PATIENT MEDICATION INFORMATION – ADMELOG® VIAL

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

ADMELOG® Vial *(Ad-mah-log)*

Insulin lispro injection

Read this carefully before you start taking **ADMELOG** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ADMELOG**.

ADMELOG is a biosimilar biologic drug (biosimilar) to the reference biologic drug Humalog. A biosimilar is authorized based on its similarity to a reference biologic drug that was already authorized for sale.

Serious Warnings and Precautions

- Hypoglycemia or low blood sugar is the most common adverse effect experienced by insulin users. Blood glucose monitoring is recommended for all patients with diabetes. Uncorrected hypoglycemic or hyperglycemic reactions can cause loss of consciousness, coma or even death. Information on how to recognize these symptoms is provided below.
- This human insulin analogue differs from other insulins because it has a unique structure, a very quick onset of action and a short duration of activity. ADMELOG should be given within 15 minutes before a meal or when necessary shortly after a meal instead (within 20 minutes of the start of the meal). The short duration of action of ADMELOG means that if you have Type 1 diabetes you also need to use a longer acting insulin, such as insulin NPH to give the best glucose control (except when using an insulin infusion pump).
- ADMELOG should not be used if it is not water-clear and colourless or if it has formed a deposit of solid particles on the wall of the vial.
- Any change of insulin should be made cautiously and only under medical supervision. Changes in purity, strength, brand (manufacturer), type (regular, NPH, etc.), species (beef, pork, beef-pork, human), and/or method of manufacture (recombinant DNA versus animal-source insulin) may result in the need for a change in dosage.
- Mixing of ADMELOG with animal insulins is not recommended.
- Patients taking ADMELOG may require a change in dosage from that used with other insulins. If an adjustment is needed, it may occur with the first dose or over a period of several weeks.
- Insulin infusion pump: when used in an insulin infusion pump, ADMELOG should not be diluted or mixed with any other insulin. Carefully read and follow the insulin infusion pump manufacturer's instructions and this insert before using ADMELOG.

What is ADMELOG used for?

Insulin is a hormone produced by the pancreas, a large gland that lies near the stomach. This hormone is necessary for the body's correct use of food, especially sugar. Diabetes occurs when the pancreas does not make enough insulin to meet your body's needs.

To control your diabetes, your doctor has prescribed injections of insulin to keep your blood glucose at a near-normal level.

How does ADMELOG work?

Insulin lispro is a recombinant DNA sourced human insulin analogue. ADMELOG consists of zinc-insulin

lispro crystals dissolved in a clear fluid. ADMELOG is used to control high blood sugar (glucose) in people with diabetes. ADMELOG takes effect more rapidly and has a shorter duration of activity as compared to regular insulin.

The rapid onset of activity requires ADMELOG to be given within 15 minutes before a meal. When necessary, ADMELOG may be given shortly after a meal instead (within 20 minutes of the start of the meal). The time course of action of any insulin may vary to some extent in different individuals or at different times in the same individual. As with all insulin preparations, the duration of action of ADMELOG is dependent on dose, site of injection, blood supply, temperature, and physical activity.

Proper control is important. Uncontrolled diabetes (hyperglycemia) over a long period of time can result in a number of serious problems such as blindness, kidney failure, poor circulation/heart attacks, strokes and/or nerve damage. These problems can be prevented or reduced by good diabetes management. This will require close and constant cooperation with your diabetes healthcare team including: yourself, your doctor and your diabetes educators (nurses, dietitians, social workers, pharmacists and other healthcare professionals). Thus, you can lead an active, healthy and productive life by eating a balanced daily diet, exercising regularly, and taking your insulin injections as prescribed.

You have been instructed to test your blood and/or your urine regularly for glucose. If your blood tests consistently show above- or below-normal glucose levels or your urine tests consistently show the presence of glucose, your diabetes is not properly controlled, and you must let your doctor know.

What are the ingredients in ADMELOG?
Medicinal ingredient: Human Insulin Analogue

Non-medicinal ingredients: m-Cresol [3.15 mg/ml]; Glycerol; Dibasic sodium phosphate; Water for injections; Zinc oxide.

Hydrochloric acid and sodium hydroxide may be used to adjust pH to 7.0 – 7.8.

