

Package leaflet: information for the user

## Admelog® 100 units/ml solution for injection in pre-filled pen insulin lispro

Each pre-filled pen delivers 1-80 units in steps of 1 unit.

## sanofi

### Is this leaflet hard to see or read? Phone 0800 035 2525 for help.

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

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

**What is in this leaflet**

- What Admelog is and what it is used for
- What you need to know before you use Admelog
- How to use Admelog
- Possible side effects
- How to store Admelog
- Contents of the pack and other information

### 1. What Admelog is and what it is used for

Admelog is used to treat diabetes. It works more quickly than normal human insulin because the insulin molecule has been changed slightly.

You get diabetes if your pancreas does not make enough insulin to control the level of glucose in your blood. Admelog is a substitute for your own insulin and is used to control glucose in the long term. It works very quickly and lasts a shorter time than soluble insulin (2 to 5 hours). You should normally use Admelog within 15 minutes of a meal.

Your doctor may tell you to use Admelog as well as a longer-acting insulin. Each kind of insulin comes with another patient information leaflet to tell you about it. Do not change your insulin unless your doctor tells you to. Be very careful if you do change insulin.

Admelog is suitable for use in adults and children.

Admelog SoloStar is a disposable pre-filled pen containing 3 ml (300 units, 100 units/ml) of insulin lispro. One Admelog pre-filled pen contains multiple doses of insulin. The Admelog pre-filled pen dials 1 unit at a time. **The number of units are displayed in the dose window, always check this before your injection.** You can give from 1 to 80 units in a single injection. **If your dose is more than 80 units, you will need to give yourself more than one injection.**

### 2. What you need to know before you use Admelog

**Do not use Admelog**

- if you think **hypoglycaemia** (low blood sugar) is starting. Further in this leaflet it tells you how to deal with mild hypoglycaemia (see section 3: If you use more Admelog than you need).
- if you are **allergic** to insulin lispro or to any of the other ingredients of this medicine (listed in section 6).

**Warnings and precautions**

Admelog in pre-filled pen is only suitable for injecting just under the skin (see also section 3). Speak to your doctor if you need to inject your insulin by another method.

Record the brand name (“Admelog”) and Lot number (included on the outer cartons and labels of each pre-filled pen) of the product you are using and provide this information when reporting any side effects.

**Skin changes at the injection site**

The injection site should be rotated to prevent skin changes such as lumps under the skin. The insulin may not work very well if you inject into a lumpy area (see “How to use Admelog”). Contact your doctor if you are currently injecting into a lumpy area 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.

Talk to your doctor, pharmacist or nurse before using Admelog:

- If your blood sugar levels are well controlled by your current insulin therapy, you may not feel the warning symptoms when your blood sugar is falling too low. Warning signs are listed later in this leaflet. You must think carefully about when to have your meals, how often to exercise and how much to do. You must also keep a close watch on your blood sugar levels by testing your blood glucose often.
- A few people who have had hypoglycaemia after switching from animal insulin to human insulin have reported that the early warning symptoms were less obvious or different. If you often have hypoglycaemia or have difficulty recognising it, please discuss this with your doctor.
- If you answer YES to any of the following questions, tell your doctor, pharmacist or diabetes nurse
  - Have you recently become ill?
  - Do you have trouble with your kidneys or liver?
  - Are you exercising more than usual?

- You should also tell your doctor, pharmacist or diabetes nurse if you are planning to go abroad. The time difference between countries may mean that you have to have your injections and meals at different times from when you are at home.
- 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).
- This pen is not recommended for use by the blind or visually impaired without the help of someone trained to use the pen.

**Other medicines and Admelog**

Your insulin needs may change if you are taking

- the contraceptive pill,
- steroids,
- thyroid hormone replacement therapy,
- oral hypoglycaemics,
- acetyl salicylic acid,
- sulpha antibiotics,
- octreotide,
- “beta<sub>2</sub> stimulants” (for example ritodrine, salbutamol or terbutaline),
- beta-blockers, or
- some antidepressants (monoamine oxidase inhibitors or selective serotonin reuptake inhibitors),
- danazol,
- some angiotensin converting enzyme (ACE) inhibitors (for example captopril, enalapril), and
- angiotensin II receptor blockers.

