APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

PRODUCT NAME

Actrapid® HM (ge); human insulin; 100 IU/mL; Solution for Injection

Read all of this leaflet carefully before you start using ACTRAPID® HM (ge)

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ACTRAPID® HM (ge) has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What ACTRAPID® HM (ge) is and what it is used for

ACTRAPID® HM (ge) is a fast-acting human insulin, 1 mL contains 100 units of human insulin.

ACTRAPID® HM (ge) is a recombinant humanised insulin with fast-acting effect. This means that it will start to lower your blood sugar about 30 minutes after injecting it, and the effect will last for approximately 8 hours.

ACTRAPID® HM (ge) is used to treat diabetes.

2. What you need to know before you use ACTRAPID® HM (ge)

Do not use ACTRAPID® HM (ge):

- In insulin infusion pumps
- If you are allergic (hypersensitive) to human insulin or any of the other ingredients in Actrapid® HM (ge) *(listed in section 6*)
- If you suspect low blood sugar (hypoglycaemia)

Before using ACTRAPID® HM (ge)

- Check the label to make sure it is the right type of insulin.
- Remove the protective cap.

Warnings and precautions

Take special care with ACTRAPID® HM (ge):

Tell your doctor or health care provider before using ACTRAPID® HM (ge)

- If you have trouble with your kidneys or liver, or with your adrenal, pituitary or thyroid gland
- If you are ill: carry on using your insulin and consult your doctor
- If you are going abroad: travelling over time zones may affect your insulin needs and the timing of your injections. Consult your doctor if you are planning such travelling
- 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 drink alcohol, watch for signs of low blood sugar (hypoglycaemia) and never drink alcohol on an empty stomach.

Skin changes at the injection site

The injection site should be rotated to help prevent changes to the fatty tissue under the skin, such as skin thickening, skin shrinking or lumps under the skin. The insulin may not work very well if you inject into a lumpy, shrunken or thickened area. Tell your doctor if

you notice any skin changes at the injection site. Tell your doctor if you are currently injecting into these affected areas before you start injecting in a different area. Your doctor may tell you to check your blood sugar more closely, and to adjust your insulin or your other antidiabetic medicines dose.

Other medicines and ACTRAPID® HM (ge)

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

Some medicines affect the way your glucose works in your body and this may influence your insulin dose. Listed below are the most common medicines which may affect your insulin treatment. Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. In particular, you should tell your doctor if you are using any medicine mentioned below that may affect your blood sugar level

If you take any of the below medicines your blood sugar level may fall (hypoglycaemia):

- Other medicines for the treatment of diabetes
- Monoamine oxidase inhibitors (used to treat depression)
- Beta-blockers (used to treat high blood pressure) such as propranolol
- Angiotensin converting enzyme (ACE) inhibitors (used to treat certain heart conditions or high blood pressure) and ARBs (Angiotensin Receptor Blockers)
- Aspirin (used to relieve pain and lower fever)
- Alcohol

If you take any of the below medicines your blood sugar level may rise (hyperglycaemia):

- Oral contraceptives (birth control pills)

- Thiazides (used to treat high blood pressure or excessive fluid retention)
- Glucocorticoids (such as “cortisone” used to treat inflammation)
- Thyroid hormones (used to treat thyroid gland disorders)
- Sympathomimetics (such as epinephrine (adrenalin), or salbutamol, terbutaline used to treat asthma)
- Growth hormone (medicines for stimulation of skeletal and somatic growth and pronounced influence on the body’s metabolic processes)
- Danazol (medicines acting on ovulation) may both increase or decrease your blood sugar level
- Beta-blockers (used to treat high blood pressure) may weaken or suppress entirely the first warning symptoms which help you to recognise low blood sugar (a hypoglycaemia).
- Octreotide (used for treatment of acromegaly, a rare hormonal disorder that usually occurs in middle-aged adults, caused by the pituitary gland producing excess growth hormone) may either increase or decrease your blood sugar level

Combination of Actrapid HM (ge) with pioglitazone

- Pioglitazone (tablets used for the treatment of type 2 diabetes) Some patients with long-standing type 2 diabetes mellitus and heart disease or previous stroke who are treated with pioglitazone in combination with insulin may develop heart failure. 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).