ADMELOG comes in the following dosage forms:
ADMELOG is a sterile solution containing insulin lispro injection. It is available in: 10 mL vial

ADMELOG is also available in:
- 3 mL cartridge (for use only with JuniorSTAR and AllStar PRO reusable pens)
- 3 mL disposable prefilled SoloSTAR injection pen.

Always keep an extra supply of ADMELOG i.e. a spare pen and cartridge or prefilled pen on hand. Always wear identification to indicate that you have diabetes so that appropriate treatment can be given if complications occur away from home.

When you receive your insulin from the pharmacy, always check to see that:
1. The name ADMELOG appears on the carton and cartridge or prefilled pen label.
2. The carton and cartridge or prefilled pen label is correct for your type of insulin.
3. The expiration date on the package will allow you to use the insulin before that date.

Do not use ADMELOG if:
- your blood sugar is too low (hypoglycemia). After treating your low blood sugar, follow your healthcare professional's instructions on the use of ADMELOG.
- if are allergic to anything in ADMELOG. A complete list of ingredients in ADMELOG is provided above.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ADMELOG. Talk about any health conditions or problems you may have, including if you:

- have trouble with your kidneys or liver, your doctor may decide to alter your insulin dose.
- drink alcohol (including wine and beer): watch for signs of hypoglycemia and never drink alcohol on an empty stomach.
- exercise more than usual or if you want to change your usual diet. Exercise may lower your body's need for insulin during and for some time after the activity. Exercise may also speed up the effect of an insulin dose, especially if the exercise involves the area of injection site.
- are ill. Illness, especially with nausea and vomiting, may cause your insulin requirements to change. Even if you are not eating, you will still require insulin. You and your doctor should establish a sick day plan for you to use in case of illness. When you are sick, test your blood/urine frequently.
- are travelling across more than 2 time zones. You should consult your doctor concerning adjustments in your insulin schedule.
- are pregnant. ADMELOG can be used in pregnancy if clinically indicated. Data on a large number of pregnancies exposed to insulin lispro (100 U/mL) do not indicate any adverse effect on pregnancy or on the health of the foetus/newborn. Good control of diabetes is especially important for you and your unborn baby. Pregnancy may make managing your diabetes more difficult. If you are planning to have a baby, are pregnant, or are nursing a baby, consult your doctor.
- use other medicines. Many medicines affect the way glucose works in your body and this may influence your insulin dose. Medicines that may affect your insulin treatment are noted in the following sections. Talk to your doctor or pharmacist if you take, or change any other medicines, even those not prescribed.
- if you develop 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 healthcare professional if you are currently injecting into a lumpy area before you start injecting in a different area. A sudden change of site may result in hypoglycemia. Your healthcare professional may tell you to check your blood sugar more closely, and to adjust your insulin or your other antidiabetic medications dose.

Other warnings you should know about:
DO NOT USE ANY OTHER INSULIN EXCEPT ON YOUR DOCTOR'S ADVICE AND DIRECTION.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with ADMELOG:
Insulin requirements may be increased if you are taking other drugs with hyperglycemic activity, such as oral contraceptives (for example, birth control pills, injections and patches), corticosteroids, or thyroid replacement therapy. Insulin requirements may be decreased in the presence of agents such as oral antidiabetic agents, salicylates (aspirin), sulfa antibiotics, certain antidepressants (monoamine oxidase inhibitors), beta-blockers, alcohol, ACE inhibitors and angiotensin II receptor blockers. Always discuss any medications you are taking with your doctor.

The use of thiazolidinediones (such as rosiglitazone and pioglitazone), alone or in combination with other antidiabetic agents (including insulin), has been associated with heart failure and swelling of the lower extremities. Please contact your physician immediately if you develop symptoms of shortness of breath, fatigue, exercise intolerance, or swelling of the lower extremities while you are on these agents.

How to take ADMELOG:
ADMELOG is a sterile solution. ADMELOG should be given by subcutaneous injection, or by continuous subcutaneous insulin infusion pump. The concentration of ADMELOG in 10 mL vials is 100 units/mL (U-100).

When used as a meal-time insulin, ADMELOG should be given within 15 minutes before a meal, or when necessary shortly after a meal instead (within 20 minutes of the start of the meal).

ADMELOG is a clear and colourless liquid with a water-like appearance and consistency. Do not use if it appears cloudy, thickened, or slightly coloured or if solid particles are visible.