Tell your doctor if you are taking, have recently taken or might take any other medicines (see also section “Warnings and precautions”).

**Admelog with alcohol**

Your blood sugar levels may change if you drink alcohol. Therefore the amount of insulin needed may change.

**Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. The amount of insulin you need usually falls during the first three months of pregnancy and increases for the remaining six months.

If you are breast-feeding, you may need to alter your insulin intake or diet.

**Driving and using machines**

Your ability to concentrate and react may be reduced if you have hypoglycaemia. Please keep this possible problem in mind in all situations where you might put yourself and others at risk (e.g. driving a car or using machines).

You should contact your doctor about the advisability of driving if you have:

- frequent episodes of hypoglycaemia
- reduced or absent warning signs of hypoglycaemia

**Admelog contains sodium**

This medicine contains less than 1 mmol (23 mg) sodium per dose, that is to say essentially “sodium-free”.

### 3. How to use Admelog

Always check the pack and the label of the pre-filled pen for the name and type of the insulin when you get it from your pharmacy. Make sure you get the Admelog that your doctor has told you to use.

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. To prevent the possible transmission of disease, each pen must be used by you only, even if the needle is changed.

**Dose**

- You should normally inject Admelog within 15 minutes of a meal. If you need to, you can inject soon after a meal. But your doctor will have told you exactly how much to use, when to use it, and how often. These instructions are only for you. Follow them exactly and visit your diabetes clinic regularly.
- If you change the type of insulin you use (for example from a human or animal insulin to an Admelog product), you may have to use more or less than before. This might just be for the first injection or it may be a gradual change over several weeks or months.
- Inject Admelog under the skin (subcutaneous use or “SC”). You should only inject it into a muscle if your doctor has told you to.

**Preparing Admelog**

- Admelog is already dissolved in water, so you do not need to mix it. But you must use it **only** if it looks like water. It must be clear, have no colour and no solid pieces in it. Check each time you inject yourself.

**Getting the SoloStar pre-filled pen ready to use (Please see user manual)**

- Admelog in pre-filled pen is only suitable for injecting just under the skin. Speak to your doctor if you need to inject your insulin by another method.
- First wash your hands.
- Read the instructions on how to use your pre-filled insulin pen. Please follow the instructions carefully. Here are some reminders.
- Use a clean needle (needles are not included).
- Always perform a safety test before each injection.

**Injecting Admelog**

- Before you make an injection, clean your skin as you have been instructed. Inject under the skin, as you were taught. Do not inject directly into a vein. After your injection, leave the needle in the skin for ten seconds to make sure you have injected the whole dose. Do not rub the area you have just injected. Make sure you inject at least half an inch (1 cm) from the last injection and that you ‘rotate’ the places you inject, as you have been taught. It doesn’t matter which injection site you use, either upper arm, thigh, buttock or abdomen, your Admelog injection will still work quicker than soluble human insulin.
- You must not administer Admelog by the intravenous route (IV). Inject Admelog as your physician or nurse has taught you. Only your physician can administer Admelog by the intravenous route. He will only do this under special circumstances such as surgery or if you are ill and your glucose levels are too high.

**After injecting**

- As soon as you have done the injection, unscrew the needle from the pre-filled pen using the outer needle cap. **Do not share your needles. Do not share your pen.** Replace the cap on your pen.

**Further injections**

- Every time you use a pre-filled pen you must use a new needle. Always perform a safety test before each injection. You can see roughly how many units of insulin are left by looking at where the plunger is on the insulin scale.
- Do not mix any other insulin in your pre-filled pen. Once the pre-filled pen is empty, do not use it again. Please get rid of it carefully – your pharmacist or diabetes nurse will tell you how to do this.

