PATIENT INFORMATION LEAFLET FOR RYZODEG®

SCHEDULING STATUS

S3

Ryzodeg®, solution for injection.

Insulin degludec / insulin aspart 100 U/mL

Sugar free.

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

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

1. What Ryzodeg® is and what it is used for

- Treatment of adult diabetes mellitus patients, as basal add on to co-medication in patients who are inadequately controlled:
  - In type 1 diabetes mellitus, Ryzodeg® should be used with short-acting soluble insulin for use at the meal times when Ryzodeg® is not used.

- In type 2 diabetes mellitus, Ryzodeg® should be used as an add on to oral antidiabetic medicines.

- Treatment of diabetes mellitus in adults, adolescents and children from the age of 2 years.

Ryzodeg® helps your body reduce your blood sugar level. Ryzodeg® contains two types of insulin medicine:

- Ultra-long acting insulin called 'insulin degludec' – this has a long blood sugar lowering effect.
- Rapid acting insulin called 'insulin aspart' – this lowers your blood sugar soon after you inject it.

2. What you need to know before you use Ryzodeg®

Do not use Ryzodeg® if:

Ryzodeg® should not be administered to you:

- you are hypersensitive (allergic) to insulin degludec, insulin aspart or any of the other ingredients in Ryzodeg® (see section 6);
- you are pregnant or are planning to become pregnant.

Do not use Ryzodeg® if any of the above applies to you.

If you are not sure, tell your doctor or health care provider.

Warnings and precautions

Take special care with Ryzodeg®:

While using Ryzodeg®, check with your doctor or health care provider before:

- exercising more than usual;
- changing your usual diet;
- travelling over time zones.

This is because it may affect your blood sugar level.

Children and adolescents

Ryzodeg® can be used in adolescents and children from the age of 2 years with diabetes mellitus.

Ryzodeg® should be used with special caution in children 2 to 5 years old.

The risk for very low blood sugar may be higher in this age group. There is no experience with the use of Ryzodeg® in children below the age of 2 years.

Other effects from diabetes

Too low blood sugar (hypoglycaemia)

Do not use Ryzodeg® if you think that your blood sugar is getting too low.

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 sweets, biscuits or fruit juice (always carry glucose tablets or high sugar snack, just in case).
- Measure your blood sugar if possible and rest.

  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 you have diabetes. Tell them what could happen, including the risk of passing out when your blood sugar gets too low.

Let them know that 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:

Flushing, 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 if you can.
- Get medical help straight away.

Switching from other insulin medicines:

Your insulin dose may need to be changed if you switch from another type, brand or manufacturer of insulin. You should talk to you doctor.

Eye disorders:

Fast improvements in your blood sugar may lead to temporary worsening of diabetic eye disorders. Talk to your doctor if you experience an eye problem while using Ryzodeg®.

Skin changes at the injection site

You should rotate the injection site to help prevent changes in 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 the injection site. Tell your doctor if you are injecting into these affected areas before you start injecting into a different area. Your doctor may want you to check your blood sugar more closely and adjust your insulin or other diabetic medicine.

Other medicines and Ryzodeg®

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines), the use of Ryzodeg® with these medicines may cause

undesirable interactions. Please consult your doctor, pharmacist or other health care provider, for advice.

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;
- sulphonamides - for infections;
- anabolic steroids - such as testosterone;
- beta-blockers - for high blood pressure;
- aspirin (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 - medicine affecting ovulation;
- 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 holding onto too much water (water retention).

Octreotide and lanreotide - used for treatment of ‘acromegaly’ (caused by the pituitary gland producing too much growth hormone). They may both increase or decrease your blood sugar level.

Beta-blockers - used for high blood pressure. They may make it harder to recognise the warning signs of too low blood sugar (hypoglycaemia).

Pioglitazone - oral antidiabetic medicine used for the treatment of type 2 diabetes mellitus. Some patients with long-standing type 2 diabetes mellitus and heart disease or previous stroke, who were treated with pioglitazone and insulin, experienced the development of 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).

If any of the above applies to you (or you are not sure), ask your doctor, pharmacist or other healthcare professional for advice.

Ryzodeg® with food, drink and alcohol

If you drink alcohol your need for insulin may change. Your blood sugar level may either rise or fall.

