

Ryzodeg®

FlexTouch®

100 units/ml

Solution for injection in pre-filled pen

insulin degludec/insulin aspart

Consumer Medication Information Leaflet (RiMUP)

What is in this leaflet

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1. What Ryzodeg® is used for

Ryzodeg® is used to treat diabetes mellitus in adults, adolescents and children from the age of 2 years. Ryzodeg® helps your body reduce your blood sugar level.

2. How Ryzodeg® works

Ryzodeg® contains two types of insulin:

- Basal 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.

3. Before you use Ryzodeg®

- When you must not use it

- ▶ If you are allergic to insulin degludec, insulin aspart or any of the other ingredients of this medicine (listed in section 8).

- Before you start to use it

Talk to your doctor, pharmacist or nurse before using Ryzodeg®. 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 6 *Side effects*.
- High blood sugar (hyperglycaemia) – if your blood sugar is too high, follow the guidance for high blood sugar in section 6 *Side effects*.

- Switching from other insulin products – the insulin dose may need to be changed if you switch from another type, brand or manufacturer of insulin. Talk to your doctor.
- Thiazolidinediones used together with insulin, see *Thiazolidinediones* below.
- Eye disorder – fast improvements in blood sugar control may lead to a temporary worsening of diabetic eye disorder. If you experience eye problems, talk to your doctor.
- Ensuring you use the right type of insulin – always check the insulin label before each injection to avoid accidentally confusing Ryzodeg® with other insulin products.

If you have poor eyesight, please see section 4 *How to use Ryzodeg®*.

Skin changes at the injection site

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

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.

- Taking other medicines

Tell your doctor, pharmacist or nurse 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 be changed.

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)
- sulfonamides – for infections
- anabolic steroids – such as testosterone
- beta-blockers – for high blood pressure. They may make it harder to recognise the warning signs of too low blood sugar (see section 5, *Warning signs of too low blood sugar*)
- acetylsalicylic acid (and other salicylates) – for pain and mild fever
- monoamine oxidase (MAO) inhibitors – for depression
- angiotensin converting enzyme (ACE) inhibitors – 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 keeps 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.

Thiazolidinediones – oral anti

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diabetic medicine used to treat type 2 diabetes mellitus. Some patients with long-standing type 2 diabetes mellitus and heart disease or previous stroke who were treated with thiazolidinediones and insulin experienced the development of heart failure. Inform your doctor immediately if you experience signs of heart failure such as unusual shortness of breath, rapid increase in weight or localised swelling (oedema).

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

4. How to use Ryzodeg[®]

- How much to use

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

Your doctor will decide with you:

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

Use in elderly (≥ 65 years old)

Ryzodeg[®] can be used in elderly, but you may need to check your blood sugar level more often. 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.

- When to use it

Flexibility in dosing time

- Always follow your doctor's recommendation for dose.
- Ryzodeg[®] can either be used once or twice each day.
- Use with the main meal(s) – you can change the time of dosing as long as Ryzodeg[®] is dosed with

the largest meal(s).

- 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.

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.

Injecting your medicine

Before you use Ryzodeg[®] for the first time, your doctor or nurse will show you how to use the pre-filled pen.

► Check the name and strength on the label of the pen to make sure it is Ryzodeg[®] 100 units/ml.

How to inject

► Ryzodeg[®] is given as an injection under the skin (subcutaneous injection). Do not inject it into a vein or muscle.

► The best places to inject are the front of your waist (abdomen), upper arms or the front of your thighs.

► Change the place within the area where you inject each day to reduce the risk of developing lumps and skin pitting (see section 6).

► Always use a new needle for each injection. Re-use of needles may increase the risk of blocked needles leading to inaccurate dosing. Dispose of the needle safely after each use.

► Do not use a syringe to remove the solution from the pen to avoid dosing errors and potential overdose.

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

- How long to use it

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 (a condition with too much acid in the blood), see advice in section 6, *Too high blood sugar*.

- If you forget to use it

If you forget a dose, inject the missed dose with your next large meal on that day and thereafter resume your usual dosing schedule. Do not take a double dose to make up for a forgotten dose.

- If you use too much (overdose)

If you use too much insulin, your blood sugar may get too low (hypoglycaemia), see advice in section 6, *Too low blood sugar*.