**If you use more Admelog than you should**
If you use more Admelog than you need or are unsure how much you have injected, a low blood sugar may occur. Check your blood sugar. If your blood sugar is low (**mild hypoglycaemia**), eat glucose tablets, sugar or drink a sugary drink. Then eat fruit, biscuits, or a sandwich, as your doctor has advised you and have some rest. This will often get you over mild hypoglycaemia or a minor insulin overdose. If you get worse and your breathing is shallow and your skin gets pale, tell your doctor at once. A glucagon injection can treat quite severe hypoglycaemia. Eat glucose or sugar after the glucagon injection. If you do not respond to glucagon, you will have to go to hospital. Ask your doctor to tell you about glucagon.

**If you forget to use Admelog**

If you use less Admelog than you need or are unsure how much you have injected, a high blood sugar may occur. Check your blood sugar.

If hypoglycaemia (low blood sugar) or hyperglycaemia (high blood sugar) is not treated, they can be very serious and cause headaches, feeling sick (nausea), being sick (vomiting), loss of fluids (dehydration), unconsciousness, coma or even death (see “Hypoglycaemia” and “Hyperglycaemia and diabetic ketoacidosis” in section 4 “Possible Side Effects”).

**Three simple steps** to avoid hypoglycaemia or hyperglycaemia are:

- Always keep spare syringes and a spare vial of Admelog, or a spare pen and cartridges, in case you lose your SoloStar pre-filled pen or it gets damaged.
- Always carry something to show you are diabetic.
- Always carry sugar with you.

**If you stop using Admelog**

If you use less Admelog than you need, a high blood sugar may occur. Do not change your insulin unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### 4. Possible side effects

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

Systemic allergy is rare (may affect up to 1 in 1,000 people). The symptoms are as follows:

- rash over the whole body
- difficulty in breathing
- wheezing
- blood pressure dropping
- heart beating fast
- sweating

If you think you are having this sort of insulin allergy with Admelog, tell your doctor at once.

Local allergy is common (may affect up to 1 in 10 people). Some people get redness, swelling or itching around the area of the insulin injection. This usually clears up in anything from a few days to a few weeks. If this happens to you, tell your doctor.

**Skin changes at the injection site**

Lipodystrophy is uncommon (it may affect up to 1 in 100 people).

If you inject insulin too often 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; how often this occurs is not known). The insulin may not work very well if you inject into a lumpy area. Change the injection site with each injection to help prevent these skin changes.

Oedema (e.g. swelling in arms, ankles; fluid retention) has been reported, particularly at the start of insulin therapy or during a change in therapy to improve control of your blood glucose.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

**Common problems of diabetes**

**A. Hypoglycaemia**

Hypoglycaemia (low blood sugar) means there is not enough sugar in the blood. This can be caused if:

- you inject too much Admelog or other insulin;
- you miss or delay meals or change your diet;
- you exercise or work too hard just before or after a meal;
- you have an infection or illness (especially diarrhoea or vomiting);
- there is a change in your need for insulin; or
- you have trouble with your kidneys or liver which gets worse.

Alcohol and some medicines can affect your blood sugar levels (see section 2).

The first symptoms of low blood sugar usually come on quickly and include the following:

- tiredness
- nervousness or shakiness
- headache
- rapid heartbeat
- feeling sick
- cold sweat

While you are not confident about recognising your warning symptoms, avoid situations, e.g. driving a car, in which you or others would be put at risk by hypoglycaemia.

**B. Hyperglycaemia and diabetic ketoacidosis**
Hyperglycaemia (too much sugar in the blood) means that your body does not have enough insulin. Hyperglycaemia can be brought about by:

- not using your Admelog or other insulin;
- using less insulin than your doctor tells you to;
- eating a lot more than your diet allows; or
- fever, infection or emotional stress.

Hyperglycaemia can lead to diabetic ketoacidosis. The first symptoms come on slowly over many hours or days. The symptoms include the following:

- feeling sleepy
- flushed face
- thirst
- no appetite
- fruity smell on the breath
- feeling or being sick

Severe symptoms are heavy breathing and a rapid pulse. **Get medical help immediately.**

**C. Illness**

If you are ill, especially if you feel sick or are sick, the amount of insulin you need may change. **Even when you are not eating normally, you still need insulin.** Test your urine or blood, follow your ‘sick rules’, and tell your doctor.