Your blood sugar level will need to be carefully monitored.

Pregnancy, breastfeeding and fertility

Safe use during pregnancy has not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before you start using Ryzodeg®. Careful control of your diabetes is needed in pregnancy.

Avoiding too low blood sugar (hypoglycaemia) is particularly important for the health of your baby.

Driving and using machines

Having too low (hypoglycaemia) or too high (hyperglycaemia) blood

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

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

Ryzodeg® contains sodium

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

3. How to use Ryzodeg®

Do not share Ryzodeg® prescribed to you with any other person.

Always use Ryzodeg® exactly as your doctor has instructed you. You should check with your doctor, or pharmacist if you are unsure.

If you are blind or have poor eyesight and you cannot read the dose counter on the pen, do not use Ryzodeg® without help. Get help from a person who is qualified to use Ryzodeg®.

You and your doctor will decide:

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

How much to use

- Always follow your doctor's recommendation for dose.
- Ryzodeg® can either be used once or twice each day.
- Use with a meal – you can choose a different meal each day (as long as it is the largest meal(s)).
- If you want to change your usual diet, check with your doctor, nurse or pharmacist first.

Based on your blood sugar level your doctor may change your dose.

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

Ryzodeg® FlexTouch®

Ryzodeg® FlexTouch® provides a max dose of 80 units in one injection in dose steps of 1 unit.

Your doctor may ask you to use Ryzodeg® FlexTouch® by itself or with other diabetes medicines.

Ryzodeg® FlexTouch® is designed to be used with NovoFine® or NovoTwist® needles.

Injecting your Ryzodeg®

Before you use Ryzodeg® FlexTouch® for the first time, your doctor or nurse will show you how to use it.

- Check the name and coloured label on the pen to make sure it is the right insulin.

Do not use Ryzodeg® FlexTouch®

- In insulin infusion pumps.
- If the pen is damaged or has not been stored correctly (see section: How to store Ryzodeg®).
- If the insulin does not appear clear and colourless.

Ryzodeg® Penfill®

Ryzodeg® also comes in a cartridge, Ryzodeg® Penfill®, which is designed to be used with Novo Nordisk insulin delivery systems and NovoFine® or NovoTwist® needles.

Your doctor may ask you to use Ryzodeg® Penfill® by itself or with other diabetes medicines.

Injecting your Ryzodeg®

Before you use Ryzodeg® Penfill® for the first time, your doctor or nurse will show you how to use it.

- Please also read the manual that comes with your insulin delivery system.
- Check the name and coloured label to make sure it is the right insulin.

Do not use Ryzodeg® Penfill®

- In insulin infusion pumps.
- If Ryzodeg® Penfill® or the delivery system you are using is damaged. Take it back to your supplier. See your delivery system manual for further instructions.
- If Ryzodeg® Penfill® is damaged or has not been stored correctly (see section: Storing and disposing of Ryzodeg®).
- If the insulin does not appear clear and colourless.

How to inject

- Ryzodeg® is given as an injection under the skin. Do not inject it into a vein or muscle.
- The best places to inject are the front of your thighs, upper arms or the front of your waist (abdomen).
- Change the place where you inject each day to avoid lumps in these areas.

Detailed instructions for use of the Ryzodeg® FlexTouch® pen are provided in the pack.

Use in elderly

Ryzodeg® can be used in elderly patients above 65 years of age but you may need to check your blood sugar level more regularly.

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 regularly.

Talk to your doctor about changes in your Ryzodeg® dose.

If you have the impression that the effect of Ryzodeg® is too strong or too weak, tell your doctor or pharmacist.

If you inject more Ryzodeg® than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control center.

If you use too much insulin your blood sugar may get too low (hypoglycaemia) – see the advice in 'Too low blood sugar' in section 4.

If you forget to inject Ryzodeg®

If you forget a dose, inject the missed dose with your next meal on that day and thereafter resume your usual dosing schedule.

Effects when treatment with Ryzodeg® is stopped

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 and ketoacidosis (see the advice in 'Too high blood sugar' in section 5: Possible side effects).

4. Possible side effects

Ryzodeg® can have side effects.

Not all side effects reported for Ryzodeg® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving Ryzodeg®, please consult your health care provider for advice.