5. While you are using it

- Things you must do

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

- Things you must not do

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

Do not use Ryzodeg[®]

► in insulin infusion pumps.

► if the pen is damaged or has not been stored correctly (see section 7 *Storage and disposal of Ryzodeg[®]*).

► if the insulin does not appear clear and colourless.

- Things to be careful of

Ryzodeg[®] with alcohol

If you drink alcohol, your need for insulin may change. 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

It is not known if Ryzodeg[®] affects the baby in pregnancy. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Your insulin dose may need to be changed during pregnancy and after

delivery. 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 or too high 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 if:

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

6. Side effects

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

Hypoglycaemia (too low blood sugar) may occur very commonly 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 to increase your blood sugar level immediately. See advice in *Too low blood sugar* below.

If you have a **serious allergic reaction** (seen rarely) to the insulin or any of the ingredients in Ryzodeg®, stop using Ryzodeg® and see a doctor straight away. The signs of a serious allergic reaction are:

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

Other side effects include:

Common (may affect up to 1 in 10 people)

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. For more information, see *serious allergic reaction* above.

Uncommon (may affect up to 1 in 100 people)

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.

Rare (may affect up to 1 in 1,000 people)

This medicine can cause allergic reactions such as hives, swelling of the tongue and lips, diarrhoea, nausea, tiredness and itching.

Frequency not known (cannot be estimated from the available data)

Skin changes at the injection site: If you inject insulin at the same place, the fatty tissue may either shrink (lipoatrophy) or thicken (lipohypertrophy). Lumps under the skin may also be caused by build-up of a protein called amyloid (cutaneous amyloidosis). The insulin may not work very well if you inject into a lumpy, shrunken or thickened area. Change the injection site with each injection to help prevent these skin changes.

General effects from diabetes treatment

▶ **Too low blood sugar (hypoglycaemia)**

Too low blood sugar may happen if you: drink alcohol; use too much insulin; exercise more than usual; eat too little or miss a meal.

Warning signs of too low blood sugar – these may come on

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

What to do if you get too low blood sugar

- Eat glucose tablets or another high sugar snack, like sweets, biscuits or fruit juice (always carry glucose tablets or a high sugar snack, just in case).
- Measure your blood sugar if possible and rest. You may need to measure your blood sugar more than once, as with all basal insulin products improvement from the period of low blood sugar may be delayed.
- Wait until the signs of too low blood sugar have gone or when your blood sugar level has settled. Then carry on with your insulin as usual.

What others need to do if you pass out

Tell everyone you spend time with that you 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
- 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

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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 used an injection of glucagon
- ▶ you have had too low blood sugar a few times recently.

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

▶ *Too high blood sugar (hyperglycaemia)*

Too high blood sugar may happen if you: eat more or exercise less than usual; drink alcohol; get an infection or a fever; have not used enough insulin; keep using less insulin than you need; forget to use your insulin or stop using insulin without talking to your doctor.

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

What to do if you get too high blood sugar

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

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 may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

7. Storage and disposal of Ryzodeg[®]

- Storage

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 pen label and carton, after 'Expiry'. The expiry date refers to the last day of that month.

Before first use

Store in a refrigerator (2°C to 8°C). Keep away from the freezing element. Do not freeze. 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 Ryzodeg[®] pre-filled pen (FlexTouch[®]) with you and keep it at room temperature (not above 30°C) or in a refrigerator (2°C to 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.

- Disposal

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.

8. Product description

- What it looks like

Ryzodeg[®] is presented as a clear and colourless solution for injection in pre-filled pen (300 units per 3 ml).

Pack sizes of 1 and 5 pre-filled pens of 3 ml. Not all pack sizes may be marketed.

- Ingredients

- Active ingredient

Insulin degludec and insulin aspart. Each ml of solution contains a total of

100 units (U) insulin degludec/insulin aspart in the ratio 70/30. Each pre-filled pen (3 ml) contains 300 units (U) of insulin degludec/insulin aspart.

- Inactive ingredients

Glycerol, metacresol, phenol, sodium chloride, zinc acetate, hydrochloric acid and sodium hydroxide (for pH adjustment) and water for injections.

