Package leaflet: Information for the patient

Fiasp 100 units/mL solution for injection in pre-filled pen

insulin aspart

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

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

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

What is in this leaflet

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

1. What Fiasp is and what it is used for

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

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

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

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

2. What you need to know before you use Fiasp

Do not use Fiasp

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

Warnings and precautions

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

• Low blood sugar (hypoglycaemia) - If your blood sugar is too low, follow the guidance for low blood sugar in section 4 'Possible side effects'. Fiasp starts to lower blood sugar faster compared to other mealtime insulins. If hypoglycaemia occurs, you may experience it earlier after an injection with Fiasp.

- High blood sugar (hyperglycaemia) If your blood sugar is too high, follow the guidance for high blood sugar in section 4 'Possible side effects'.
- Switching from other insulin medicinal products The insulin dose may need to be changed if you switch from another insulin.
- Pioglitazone used together with insulin This may increase the risk of heart failure, see under 'Other medicines and Fiasp' below.
- Eye disorder Fast improvements in blood sugar control may lead to a temporary worsening of diabetic eye disorder.
- Pain due to nerve damage If your blood sugar level improves very fast, you may get nerve related pain, this is usually temporary.
- Swelling around your joints When you first start using your medicine, your body may keep more water than it should. This causes swelling around your ankles and other joints. This is usually only short-lasting.

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

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

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

Children and adolescents

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

Other medicines and Fiasp

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

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

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

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

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

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

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

<u>Pioglitazone</u> - oral anti-diabetic medicine used to treat type 2 diabetes. Some patients with long-standing type 2 diabetes and heart disease or previous stroke who were treated with pioglitazone and

insulin developed heart failure. Tell your doctor immediately if you have signs of heart failure such as unusual shortness of breath, rapid increase in weight or localised swelling (oedema).

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

Fiasp with alcohol

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

Pregnancy and breast-feeding

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

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

Driving and using machines

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

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

Important information about some of the ingredients of Fiasp

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

3. How to use Fiasp

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

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

The pre-filled pen can provide a dose of 1–80 units in one injection in steps of 1 unit.

When to use Fiasp

Fiasp is a mealtime insulin.

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

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

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

Fiasp dose

Dose for type 1 and type 2 diabetes

Your doctor will decide together with you:

• how much Fiasp you will need at each meal

• when to check your blood sugar level and if you need a higher or lower dose.

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

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

Dose adjustment for type 2 diabetes

The daily dose should be based on your blood sugar level at mealtimes and bedtime from the previous day.

- Before breakfast dose should be adjusted according to the blood sugar level before lunch the previous day.
- Before lunch dose should be adjusted according to the blood sugar level before dinner the previous day.
- Before dinner dose should be adjusted according to the bedtime blood sugar level the previous day.

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

Use in elderly patients (65 years or older)

This medicine can be used in elderly patients. Talk to your doctor about changes in your dose.

If you have kidney or liver problems

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

Injecting Fiasp

This medicine is only suitable for injection under the skin (subcutaneous injection).

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

Where to inject

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

Do not use Fiasp

- if the pen is damaged or if it has not been stored correctly (see section 5 'How to store Fiasp').
- if the insulin does not appear clear (e.g., cloudy) and colourless.

Detailed instructions for use are provided on the other side of this leaflet.

If you use more Fiasp than you should

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

If you forget to use Fiasp

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

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

- Always keep a spare pen in case you lose your pen or it gets damaged.
- Always carry something to show you have diabetes.
- Always carry products containing sugar with you. See section 4 under 'What to do if you get low blood sugar'.

If you stop using Fiasp

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

4. Possible side effects

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

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

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

Signs of a serious allergic reaction may include:

- local reactions (e.g., rash, redness and itching) spread to other parts of your body
- you suddenly feel unwell with sweating
- you start being sick (vomiting)
- you experience difficulty in breathing
- you experience rapid heartbeat or feeling dizzy.

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

Other side effects include:

Common (may affect up to 1 in 10 people)

<u>Reaction at administration site:</u> Local reactions at the place you inject yourself may occur. The signs may include: rash, redness, inflammation, bruising, irritation, pain and itching. The reactions usually disappear after a few days.

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

Uncommon (may affect up to 1 in 100 people)

<u>Changes under the skin where you use the injection (lipodystrophy):</u> Fatty tissue under the skin may shrink (lipoatrophy) or get thicker (lipohypertrophy). Changing where you inject each time may reduce the risk of developing these skin changes. If you notice these skin changes, tell your doctor or nurse. If you keep injecting in the same place, these reactions can become more severe and affect the amount of medicine your body gets.

General effects from insulin treatment including Fiasp

• Low blood sugar (hypoglycaemia) (very common)

Low blood sugar may happen if you:

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

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

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

What to do if you get low blood sugar

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

What others need to do if you pass out

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

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

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

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

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

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

Talk to your doctor if:

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

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

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

High blood sugar may happen if you:

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

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

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

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

What to do if you get high blood sugar

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in <u>Appendix V</u>. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fiasp

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton, after 'EXP'. The expiry date refers to the last day of that month.

Before first use:

Store in a refrigerator ($2^{\circ}C-8^{\circ}C$). Do not freeze. Keep away from the freezing element. Keep the cap on the pen in order to protect from light.

After first opening or if carried as a spare: You can carry your pre-filled pen (FlexTouch) with you and keep it at room temperature (not above 30°C) or in a refrigerator (2°C–8°C) for up to 4 weeks. Always keep the cap on the pen when you are not using it in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Fiasp contains

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

What Fiasp looks like and contents of the pack

Fiasp is presented as a clear, colourless and aqueous solution for injection in pre-filled pen.

Pack sizes of 1, 5 or a multipack with 2 x 5 pre-filled pens of 3 mL. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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

Now turn over for information on how to use your FlexTouch.

This leaflet was last revised in

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency website: http://www.ema.europa.eu.

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 high or 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.

A 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) Outer needle cap Inner needle cap Paper tab Insulin scale Insulin window Pen label Dose counter Dose pointer Dose selector Dose button

Dose button with two lines

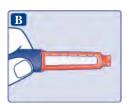
1 Prepare your pen with a new needle

- 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.

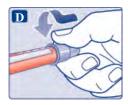
Look through the insulin window. If the insulin looks cloudy, do not use the pen.



• 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 prick or injure 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.



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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 is flowing properly.

If no drop appears, no insulin will be injected, 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 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.



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 to set the dose. 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. The dose selector clicks differently when turned forwards, backwards or past the number of units left.

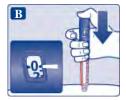
4 Inject your dose

- **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.

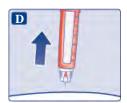
The 0 must line up with the dose pointer. You may then hear or feel a click.



- 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 on the skin for a few minutes to stop the bleeding. 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 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.

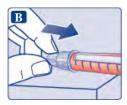
This can interrupt the injection.

5 After your injection

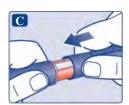
• **Lead the needle tip into the outer needle cap** on a flat surface without touching the needle or the outer cap.



- Once the needle is covered, carefully push the outer needle cap completely on.
- **Unscrew the needle** and dispose of it as instructed by your doctor, nurse, pharmacist or local authorities.

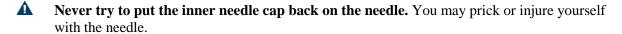


• **Put the pen cap on** your pen after each use to protect the insulin from light.



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.



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.

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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 high or low blood sugar levels.

A 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 them.
- 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 high or low blood sugar levels.

- **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.