Always check the appearance of your vial of ADMELOG before using, and if you note anything unusual in its appearance or notice your insulin requirements changing markedly, consult your doctor.

Injection Procedure

Correct Syringe:
It is important to use a syringe that is marked for U-100 insulin preparations since ADMELOG contains 100 units/mL. Using an incorrect syringe could lead to a mistake in dosing and cause serious medical problems for you, such as a blood glucose level that is too low or too high.

Syringe Use:
To help avoid contamination and possible infection, follow these instructions exactly.

Disposable plastic syringes and needles should be used only once and then discarded in a closable, puncture-resistant sharps container (like a biohazard container) or as directed by your healthcare professional. NEEDLES AND SYRINGES MUST NOT BE SHARED, as this may risk transmission of infectious agents.

Reusable glass syringes and needles must be sterilized before each injection. Follow the package directions supplied with your syringe.

Preparing the Dose:
1. To avoid medication errors, check the vial label of the insulin before each injection.
2. Inspect the insulin. ADMELOG should be a clear and colorless solution with no visible particles. Do not use it if you notice anything unusual in the appearance of the solution.
3. Make sure the insulin is at room temperature to minimize local irritation at the injection site.
4. Wash your hands.
5. Flip off the plastic protective cap but do not remove the stopper if using a new vial.
6. Wipe the top of the vial with an alcohol swab.
7. If you are mixing insulins, refer to the instructions for mixing below.
8. A new sterile syringe must be used.
9. Remove the cover from the needle. Draw air into the syringe equal to your ADMELOG dose. Put the needle through the rubber top of the ADMELOG vial and inject the air into the vial.
10. Turn the vial and syringe upside down. Hold the vial and syringe firmly in one hand.
11. Making sure the tip of the needle is in the ADMELOG vial, withdraw the correct dose into the syringe.
12. Before removing the needle from the vial, check your syringe for air bubbles, which reduce the amount of ADMELOG. If bubbles are present, hold the syringe straight up and tap its side until the bubbles float to the top. Push them out with the plunger and withdraw the correct dose.
13. Remove the needle from the vial and lay the syringe down so that the needle does not touch anything.
14. An empty vial must never be reused and must be properly discarded.

Mixing ADMELOG With Longer-Acting Insulin Formulations (insulin NPH)

MIXING ADMELOG WITH ANIMAL INSULINS IS NOT RECOMMENDED.

1. ADMELOG should be mixed with longer-acting insulins such as insulin NPH only on the advice of your doctor.
2. Draw air into your syringe equal to the amount of longer-acting insulin (insulin NPH) you are taking. Insert the needle into the longer-acting insulin vial and inject the air, taking care not to come in contact with the insulin in the vial. Withdraw the needle.
3. Now inject air into your ADMELOG vial in the same manner, but do not withdraw the needle.
4. Turn the vial and syringe upside down.
5. Making sure the tip of the needle is in the ADMELOG, withdraw the correct dose of ADMELOG into the syringe.
6. Before removing the needle from the vial of ADMELOG, check your syringe for air bubbles, which reduce the amount of ADMELOG in it. If bubbles are present, hold the syringe straight up and tap its side until the bubbles float to the top. Push them out with the plunger and withdraw the correct dose. Gently roll or shake the long acting insulin (insulin NPH) vial until the insulin is mixed.
7. Remove the needle from the vial of ADMELOG and insert it into the vial of the longer-acting insulin (insulin NPH). Turn the vial and syringe upside down. Making sure the tip of the needle is in the insulin, withdraw your dose of longer-acting insulin.
8. Remove the needle and lay the syringe down so that the needle does not touch anything.

Follow your doctor's instructions on mixing your insulin just before giving your injection. ADMELOG should be injected immediately after mixing. It is important to be consistent in your method.

Syringes from different manufacturers may vary in the amount of space between the bottom line and the needle. Because of this, do not change the sequence of mixing, or the model and brand of syringe or needle that the doctor has prescribed.

Injection:

Injection sites within an injection area (abdomen, thigh, buttock or upper arm) must be rotated from one injection to the next as instructed by your healthcare professional. This will reduce the risk of skin shrinking or thickening or lumps at the site.

- **Do not** inject where the skin has pits, is thickened, or has lumps.
- **Do not** inject where the skin is tender, bruised, scaly or hard, or into scars or damaged.