### 5. How to store Admelog

Keep out of the sight and reach of children.

Do not use Admelog in pre-filled pen after the expiry date which is stated on the label and the carton. The expiry date refers to the last day of that month.

Before the first use store your pre-filled pen in a refrigerator (2 °C – 8 °C). Do not freeze. Keep the pre-filled pen in the outer carton in order to protect from light.

Keep your Admelog pre-filled pen in use at room temperature (below 30 °C) and dispose of after 4 weeks. Do not keep the pre-filled pen that you are using in the fridge. The pre-filled pen should not be stored with the needle attached. Always keep the cap on the pre-filled pen when you are not using it in order to protect from light.

Do not use Admelog pre-filled pen if the solution is coloured or it has solid pieces in it. You must use it **only** if it looks like water. Check this each time you inject yourself.

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 to protect the environment.

### 6. Contents of the pack and other information

**What Admelog contains**

- The active substance is insulin lispro. Each ml of the solution contains 100 units (equivalent to 3.5 mg) of insulin lispro. Each pre-filled pen contains 3 ml of solution for injection, equivalent to 300 units.
- The other ingredients are: metacresol, glycerol, disodium hydrogen phosphate heptahydrate, zinc oxide and water for injection. Sodium hydroxide or hydrochloric acid may have been used to adjust the acidity (see section 2 “Admelog contains sodium”).

**What Admelog looks like and contents of the pack**
Admelog, solution for injection is a clear, colourless, aqueous solution. Each pre-filled pen contains 3 ml. The Admelog in pre-filled pen (SoloStar) comes in a pack of 1, 3, 5 or 10 pre-filled pens. Not all pack sizes may be marketed.

The Admelog in your pre-filled pen is the same as the Admelog, which comes in separate Admelog cartridges. The pre-filled pen simply has a built-in cartridge. When the pre-filled pen is empty you cannot use it again.

**Marketing Authorisation Holder**
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Tel: 0800 035 2525
Email: [uk-medicalinformation@sanofi.com](mailto:uk-medicalinformation@sanofi.com)

**Manufacturer**

Sanofi-Aventis Deutschland GmbH, D-65926 Frankfurt am Main, Germany.

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist

**This leaflet was last revised in February 2022**

# Admelog solution for injection in pre-filled pen (SoloStar) INSTRUCTIONS FOR USE

**Read this first**

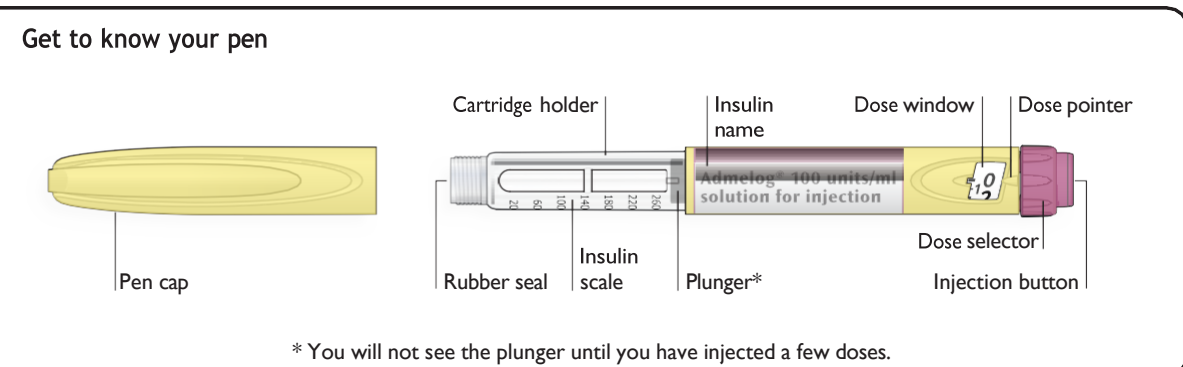
- Important information**
- Never share your pen – it is only for you.
  - Never use your pen if it is damaged or if you are not sure that it is working properly.
  - Always perform a safety test.
  - Always carry a spare pen and spare needles in case they got lost or stop working.
  - **Never re-use needles.** If you do you might not get your dose (underdosing) or get too much (overdosing) as the needle could block.