ACTRAPID® HM (ge) with food and drink and alcohol

If you drink alcohol, watch for signs of low blood sugar and never drink alcohol on an empty stomach. Alcohol may intensify and prolong the hypoglycaemic effect of insulin.

Pregnancy and breastfeeding:

Ask your doctor or pharmacist for advice before using Actrapid® HM (ge).

If you are pregnant, planning a pregnancy or breastfeeding please contact your doctor for advice. Intensified blood glucose control and monitoring of pregnant women with diabetes are recommended throughout pregnancy and when contemplating a pregnancy.

Breastfeeding whilst taking insulin does not put your baby at risk, however your insulin dosage may need to be monitored more frequently. Therefore it is important to consult your doctor immediately to discuss your insulin needs in order to control your diabetes and thereby avoid hyperglycaemia (high blood sugar) and hypoglycaemia (low blood sugar) as these conditions could harm you and your baby.

Driving and using machines

Your ability to concentrate and react may be reduced if you have hypoglycaemia (low blood sugar). Please keep this possible problem in mind in all situations where you might put yourself and other people at risk (e.g. when driving a car or operating machinery).

You must contact your doctor about the advisability of driving if you have frequent episodes of hypoglycaemia or have reduced or absent awareness of warning signs of hypoglycaemia.

ACTRAPID HM (ge) contains sodium

Actrapid HM (ge) contains less than 1 mmol sodium (23 mg) per dose, i.e. Actrapid HM (ge) essentially ‘sodium-free’.

3. How to use ACTRAPID® HM (ge)

Do not share medicines prescribed for you with any other person.

Always use your Actrapid HM (ge) exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Actrapid® HM (ge) should be generally administered 30 minutes before a meal. Dosage of Actrapid® HM (ge) is individualised.

How and where to inject

The injection can be administered subcutaneously by injection in the abdominal wall, the thigh or the deltoid region, or the gluteal region. Injection sites should be rotated within the same region. The best places to give yourself an injection are: the front of your waist (abdomen); the front of your thighs or upper arms.

Your insulin will work more quickly if you inject it around the waist. Always vary the sites you inject within the same region to avoid or reduce the risk of developing lumps or skin pitting. Injection into a lifted skin fold minimizes the risk of intra-mascular injection.
Keep the needle under the skin for at least 6 seconds to make sure the entire dose is injected.

Do not inject Actrapid® HM (ge):

Vial:

- If the protective cap is loose or missing. Each vial has a protective, tamper-proof plastic cap. If it is not in perfect condition when you get the vial, return the vial to your supplier

Penfill®:

- If the cartridge or the device containing cartridge is dropped, damaged or crushed.
- If the insulin does not appear clear and colourless

FlexPen®:

- If FlexPen® is dropped, damaged or crushed
- If it has not been stored correctly or has been frozen

If you inject more ACTRAPID® HM (ge) than you should

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.

Hypoglycaemia may develop if too high doses are administered, for more information see "What to do in an emergency" *See Summary of serious and very common side effects in section 4.*

If you forget to inject ACTRAPID® HM (ge)

Inadequate dosing or discontinuation of treatment may, especially in type 1 diabetes lead to hyperglycaemia i.e. blood sugar gets too high.

If you stop using ACTRAPID® HM (ge)

You must never stop using your Actrapid® HM (ge) without speaking to a doctor, who will tell you what needs to be done. Discontinuation of treatment may lead to hyperglycaemia (high blood glucose) especially in type 1 diabetes, and ketoacidosis.

Causes of hyperglycaemia

- Having forgotten to inject your insulin
- Repeatedly taking less insulin than you need
- An infection or a fever
- Eating more than usual
- Less exercise

Do not take a double dose to make up for forgotten individual doses.

The warning signs of hyperglycaemia appear gradually. They include:

Increased urination; feeling thirsty; losing your appetite; feeling sick (nausea or vomiting); feeling drowsy or tired; flushed, dry skin; dry mouth and a fruity (acetone) smell of the breath.

What to do if you experience high blood sugar

If you get any of these signs, test your blood sugar level and test your urine for ketones if you can. Then seek medical help immediately. These may be signs of a very serious condition called diabetic ketoacidosis (build-up of acid in the blood because the body is breakdown fat instead of sugar). If you do not treat it, this could lead to diabetic coma and eventually death.