Prepare the injection site as directed by your healthcare professional. Insert the needle as instructed by your doctor. Push the plunger in as far as it will go. Pull the needle out and apply gentle pressure over the injection site for several seconds. Do not rub the area. To avoid tissue damage, give the next injection at a site at least 1 cm (0.5 inches) from the previous injection site.

Use of ADMELOG in an Insulin Infusion Pump:

1. Health Canada approved insulin infusion pumps may be used to infuse ADMELOG U-100. Read and follow the instructions that accompany the infusion pump.
2. Be sure to use the correct reservoir and catheter for the pump.
3. Change the ADMELOG in the reservoir at least every 14 days. Change the infusion set as recommended in pump manufacturers' instructions (typically every 3 days is recommended) or as directed by your healthcare professional. Use aseptic technique when inserting the infusion set.

4. In the event of a hypoglycemic episode, the infusion should be stopped until the episode is resolved. If repeated or severe low blood glucose levels occur, notify your health care professional and consider the need to reduce or temporarily stop your insulin infusion.
5. A pump malfunction or obstruction of the infusion set can result in a rapid rise in glucose levels. If an interruption to insulin flow is suspected, follow the instructions in the product literature and if appropriate, notify your health care professional.
6. When used with an insulin infusion pump, ADMELOG should not be mixed with any other insulin.

Usual dose:
Your doctor has told you which insulin to use, how much, and when and how often to inject it. Because each patient's case of diabetes is different, this schedule has been individualized for you.

Your usual ADMELOG dose may be affected by changes in your food, activity, or work schedule. Carefully follow your doctor's instructions to allow for these changes. Other things that may affect your ADMELOG dose are illness, pregnancy, medication, exercise and travel.

Overdose:
Hypoglycemia (too little glucose in the blood) is one of the most frequent adverse events experienced by insulin users. It can be brought about by:

1. Missing or delaying meals
2. Taking too much insulin
3. Exercising or working more than usual
4. An infection or illness (especially with diarrhea or vomiting)
5. A change in the body's need for insulin
6. Diseases of the adrenal, pituitary, or thyroid gland, or progression of kidney or liver disease
7. Interactions with other drugs that lower blood glucose, such as oral hypoglycemics, salicylates, sulfa antibiotics, and certain antidepressants
8. Consumption of alcoholic beverages

Dietary Implications:
If a usual meal cannot be obtained at the appropriate time, then to avoid hypoglycemia, you should take the amount of carbohydrate prescribed for this meal in the form of orange juice, syrup, candy, or bread and milk, without changing your insulin dosage. If it becomes necessary to omit a meal on account of nausea and vomiting, you should test your blood sugar level and notify your doctor.

Mild to moderate hypoglycemia may be treated by eating foods or drinks that contain sugar. Patients should always carry a quick source of sugar, such as candy mints or glucose tablets.

More severe hypoglycemia may require the assistance of another person. Patients who are unable to take sugar orally or who are unconscious should be treated with intravenous administration of glucose at a medical facility or should be given an injection of glucagon (either intramuscular or subcutaneous). The patient should be given oral carbohydrates as soon as consciousness is recovered.

If you think you have taken too much ADMELOG, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

What are possible side effects from using ADMELOG?
These are not all the possible side effects you may feel when taking ADMELOG. If you experience any side effects not listed here, contact your healthcare professional. Please also see Serious Warnings and Precautions.

Hypoglycemia:
One of the most frequent adverse events experienced by insulin users is hypoglycemia (see To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ADMELOG.).

Diabetic Acidosis and Coma:
Diabetic acidosis may develop if your body has too little insulin (this is the opposite of insulin reaction, which is the result of too much insulin in the blood). Diabetic acidosis may be brought on if you omit your insulin or take less than the doctor has prescribed, eat significantly more than your diet calls for, or develop a fever or infection. With acidosis, urine tests show a large amount of sugar and acetone.

The first symptoms of diabetic acidosis usually come on gradually, over a period of hours or days, and include a drowsy feeling, flushed face, thirst, and loss of appetite. Heavy breathing and a rapid pulse are more severe symptoms.

If uncorrected, loss of consciousness, coma, or death can result. Therefore, it is important that you obtain medical assistance immediately.

Injection Site Reactions:
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 (localized cutaneous amyloidosis). The insulin may not work very well if you inject into a lumpy area. If you notice either of these conditions, consult your healthcare professional as a sudden change of site may result in hypoglycemia. A change in your injection technique may help alleviate the problem.