Important information about some of the ingredients in Ryzodeg[®]

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

- MAL number

MAL18046010AZ

9. Manufacturer

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

10. Product Registration Holder

Novo Nordisk Pharma (Malaysia)
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50470 Kuala Lumpur
Malaysia

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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.

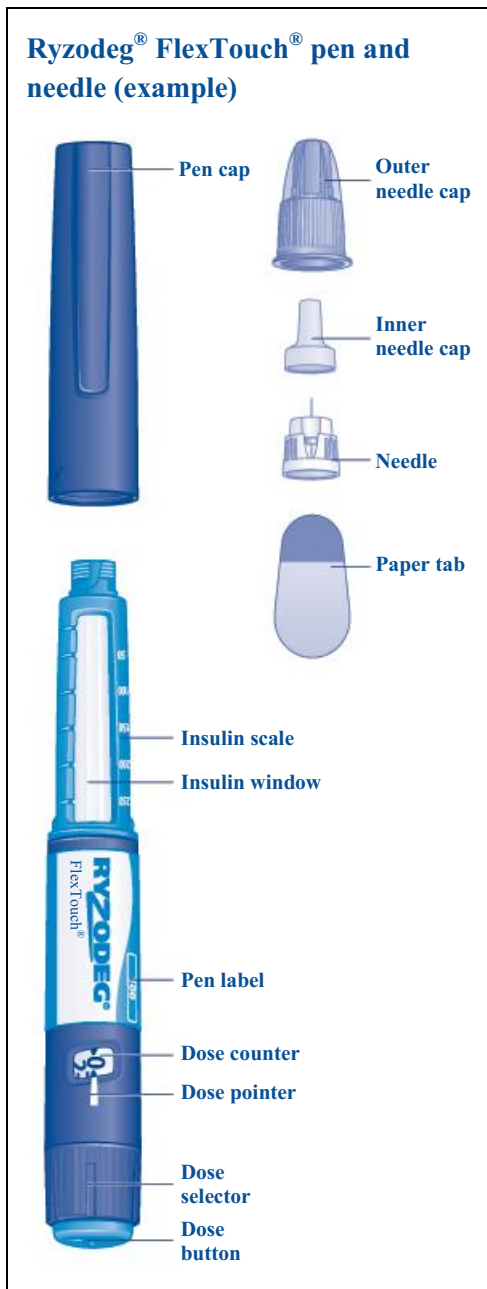
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1. Prepare your pen

- **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.**

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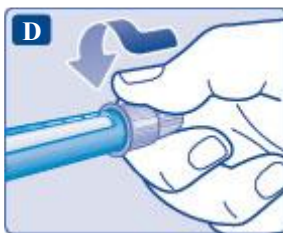
- **Check that the insulin in your pen is clear and colourless.** Look through the insulin window. If the insulin looks cloudy, do not use the pen.



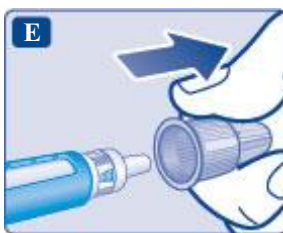
- **Take a new needle** and tear off the paper tab.



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

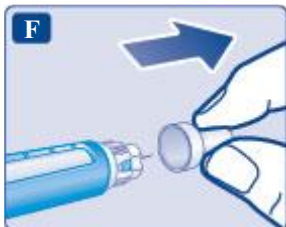


- **Pull off the outer needle cap and keep it for later.** You will need it after the injection, to correctly remove the needle from the pen.



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

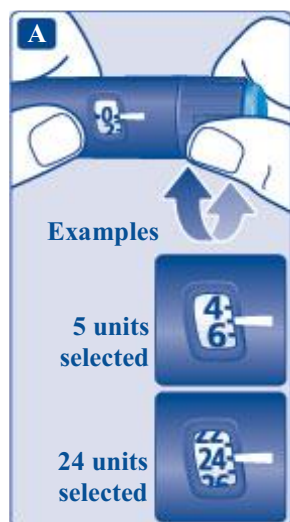
If a drop of insulin still does not appear, dispose of the pen and use a new one.