If any of the following happens, stop using Ryzodeg® and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, tongue, lips, mouth or throat, which may cause difficulty in swallowing or breathing (you suddenly feel unwell with sweating, you start being sick (vomiting), you experience rapid heartbeat or feeling dizzy);
- rash, hives or itching (the local reactions spread to other parts of your body);
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to Ryzodeg®. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects

- Too low blood sugar (hypoglycaemia) - see advice in 'Too low blood sugar'.
- Local reactions:

Local reactions at the place you inject yourself may occur. The signs may include: pain, redness, hives, swelling and itching. The reactions usually disappear after a few days. See your doctor if they do not disappear after a few weeks. Stop using Ryzodeg® and see a doctor straight away if the reactions become serious. See above for details on serious allergic reactions.

Less frequent side effects

- Swelling around your joints, your hands, feet, arms or legs due to water retention:

When you first start using your Ryzodeg®, your body may hold onto more water than it should. This causes swelling around your ankles and other joints. This is usually only short lasting.

Other side effects which may occur but the frequency is not known

- Skin changes where you inject Ryzodeg® (lipodystrophy):

It is not known if Ryzodeg® may cause lipodystrophy but such skin changes have been seen with other types of insulin. If you inject yourself too often in the same place, fatty tissue under the skin may shrink (lipoatrophy) or get thicker (lipohypertrophy). Lumps under the skin may also be caused by a build-up of protein called amyloid (cutaneous amyloidosis). Changing where you inject each time may help to avoid 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 from the pen.

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of Ryzodeg®.

5. How to store Ryzodeg®

Store all medicines out of reach of children.

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

Before opening

Store in a refrigerator (2 °C to 8 °C). Keep away from the cooling element.

Do not freeze.

During use or if carried as a spare:

You can carry Ryzodeg® FlexTouch® with you and keep it at room temperature (at or below 30 °C) or in a refrigerator (2 °C to 8 °C) for up to 4 weeks. Discard any unused portion after 4 weeks of use.

Penfill®: Do not refrigerate. You can carry your Ryzodeg® cartridge (Penfill®) with you and keep it at room temperature (at or below 30 °C) for up to 4 weeks.

Always keep the cap on the Ryzodeg® FlexTouch® pen when you are not using it in order to protect it from light.

Always keep the Ryzodeg® Penfill® in the outer carton when you are not using it in order to protect it from light.

Ryzodeg® must be protected from excessive heat and light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

Do not use Ryzodeg® if you notice any particles in the solution.

6. Contents of the pack and other information

What Ryzodeg® contains

The active substances are insulin degludec and insulin aspart 100 units/mL. (70 % soluble insulin degludec and 30 % soluble insulin aspart).

The other ingredients are: glycerol (E422), hydrochloric acid (for pH adjustment) (E507), phenol (preservative), metacresol preservative), sodium chloride, sodium hydroxide (for pH adjustment) (E524), zinc acetate (E650), and water for injections.

What Ryzodeg® looks like and contents of the pack

Ryzodeg® is a colourless solution free from turbidity and particulate matter.

Ryzodeg® FlexTouch®:

3 mL solution in a cartridge made of clear, colourless type 1 glass with a red plunger (halobutyl) and a cream stopper (halobutyl/polyisoprene) contained in a pre-filled multidose disposable pen made of polypropylene. The pen(s) is/are packed in a carton box.

Pack sizes: 1 x 3 mL, 1 x 3 mL (including needle pack), 5 x 3 mL, multipack: 2 x (5 x 3 mL).

Ryzodeg® Penfill®:

3 mL solution in a cartridge made of clear, colourless type 1 glass with a red plunger (halobutyl) and a cream 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 size: 1 x 3 mL, 5 x 3 mL and 10 x 3 mL.