Allergy to Insulin:
Patients occasionally experience redness, swelling, and itching at the site of injection of insulin. This condition, called local allergy, usually clears up in a few days to a few weeks. If you have local reactions, contact your doctor, who may recommend a change in the type or species of insulin.

Less common, but potentially more serious, is generalized allergy to insulin, which may cause rash over the whole body, shortness of breath, wheezing, reduction in blood pressure, fast pulse, or sweating. Severe cases of generalized allergy may be life threatening. If you think you are having a generalized allergic reaction to insulin, notify a doctor immediately. Your doctor may recommend skin testing, that is, injecting small doses of other insulins into the skin, in order to select the best insulin for you to use. Patients who have had severe generalized allergic reactions to insulin should be skin tested with each new preparation to be used before treatment with that preparation is started.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects
You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:
Prior to first use, ADMELOG insulin vials should be stored in a refrigerator between 2° and 8°C. Do not freeze. Do not expose to excessive heat or sunlight. The vial of ADMELOG that you are currently using can be kept unrefrigerated, for up to 28 days, as long as it is kept as cool as possible (below 30°C) and away from direct heat and light. Vials in use, or not refrigerated, should be discarded after 28 days even if they still contain ADMELOG. Do not use ADMELOG if it has been frozen.

DO NOT USE A VIAL OF ADMELOG AFTER THE EXPIRATION DATE STAMPED ON THE LABEL.

Keep out of reach and sight of children.

If you want more information about ADMELOG:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website; Sanofi's website at http://www.sanofi.ca, or by calling 1-888-852-6887.

This leaflet was prepared by sanofi-aventis Canada Inc.

Last Revised: December 02, 2021

PATIENT MEDICATION INFORMATION - ADMELOG® Cartridge

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

ADMELOG® Cartridge (*Ad-mah-log*)

Insulin lispro injection

Cartridges are for use ONLY with AllStar® PRO and JuniorSTAR® pens.

Read this carefully before you start taking **ADMELOG** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ADMELOG**.

ADMELOG is a biosimilar biologic drug (biosimilar) to the reference biologic drug Humalog. A biosimilar is authorized based on its similarity to a reference biologic drug that was already authorized for sale.

Serious Warnings and Precautions

- Hypoglycemia or low blood sugar is the most common adverse effect experienced by insulin users. Blood glucose monitoring is recommended for all patients with diabetes. Uncorrected hypoglycemic or hyperglycemic reactions can cause loss of consciousness, coma or even death. Information on how to recognize these symptoms is provided below.
- This human insulin analogue differs from other insulins because it has a unique structure, a very quick onset of action and a short duration of activity. ADMELOG should be given within 15 minutes before a meal or when necessary shortly after a meal instead (within 20 minutes of the start of the meal). The short duration of action of ADMELOG means that if you have Type 1 diabetes you also need to use a longer acting insulin such as insulin NPH to give the best glucose control (except when using an insulin infusion pump).
- ADMELOG should not be used if it is not water-clear and colourless or if it has formed a deposit of solid particles on the wall of the cartridge.
- Any change of insulin should be made cautiously and only under medical supervision. Changes in purity, strength, brand (manufacturer), type (regular, NPH, etc.), species (beef, pork, beef-pork, human), and/or method of manufacture (recombinant DNA versus animal-source insulin) may result in the need for a change in dosage.
- Mixing of ADMELOG with animal insulins is not recommended.
- Patients taking ADMELOG may require a change in dosage from that used with other insulins. If an adjustment is needed, it may occur with the first dose or over a period of several weeks.

What is ADMELOG used for?

Insulin is a hormone produced by the pancreas, a large gland that lies near the stomach. This hormone is necessary for the body's correct use of food, especially sugar. Diabetes occurs when the pancreas does not make enough insulin to meet your body's needs.

To control your diabetes, your doctor has prescribed injections of insulin to keep your blood glucose at a near-normal level.

How does ADMELOG work?

Insulin lispro is a recombinant DNA sourced human insulin analogue. ADMELOG consists of zinc-insulin lispro crystals dissolved in a clear fluid. ADMELOG is used to control high blood sugar (glucose) in people

with diabetes. ADMELOG takes effect more rapidly and has a shorter duration of activity as compared to regular insulin.