- △ **Always make sure that a drop appears** at the needle tip before you inject. This makes sure that the insulin flows. If no drop appears, you will **not** inject any insulin, even though the dose counter may move. This may indicate a blocked or damaged needle.
- △ **Always check the flow before you inject**. If you do not check the flow, you may get too little insulin or no insulin at all. This may lead to 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.**

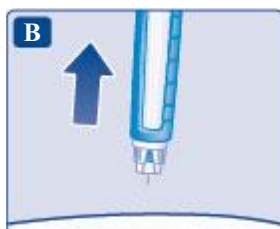
Do not count the pen clicks. If you select and inject the wrong dose, your blood sugar level may get too high or too low. Do not use the insulin scale, it only shows approximately how much insulin is left in your pen.

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.

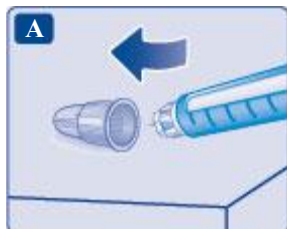


You may see a drop of insulin at the needle tip after injecting. This is normal and does not affect your dose.

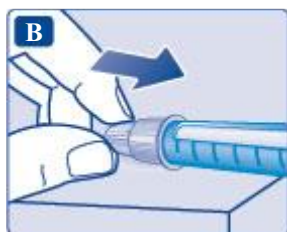
- ⚠ **Always watch the dose counter to know how many units you inject.**
The dose counter will show the exact number of units. Do not count the pen clicks.
Hold the dose button down until the dose counter returns to 0 after the injection. If the dose counter stops before it returns to 0, the full dose has not been delivered, which may result in too high blood sugar level.

5. After your injection

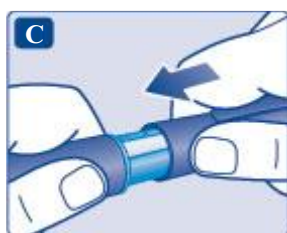
- **Lead the needle tip into the outer needle cap** on a flat surface without touching the needle or the outer cap.



- 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.

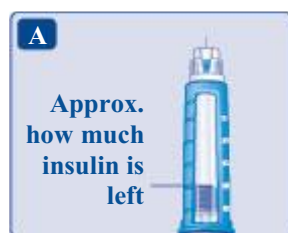


Always dispose of the needle after each injection. This reduces the risk of contamination, infection, leakage of insulin, blocked needles and inaccurate dosing. If the needle is blocked, you will **not** inject any insulin. When the pen is empty, throw it away **without** a needle on as instructed by 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 after each injection** and store your pen without the needle attached. This reduces the risk of contamination, infection, leakage of insulin, blocked needles and inaccurate dosing.

6. How much insulin is left?

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



- **To see precisely how much insulin is left**, use the dose counter:
Turn the dose selector until the **dose counter stops**. If it shows 80, **at least 80** units are left in your pen. If it shows **less than 80**, the number shown is the number of units left in your pen.



- Turn the dose selector back until the dose counter shows 0.
 - If you need more insulin than the units left in your pen, you can split your dose between two pens.
- ⚠ **Be very careful to calculate correctly if splitting your dose.**
If in doubt, take the full dose with a new pen. If you split the dose wrong, you will inject too little or too much insulin, which can lead to too high or too low blood sugar level.
- ⚠ **Further important information**
- **Always keep your pen with you.**
 - **Always carry an extra pen and new needles** with you, in case of loss or damage.
 - Always keep your pen and needles **out of sight and reach of others**, especially children.
 - **Never share** your pen or your needles with other people. It might lead to cross-infection.
 - **Never share** your pen with other people. Your medicine might be harmful to their health.
 - Caregivers must **be very careful when handling used needles** – to reduce the risk of needle injury and cross-infection.

Caring for your pen

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

- **Do not leave the pen in a car** or other place where it can get too hot or too cold.
- **Do not expose your pen to dust, dirt or liquid.**
- **Do not wash, soak or lubricate your pen.** If necessary, clean it with mild detergent on a moistened cloth.
- **Do not drop your pen** or knock it against hard surfaces.
If you drop it or suspect a problem, attach a new needle and check the insulin flow before you inject.
- **Do not try to refill your pen.** Once empty, it must be disposed of.
- **Do not try to repair your pen** or pull it apart.