4. Possible side effects

Actrapid® HM (ge) can have side effects.

Not all side effects reported for Actrapid® HM (ge) are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using Actrapid® HM (ge), please consult your health care provider for advice.

The following side effects may occur during Actrapid® HM (ge) treatment:

- Serious allergic reaction (Anaphylactic reactions) to Actrapid HM (ge) or one of its ingredients).

Symptoms of generalised hypersensitivity may include generalised skin rash, itching, sweating, gastrointestinal upset, swelling of face lips, tongue and throat (angioneurotic oedema), difficulties in breathing, palpitation, reduction in blood pressure and fainting/loss of consciousness. Generalised hypersensitivity reactions are potentially life threatening. If you develop any of these symptoms seek medical attention or hospitalisation immediately.

Side effects reported very frequently

- *Low blood sugar (hypoglycaemia)*

Hypoglycaemia may occur:

- If you eat too little or miss a meal
- If you exercise more than usual.
- If you inject too much insulin

- If you drink alcohol

Signs of low blood sugar:

Tell your doctor if you notice any of the following

The warning signs of a hypo may come on suddenly and can include: cold sweat; cool pale skin; headache; rapid heartbeat; feeling sick; feeling very hungry; temporary changes in vision; drowsiness; unusual tiredness and weakness; nervousness or tremor; feeling anxious; feeling confused; difficulty in concentrating.

What to do if you experience low blood sugar:

If you get any of these signs, eat glucose tablets or a high sugar snack (sweets, biscuits, fruit juice), then rest.

Do not inject any insulin if you feel low blood sugar coming on.

Carry glucose tablets or sugar containing products.

Severe hypoglycaemia

Severe hypoglycaemia where by you become unconscious can be treated by administration of glucagon intramuscularly or subcutaneously by a trained person, or glucose can be given intravenously by a healthcare professional. After regaining consciousness, oral administration of any sugar containing products is recommended to avoid any relapse.

Always tell your relatives, friends and close colleagues that if you pass out (become unconscious), they must turn you on your side and seek medical advice immediately. They must not give you any food or drink as it could choke you.

Less frequent side effects

Side effects reported less frequently

- Vision problems

When you first start your Actrapid® HM (ge) treatment, it may disturb your vision, but the disturbance is usually temporary

- Skin changes at the injection site (lipodystrophy)

The fatty tissue under the skin at the injection site may shrink (lipoatrophy) or thicken (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 the site with each injection may help to reduce the risk of developing such skin changes. If you notice your skin pitting or thickening at the injection site, tell your doctor or other healthcare professionals. These reactions can become more severe, or they may change the absorption of your insulin, if you inject in such a site. These symptoms usually disappear after a few weeks of taking Actrapid® HM (ge). If they do not disappear please consult your doctor or pharmacist.

- Signs of allergy.

Reactions (redness, swelling, itching) at the injection site may occur (local allergic reactions). If they do not disappear, tell your doctor/pharmacist.

Seek medical advice immediately:

- If signs of allergy spread to other parts of the body or
- If you suddenly feel unwell, and you: start sweating, start being sick (vomiting), have difficulty in breathing, have a rapid heartbeat, feel dizzy.

- Painful neuropathy (pain due to nerve damage):

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.

- Blurred vision:

May occur upon initiation of Actrapid® HM (ge) therapy. These symptoms are usually of transitory nature.

- Swollen joints (oedema):

When you start taking Actrapid® HM (ge), water retention may cause swelling around your ankles and joints, usually this soon disappears.

Other side effects reported:

- Diabetic retinopathy.

Diabetic retinopathy (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 or pharmacist about this.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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 Actrapid® HM (ge).

5. How to store Actrapid® HM (ge)

Store all medicines out of reach of children.

Before opening:

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

Optional storage by patient

If there are 6 months or more until the expiry date, the product may be stored outside of the refrigerator (at or below 30 °C) for up to 4 weeks before it is taken into use or carried

as a spare. The product must not be returned to the refrigerator after it has been stored outside of the refrigerator. Please record the beginning of storage outside of the refrigerator on the product carton.