The rapid onset of activity requires ADMELOG to be given within 15 minutes before a meal. When necessary, ADMELOG may be given shortly after a meal instead (within 20 minutes of the start of the meal). The time course of action of any insulin may vary to some extent in different individuals or at different times in the same individual. As with all insulin preparations, the duration of action of ADMELOG is dependent on dose, site of injection, blood supply, temperature, and physical activity.

Proper control is important. Uncontrolled diabetes (hyperglycemia) over a long period of time can result in a number of serious problems such as blindness, kidney failure, poor circulation/heart attacks, strokes and/or nerve damage. These problems can be prevented or reduced by good diabetes management. This will require close and constant cooperation with your diabetes healthcare team including: yourself, your doctor and your diabetes educators (nurses, dietitians, social workers, pharmacists and other healthcare professionals). Thus, you can lead an active, healthy and productive life by eating a balanced daily diet, exercising regularly, and taking your insulin injections as prescribed.

You have been instructed to test your blood and/or your urine regularly for glucose. If your blood tests consistently show above- or below-normal glucose levels or your urine tests consistently show the presence of glucose, your diabetes is not properly controlled, and you must let your doctor know.

What are the ingredients in ADMELOG?
Medicinal ingredient: Human Insulin Analogue

Non-medicinal ingredients: m-Cresol [3.15 mg/ml]; Glycerol; Dibasic sodium phosphate; Water for injections; Zinc oxide.

Hydrochloric acid and sodium hydroxide may be used to adjust pH to 7.0 – 7.8.

ADMELOG comes in the following dosage forms:
ADMELOG is a sterile solution containing insulin lispro injection. It is available in: 3 mL cartridge (for use only with JuniorSTAR and AllStar PRO reusable pens)

ADMELOG is also available in:
- 10 mL vial
- 3 mL disposable prefilled SoloSTAR injection pen.

Always keep an extra supply of ADMELOG i.e. a spare pen and cartridge on hand. Always wear identification to indicate that you have diabetes so that appropriate treatment can be given if complications occur away from home.

When you receive your insulin from the pharmacy, always check to see that:
1. The name ADMELOG appears on the carton and cartridge label.
2. The carton and cartridge label is correct for your type of insulin.
3. The expiration date on the package will allow you to use the insulin before that date.

Do not use ADMELOG if:
- Your blood sugar is too low (hypoglycemia). After treating your low blood sugar, follow your healthcare professional's 's instructions on the use of ADMELOG.
- You are allergic to anything in ADMELOG. A complete list of ingredients in ADMELOG is provided above.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ADMELOG. Talk about any health conditions or problems you may have, including if you:

- have trouble with your kidneys or liver, your doctor may decide to alter your insulin dose.
- drink alcohol (including wine and beer): watch for signs of hypoglycemia and never drink alcohol on an empty stomach.
- exercise more than usual or if you want to change your usual diet. Exercise may lower your body's need for insulin during and for some time after the activity. Exercise may also speed up the effect of an insulin dose, especially if the exercise involves the area of injection site.
- are ill. Illness, especially with nausea and vomiting, may cause your insulin requirements to change. Even if you are not eating, you will still require insulin. You and your doctor should establish a sick day plan for you to use in case of illness. When you are sick, test your blood/urine frequently.
- are travelling across more than 2 time zones. You should consult your doctor concerning adjustments in your insulin schedule.
- are pregnant. ADMELOG can be used in pregnancy if clinically indicated. Data on a large number of pregnancies exposed to insulin lispro (100 U/mL) do not indicate any adverse effect on pregnancy or on the health of the foetus/newborn. Good control of diabetes is especially important for you and your unborn baby. Pregnancy may make managing your diabetes more difficult. If you are planning to have a baby, are pregnant, or are nursing a baby, consult your doctor.
- use other medicines. Many medicines affect the way glucose works in your body and this may influence your insulin dose. Medicines that may affect your insulin treatment are noted in the following sections. Talk to your doctor or pharmacist if you take, or change any other medicines, even those not prescribed.
- if you develop 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 healthcare professional if you are currently injecting into a lumpy area before you start injecting in a different area. A sudden change of site may result in hypoglycemia. Your healthcare professional may tell you to check your blood sugar more closely, and to adjust your insulin or your other antidiabetic medications dose.