- Learn to inject**
- Talk with your doctor, pharmacist or nurse about how to inject, before using your pen.
  - Ask for help if you have problems handling the pen, for example if you have problems with your sight.
  - This pen is not recommended for use by the blind or visually impaired without the help of someone trained to use the pen.
  - Read all of these instructions before using your pen. If you do not follow all of these instructions, you may get too much or too little insulin.

**Need help?**

If you have any questions about your pen or about diabetes, ask your doctor, pharmacist or nurse or call the Sanofi number on the front of this leaflet.

- Extra items you will need:**
- a new sterile needle (see STEP 2).
  - a puncture resistant container for used needles and pens (see **Throwing your pen away**).



- How to care for your pen**
- Handle your pen with care**
- Do not drop your pen or knock it against hard surfaces.
  - If you think that your pen may be damaged, do not try to repair it, use a new one.
- Protect your pen from dust and dirt**
- You can clean the outside of your pen by wiping it with a damp cloth (water only). Do not soak, wash or lubricate your pen – this may damage it.
- For further information on the storage and use of your pen, please refer to sections 2 and 5 of the package leaflet.

- Throwing your pen away**
- Remove the needle before throwing your pen away.
  - Throw away your used pen as told by your pharmacist or local authority.

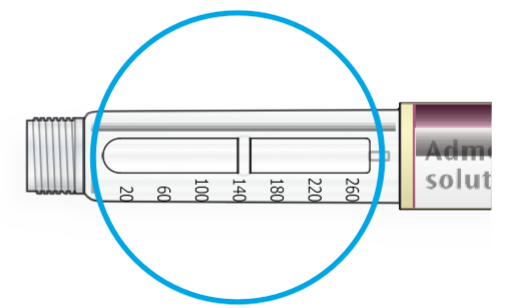
- STEP 1: Check your pen**
- Take a new pen out of the fridge at least 1 hour before you inject. Cold insulin is more painful to inject.

- A Check the name and expiry date on the label of your pen.**
- Make sure you have the correct insulin. This is especially important if you have other injector pens.
  - Never use your pen after the expiry date.



- B Pull off the pen cap.**
- 

- C Check that the insulin is clear.**
- Do not use the pen if the insulin looks cloudy, coloured or contains particles.



- STEP 2: Attach a new needle**
- Always use a new sterile needle for each injection. This helps stop blocked needles, contamination and infection.
  - Only use needles that are compatible for use with Admelog.

- A Take a new needle and peel off the protective seal.**
- 
- B Keep the needle straight and screw it onto the pen until fixed. Do not overtighten.**
- 

- C Pull off the outer needle cap. Keep this for later.**
- 

- D Pull off the inner needle cap and throw away.**
- 

- i Handling needles**
- Take care when handling needles – this is to prevent needle injury and cross-infection.

- STEP 3: Do a safety test**
- Always do a safety test before each injection – this is to:
    - check your pen and the needle are working properly.
    - make sure that you get the correct insulin dose.

