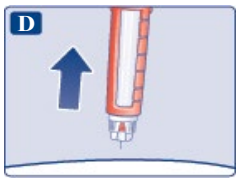
- **Press and hold down the dose button until the dose counter shows 0.**
  The 0 must line up with the dose pointer. You may then hear or feel a click.



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



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



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

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

How to identify a blocked or damaged needle?

- If 0 does not appear in the dose counter after continuously pressing the dose button, you may have used a blocked or damaged needle.

- In this case - you have **not** received **any** medicine - even though the dose counter has moved from the original dose that you have set.

How to handle a blocked needle?

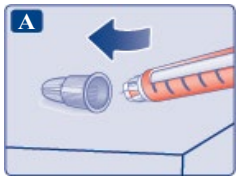
Remove the needle as described in section 5 and repeat all steps starting with section 1: Prepare your pen with a new needle. Make sure you select the full dose you need.

Never touch the dose counter when you inject.

This can interrupt the injection.

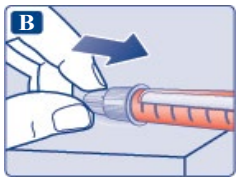
5. After your injection

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

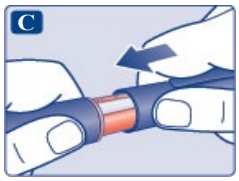


- Once the needle is covered, **carefully push the outer needle cap completely on.**

- **Unscrew the needle** and dispose of it carefully.



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



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

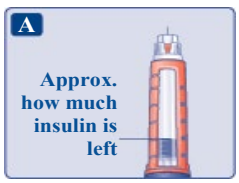
When the pen is empty, throw it away **without** a needle on as instructed by your doctor, nurse, pharmacist or local authorities.

⚠ **Never try to put the inner needle cap back on the needle.** You may stick yourself with the needle.

⚠ **Always remove the needle from your pen after each injection** and store your pen without the needle attached**.** This reduces the risk of contamination, infection, leakage of insulin, blocked needles and inaccurate dosing.

6. How much insulin is left?

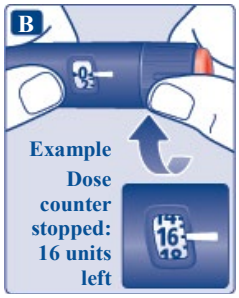
- The **insulin scale** shows you **approximately** how much insulin is left in your pen.



- **To see precisely how much insulin is left,** use the dose counter:
  Turn the dose selector until the **dose counter stops**.

If it shows 80, **at least 80** units are left in your pen.

If it shows **less than 80,** the number shown is the number of units left in your pen.



- Turn the dose selector back until the dose counter shows 0.

- If you need more insulin than the units left in your pen, you can split your dose between two pens.

⚠ **Be very careful to calculate correctly if splitting your dose.**
If in doubt, take the full dose with a new pen. If you split the dose wrong, you will inject too little or too much insulin, which can lead to too high or too low blood sugar level.

⚠ **Further important information**

- **Always keep your pen with you.**
- **Always carry an extra pen and new needles** with you, in case of loss or damage.
- Always keep your pen and needles **out of sight and reach of others,** especially children.
- **Never share** your pen or your needles with other people. It might lead to cross-infection.
- **Never share** your pen with other people. Your medicine might be harmful to their health.
- Caregivers must **be very careful when handling used needles** – to reduce the risk of needle injury and cross-infection.

Caring for your pen

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

- **Do not leave the pen in a car** or other place where it can get too hot or too cold.
- **Do not expose your pen to dust, dirt or liquid.**
- **Do not wash, soak or lubricate your pen.** If necessary, clean it with mild detergent on a moistened cloth.

- **Do not drop your pen** or knock it against hard surfaces.
  If you drop it or suspect a problem, attach a new needle and check the insulin flow before you inject.
- **Do not try to refill your pen.** Once empty, it must be disposed of.
- **Do not try to repair your pen** or pull it apart.

Appendix 2

How to inject Fiasp® 10 ml vial

Using syringe

Before you inject Fiasp® for the first time, your doctor, pharmacist or other healthcare professional will show you how to use it.

1. Check the name and strength on the label of the vial to make sure it is Fiasp®.

2. Remove the protective cap from the vial.

3. Always use a new needle for each injection to prevent contamination. Needles and syringes must not be shared.

4. Draw into the syringe the same amount of air as the dose of insulin you are going to inject. Inject the air into the vial.

5. Turn the vial and syringe upside down and draw the correct insulin dose into the syringe.

   - Pull the needle out of the vial.

   - Push the air out of the syringe and check that the dose is correct.

6. Inject the insulin under the skin. Use the injection technique advised by your doctor, pharmacist or other healthcare professional.

7. Throw away the needle after each injection.

Vial:

For use in an infusion pump system

Follow the instructions and recommendations from your doctor regarding the use of Fiasp® in a pump. Before using FIASP® in the pump system, you must have received a comprehensive instruction in the use and information about any actions to be taken in case of illness, too high or too low blood sugar or failure of the pump system.

Filling the pump

►FIASP® should never be diluted or mixed with any other insulin.

►Before inserting the needle, use soap and water to clean your hands and the skin where the needle is inserted to avoid any infection at the infusion site.

►When you fill a new reservoir, do not leave large air bubbles in either the syringe or the tubing.

►Changing of the infusion set (tubing and needle) must be done according to the instructions in the product information supplied with the infusion set.

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

What to do if the pump system fails

You should always have an alternative delivery method for your insulin available for injection under the skin in case the pump system fails.