Keep away from the cooling element.

Do not freeze.

During use or when carried as a spare:

Actrapid® HM (ge) vial, FlexPen® and Penfill® in use may be kept at room temperature at or below 30 °C) for 6 weeks (42 days). Please record the beginning of use on the product carton.

Discard any unused portion after one month,

Always keep the vial in the outer carton when you are not using it, in order to protect from light.

Do not expose Actrapid® HM (ge) to excessive heat or sunlight.

Do not use Actrapid® HM (ge) after the expiry date stated on the label and carton.

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

Return all unused medicine to your pharmacist

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Actrapid® HM (ge) contains

The active substance is human insulin, 1 mL contains 100 units of human insulin.

The other ingredients are:

Glycerol, metacresol (preservative), sodium hydroxide, hydrochloric acid, zinc oxide and water for injections.

What ACTRAPID® HM (ge) looks like and contents of the pack

Actrapid® HM (ge) is a solution for injection, a colourless liquid, free from turbidity and foreign matter.

- Actrapid® HM (ge) vial: 10 mL vial made of glass (type 1). The vial is closed with a rubber closure and packed in a carton.

  Pack size: 1 x 10 mL

- Actrapid® HM (ge) FlexPen®: FlexPen® is a pre-filled (multidose disposable pen) in which a Penfill® cartridge of 3 ml is inserted. The cartridge is made of glass (Type 1), containing a bromobutyl rubber plunger and a bromobutyl/polyisoprene rubber stopper. 5 x 3 mL Actrapid® HM (ge) FlexPen® packed in a carton.

- Actrapid Penfill: 3 mL Penfill cartridge. The cartridge is made of glass (Type 1), containing a bromobutyl rubber plunger and a bromobutyl/polyisoprene rubber stopper. 5 x 3 mL Actrapid HM (ge) Penfill packed in a carton.

Holder of Certificate of Registration

Novo Nordisk (Pty) Ltd

150 Rivonia Road

10 Marion Street Office Park

Building C1

Sandton, Johannesburg

2196

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Registration number

W/21.1/288

Implemented as type IB – 06 Oct 2023, storage instructions

Appendix 1

10 mL vial instructions for use

Actrapid® HM (ge) may also be administered intravenously in special situations by your healthcare professionals.

Note:

Check the name and coloured label of your vial to make sure that the vial you are preparing injection contains the correct type of insulin*. If you administer the wrong type of insulin, your blood sugar level may get too high or too low.*

Make sure you have the correct syringe with the corresponding unit scale for insulin injections.

- Clean the skin
- Wipe the rubber disc on the vial with alcohol
- Draw air into the syringe, in the same amount as the dose of insulin you need.
- Follow the instructions given by your healthcare professional.
- Gently agitate the vial of insulin. Then pierce the rubber disc with the needle, then push the piston home, and turn the vial upside down.
- Draw the required amount of insulin into the syringe. Avoid air in the syringe and needle by working the piston slightly up and down.
- Make the injection at a suitable depth under the skin (subcutaneously).

  It is important that the injection is made with a syringe which is marked for use with an insulin preparation containing 100 units per ml. Failure to use the correct syringe, can lead to dosage errors.

- Keep the needle under your skin for at least 6 seconds to make sure that the full dose has been delivered.
- Always use the injection technique advised by your doctor or nurse.

Appendix 2

Penfill® instructions for use

Actrapid® HM (ge) Penfill cartridges are designed to be used with Novo Nordisk insulin delivery system and NovoFine® or NovoTwist® needles.

Note:

Check the name and coloured label of your vial to make sure that the vial you are preparing injection contains the correct type of insulin*. If you administer the wrong type of insulin, your blood sugar level may get too high or too low.*

General instructions for use of cartridges (Penfill®)

- Always ensure that the injection device is assembled according to manufacturer's directions. Please refer to the instructions included with the device.
- Before use check that the Penfill® cartridge is intact (e.g. no fissures).
- Do not use the Penfill® if any damage is seen, or if more of the rubber piston is visible than equal to the width of the white bar code band.
- Always expel air, with the needle pointing upwards, before injection.
- The needle should be removed immediately after each injection and discarded. If the needle is not removed, temperature changes can result in some liquid being expelled from the cartridge causing a change in the insulin concentration (strength) in the Penfill®.
- Do not empty the Penfill® beyond the coloured band
- Actrapid® HM (ge) Penfill® must not be used or refilled with conventional syringes.
- The site of the injection should be changed each time to avoid complications caused by repeated injections at the same site. Insulin can be injected into the upper arms, buttocks, the abdominal region and the thighs

How to inject Actrapid® HM (ge)

► **Inject the insulin** under the skin. Use the injection technique advised by your doctor or nurse and as described in your delivery system manual.