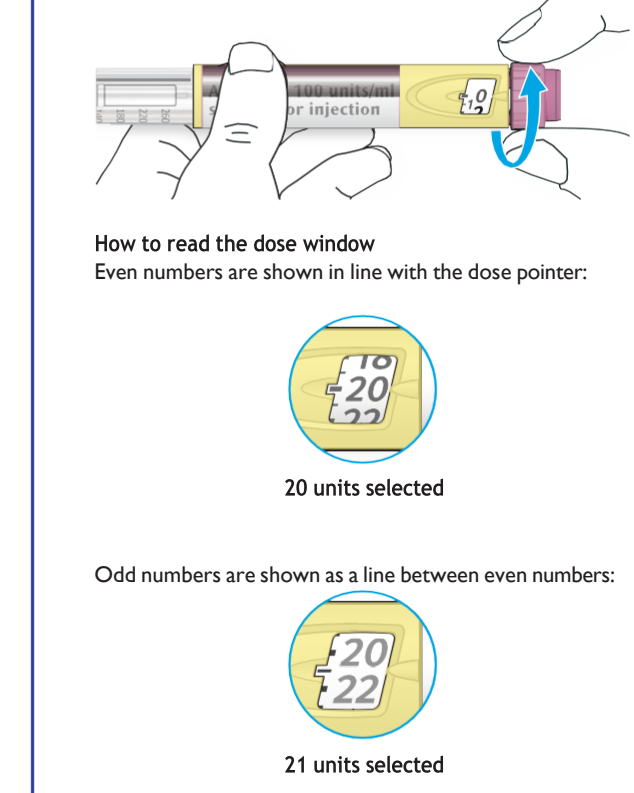
- A Select 2 units by turning the dose selector until the dose pointer is at the 2 mark.**
- 
- B Press the injection button all the way in.**
- When insulin comes out of the needle tip, your pen is working correctly.
- 

- If no insulin appears:**
- You may need to repeat this step up to 3 times before seeing insulin.
  - If no insulin comes out after the third time, the needle may be blocked. If this happens:
    - change the needle (see STEP 6 and STEP 2),
    - then repeat the safety test (STEP 3).
  - Do not use your pen if there is still no insulin coming out of the needle tip. Use a new pen.
  - Never use a syringe to remove insulin from your pen.

- i If you see air bubbles**
- You may see air bubbles in the insulin. This is normal, they will not harm you.

- STEP 4: Select the dose**
- Never select a dose or press the injection button without a needle attached. This may damage your pen.

- A Make sure a needle is attached and the dose is set to '0'.**
- 
- B Turn the dose selector until the dose pointer lines up with your dose.**
- If you turn past your dose, you can turn back down.
  - If there are not enough units left in your pen for your dose, the dose selector will stop at the number of units left.
  - If you cannot select your full prescribed dose, use a new pen or inject the remaining units and use a new pen to complete your dose.



- i Units of insulin in your pen**
- Your pen contains a total of 300 units of insulin. You can select doses from 1 to 80 units in steps of 1 unit. Each pen contains more than one dose.
  - You can see roughly how many units of insulin are left by looking at where the plunger is on the insulin scale.

- STEP 5: Inject your dose**
- If you find it hard to press the injection button in, do not force it as this may break your pen. See the **i** section below for help.

- A Choose a place to inject as shown in the picture.**
- 
- B Push the needle into your skin as shown by your doctor, pharmacist or nurse.**
- Do not touch the injection button yet.

- C Place your thumb on the injection button. Then press all the way in and hold.**
- Do not press at an angle – your thumb could block the dose selector from turning.

- D Keep the injection button held in and when you see "0" in the dose window, slowly count to 10.**
- This will make sure you get your full dose.
- 

- E After holding and slowly counting to 10, release the injection button. Then remove the needle from your skin.**
- 

- i If you find it hard to press the button in:**
- Change the needle (see STEP 6 and STEP 2) then do a safety test (see STEP 3).
  - If you still find it hard to press in, get a new pen.
  - Never use a syringe to remove insulin from your pen.

- STEP 6: Remove the needle**
- Take care when handling needles – this is to prevent needle injury and cross-infection.
  - Never put the inner needle cap back on.

- A Put the outer needle cap back on the needle, and use it to unscrew the needle from the pen.**
- To reduce the risk of accidental needle injury, never replace the inner needle cap.
  - If your injection is given by another person, or if you are giving an injection to another person, special caution must be taken by this person when removing and disposing of the needle.
  - Follow recommended safety measures for removal and disposal of needles (contact your doctor, pharmacist or nurse) in order to reduce the risk of accidental needle injury and transmission of infectious diseases.

- B Throw away the used needle in a puncture resistant container, or as told by your pharmacist or local authority.**
- 

- C Put the pen cap back on.**
- Do not put the pen back in the fridge.
-