Holder of certificate of registration

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Instructions on how to use Ryzodeg® 100 units/ mL solution for injection in pre-filled pen (FlexTouch®)

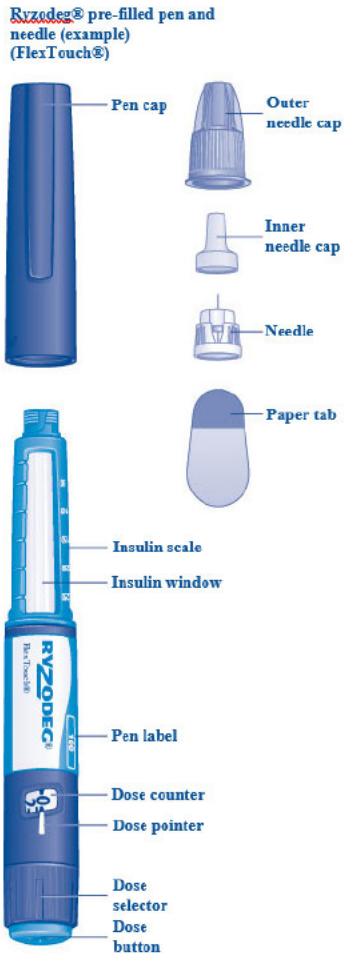
Please read these instructions carefully before using your FlexTouch® pre-filled pen. If you do not follow the instructions carefully, you may get too little or too much insulin, which can lead to too high or too low blood sugar level.

Do not use the pen without proper training from your doctor or nurse.
Start by checking your pen to **make sure that it contains Ryzodeg® 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® or NovoFine® single-use disposable needles up to a length of 8 mm. Needles are not included in the pack.

⚠ Important information

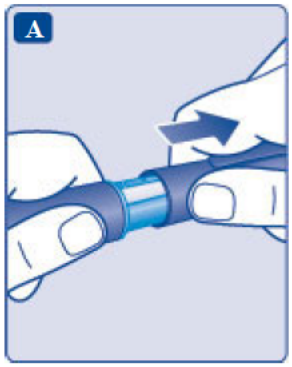
Pay special attention to these notes as they are important for correct use of the pen.



1. Prepare your pen

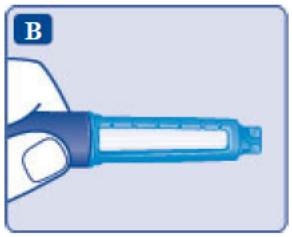
Check the name and strength on the label of your pen, to make sure that it contains Ryzodeg® 100 units/ mL. This is especially important if you take more than one type of insulin. If you take a wrong type of insulin, your blood sugar level may get too high or too low.

Pull off the pen cap.

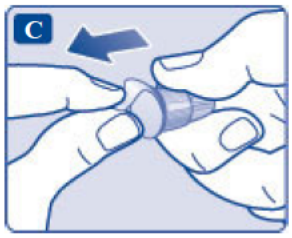


Check that the insulin in your pen is clear and colourless.

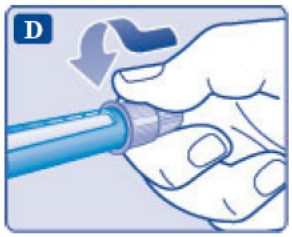
Look through the insulin window. If the insulin looks cloudy, do not use the pen.



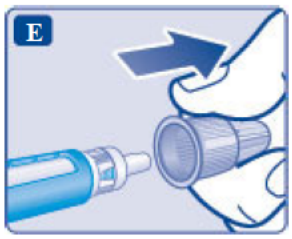
Take a new needle and tear off the paper tab.



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

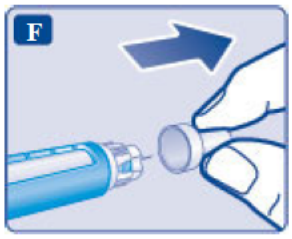


Pull off the outer needle cap and keep it for later. You will need it after the injection, to correctly remove the needle from the pen.



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.



⚠ **Always use a new needle for each injection.**

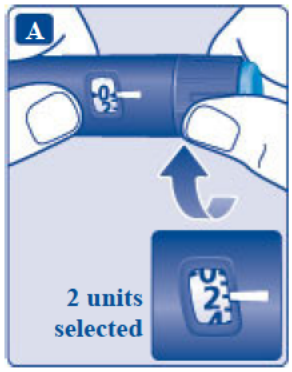
This reduces the risk of contamination, infection, leakage of insulin, blocked needles and inaccurate dosing.