► **Keep the needle under your skin** for at least 6 seconds. Keep the push button fully depressed until the needle has been withdrawn. This will ensure correct delivery and limit possible flow of blood into the needle or insulin reservoir.

► **After each injection** be sure to remove and discard the needle and store Actrapid® without the needle attached,

If you are treated with Actrapid® HM (ge) Penfill® and another insulin Penfill® cartridge, you should use two insulin delivery systems, one for each type of insulin.
As a precautionary measure, always carry a spare insulin delivery device in case your Penfill® is lost or damaged.

Delivery of dosage using NovoPen®:

► Use the injection technique advised by the healthcare practioner.

► With NovoPen® it is possible to select a dose larger than the number of units remaining in the Penfill®. For your convenience the cartridge holder has marks which show the approximate dose remaining in the Penfill.

► Do not dial up more than what is available.

► Do not initiate injection if the rubber piston can be seen in the small inspection windows as the glass ball needs room to resuspend the insulin.

► When a dosage greater than the insulin remaining in the cartridge is required, the following options can be exercised:

(i) The dosage remaining in the current Penfill can be administered. A new Penfill is then inserted according to the manufacturer's instructions, and the balance of the required dosage is administered from the new Penfill

or

(ii) The current Penfill® can be discarded. A new Penfill® is then inserted according to the manufacturer's instructions and the full dosage is administered from the new Penfill®.

To avoid possible transmission of disease, Penfill® is for single person use only.

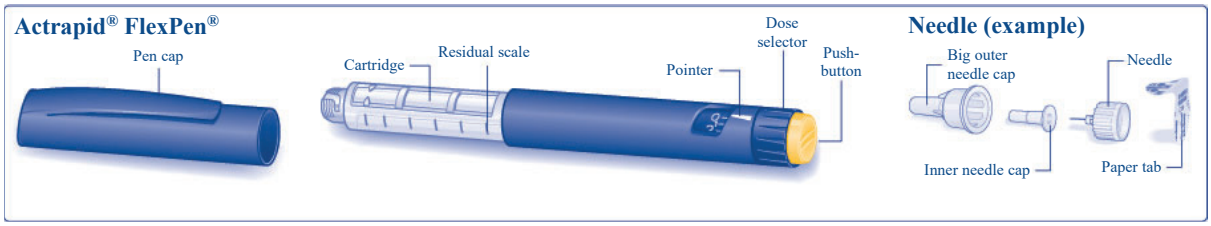
Appendix 3

FlexPen® Instructions for use

Patient: Instructions on how to use Actrapid® HM (ge) solution for injection in FlexPen®

Read the following instructions carefully before using your FlexPen®. 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.

Your FlexPen® is a pre-filled dial-a-dose insulin pen. You can select doses from 1 to 60 units in increments of 1 unit. FlexPen® is designed to be used with NovoFine® or NovoTwist® disposable needles up to a length of 8 mm. As a precautionary measure, always carry a spare insulin delivery device in case your FlexPen® is lost or damaged.



Caring for your pen

Your FlexPen® must be handled with care.

If it is dropped, damaged or crushed, there is a risk of insulin leakage. This may cause inaccurate dosing, which can lead to too high or too low blood sugar level.

You can clean the exterior of your FlexPen® by wiping it with a medicinal swab. Do not soak it, wash or lubricate it as it may damage the pen.

Do not refill your FlexPen®.

Preparing your Actrapid® HM (ge) FlexPen®

Check the name and coloured label of your pen to make sure that it contains the correct type of insulin. This is especially important if you take more than one type of insulin. If you take the wrong type of insulin, your blood sugar level may get too high or too low.