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

2. Check the insulin flow

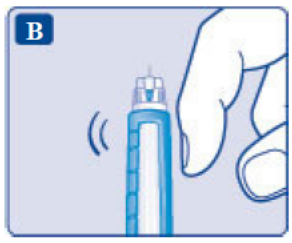
Always check the insulin flow before you start. This helps you to ensure that you get your full insulin dose.

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.
- ⚠ **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

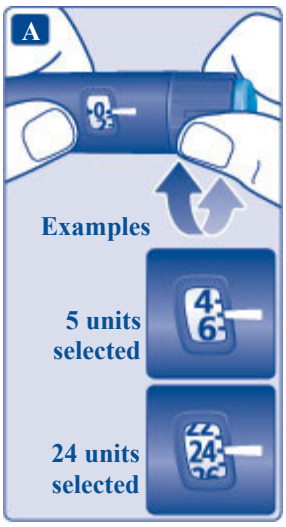
Make sure the dose counter shows 0 before you start.

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.

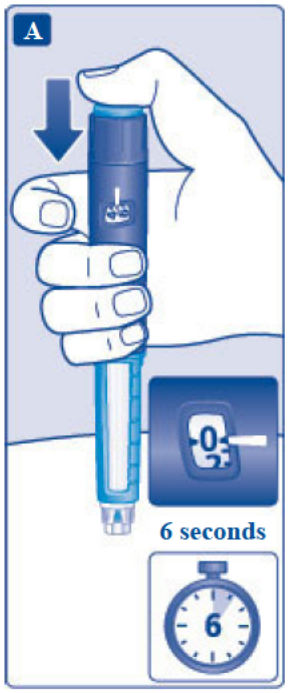
Do not touch the dose counter with your fingers. This could interrupt the injection.

Press and hold down the dose button until the dose counter returns to 0.

The 0 must line up with the dose pointer.

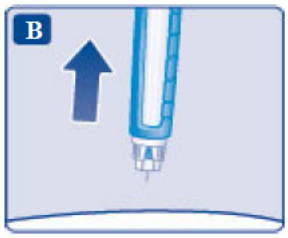
You may then hear or feel a click.

Leave the needle under the skin for at least 6 seconds to make sure you get your full dose.



Pull the needle and pen straight up from your skin.

If blood appears at the injection site, press lightly with a cotton swab. 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.

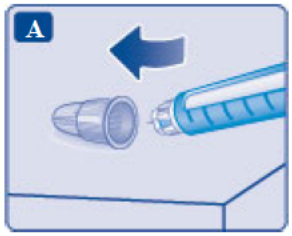
⚠ **Always watch the dose counter to know how many units you inject.**

The dose counter will show the exact number of units. Do not count the pen clicks.

Hold the dose button down until the dose counter returns to 0 after the injection. If the dose counter stops before it returns to 0, the full dose has not been delivered, which may result in too high blood sugar level.

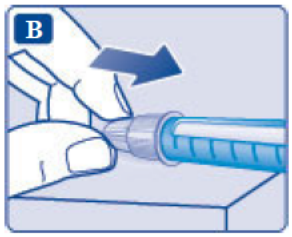
5 After your injection

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

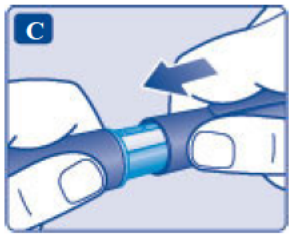


Once the needle is covered, **carefully push the outer needle cap completely on.**

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.

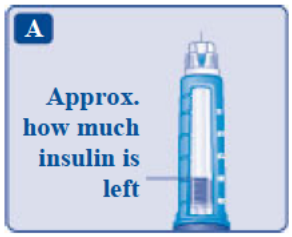
⚠ **Never try to put the inner needle cap back on the needle.** You may stick yourself with the needle.

⚠ **Always remove the needle from your pen after each injection.**

This may prevent blocked needles, 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.

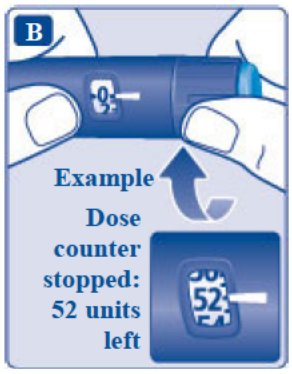


To see precisely how much insulin is left, use the dose counter:

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 prevent 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.