A

Pull off the pen cap (see A).



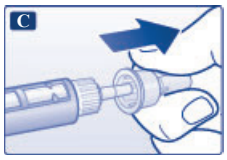
B

Remove the paper tab from a new disposable needle.
Screw the needle straight and tightly onto your FlexPen®.



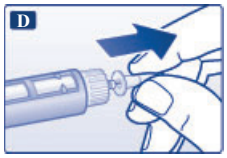
C

Pull off the big outer needle cap and keep it for later.



D

Pull off the inner needle cap and dispose of it.
Never try to put the inner needle cap back on the needle. You may stick yourself with the needle.



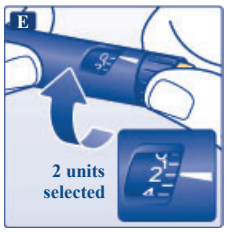
- Always use a new needle for each injection. This reduces the risk of contamination, infection, leakage of insulin, blocked needles and inaccurate dosing.
- Be careful not to bend or damage the needle before use.

Checking the insulin flow

E

Prior to each injection, small amounts of air may collect in the cartridge during normal use. To avoid injection of air and ensure proper dosing:

Turn the dose selector to select 2 units.



F

Hold your FlexPen® with the needle pointing upwards and tap the cartridge gently with your finger a few times to make any air bubbles collect at the top of the cartridge.

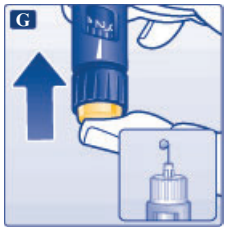


G

Keeping the needle upwards, press the push-button all the way in. The dose selector returns to 0.

A drop of insulin should appear at the needle tip. If not, change the needle and repeat the procedure no more than 6 times.

If a drop of insulin still does not appear, the pen is defective, and you must 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 selector 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.

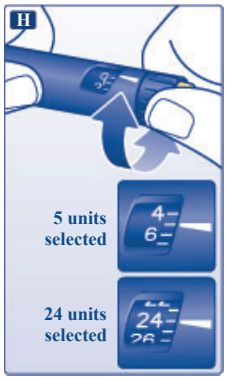
Selecting your dose

H

Check that the dose selector is set at 0.
Turn the dose selector to select the number of units you need to inject.

The dose can be corrected either up or down by turning the dose selector in either direction until the correct dose lines up with the pointer. When turning the dose selector, be careful not to push the push-button as insulin will come out.

You cannot select a dose larger than the number of units left in the cartridge.



- Always use the dose selector and the 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 residual scale, it only shows approximately how much insulin is left in your pen.

Making the injection

I

Insert the needle into your skin. Use the injection technique shown by your doctor, pharmacist or other health care professional.

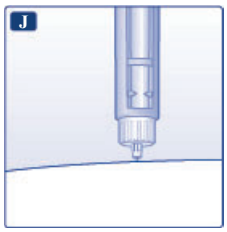
Inject the dose by pressing the push-button all the way in until 0 lines up with the pointer. Be careful only to push the push-button when injecting.
Turning the dose selector will not inject insulin.



J

Keep the push-button fully depressed and let the needle remain under the skin for at least 6 seconds. This will make sure you get the full dose.

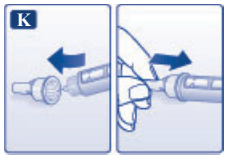
Withdraw the needle from the skin, then release the pressure on the push-button.
Always make sure that the dose selector returns to 0 after the injection. If the dose selector stops before it returns to 0, the full dose has not been delivered, which may result in too high blood sugar level.



K

Lead the needle into the big outer needle cap without touching it. When the needle is covered, carefully push the big outer needle cap completely on and then unscrew the needle.

Dispose of it carefully and put the pen cap back on.



- Always remove the needle after each injection and store your FlexPen® without the needle attached. This reduces the risk of contamination, infection, leakage of insulin, blocked needles and inaccurate dosing.

Further important information

- Caregivers must be very careful when handling used needles – to reduce the risk of needle sticks and cross-infection.
- Dispose of your used FlexPen® carefully without the needle attached.
- 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.
- Always keep your pen and needles out of sight and reach of others, especially children.