Other warnings you should know about:
DO NOT USE ANY OTHER INSULIN EXCEPT ON YOUR DOCTOR'S ADVICE AND DIRECTION.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with ADMELOG:
Insulin requirements may be increased if you are taking other drugs with hyperglycemic activity, such as oral contraceptives (for example, birth control pills, injections and patches), corticosteroids, or thyroid replacement therapy. Insulin requirements may be decreased in the presence of agents such as oral antidiabetic agents, salicylates (aspirin), sulfa antibiotics, certain antidepressants (monoamine oxidase inhibitors), beta-blockers, alcohol, ACE inhibitors and angiotensin II receptor blockers. Always discuss any medications you are taking with your doctor.

The use of thiazolidinediones (such as rosiglitazone and pioglitazone), alone or in combination with other antidiabetic agents (including insulin), has been associated with heart failure and swelling of the lower extremities. Please contact your physician immediately if you develop symptoms of shortness of breath, fatigue, exercise intolerance, or swelling of the lower extremities while you are on these agents.

How to take ADMELOG:
Use ADMELOG exactly as your healthcare professional tells you to. Your healthcare professional should tell you how much ADMELOG to use and when to use it.

- Check your insulin label each time you give your injection to make sure you are using the correct insulin;
- **Use the ADMELOG cartridge only with AllStar PRO and JuniorSTAR pens.**
- **Do not** make any dose changes unless your healthcare professional tells you to;
- ADMELOG is injected under your skin (subcutaneously);
- Change (rotate) your injection sites within the area you chose with each dose;
- **Do not** use the exact spot for each injection;
- **Do not** inject ADMELOG into your vein (intravenously);
- **Keep ADMELOG and all medicines out of the reach of children.**

ADMELOG is a clear solution and looks like some long-acting insulins. Always check for the name of the insulin on your carton and your ADMELOG cartridge label when you pick it up from the pharmacy to make sure it is the same as what your doctor recommended.

CAREFULLY FOLLOW THE DIRECTIONS SUPPLIED BY YOUR HEALTH PROFESSIONAL ON THE CORRECT USE OF YOUR AllStar PRO and JuniorSTAR, TO:

- **HELP AVOID CONTAMINATION AND POSSIBLE INFECTION**
- **OBTAIN AN ACCURATE DOSE.**

× The ADMELOG cartridge is for single patient use. Do not share it with anyone including other family members. Do not use on multiple patients.
✓Always perform a safety test.
✓Always carry a spare cartridge and spare needles in case they got lost or stop working.

As with all insulins, if patients are blind or have poor eyesight and cannot read the dose counter on the pen, they should get help from a person with good eyesight who is trained to use the insulin device.

Do not re-use the needle. A new sterile needle must be attached before each injection. Re-use of needles may increase the risk of blocked needles which may cause inaccurate dose delivery. Using a new sterile needle for each injection also minimizes the risk of contamination and infection.

Using the cartridge in any other injection pen not suitable for the ADMELOG cartridge could lead to a mistake in dosing and cause medical problems for you, such as a blood glucose level that is too low or too high.

JuniorSTAR delivers ADMELOG in 0.5 unit dose increments. AllStar PRO delivers ADMELOG in 1 unit dose increments.

Although rare, technical problems with the cartridge can occur which may prevent correct dosing. They include: broken, cracked or damaged cartridges, air bubbles or foam, and blocked needles. If technical problems occur or are suspected, contact the call center, your physician, pharmacist or nurse.

Injection Procedure

Preparing the ADMELOG Cartridge for Insertion into the injection pen

1. To avoid medication errors, check the cartridge label of the insulin before each insertion.
2. Inspect the insulin cartridge. ADMELOG should be a clear and colorless solution with no visible particles. Do not use it if you notice anything unusual in the appearance of the solution.
3. Make sure the insulin is at room temperature to minimize local irritation at the injection site.
4. Wash your hands.

5. Carefully follow the injection pen directions for loading the cartridge into the injection pen.

Injecting the Dose:

1. Wash your hands.
2. Inspect the insulin. ADMELOG should be a clear and colorless solution with no visible particles. Do not use it if you notice anything unusual in the appearance of solution.
3. It is not necessary to shake or rotate the cartridge inserted into the injection pen before use.
4. Remove the protective cap.
5. Follow the injection pen directions for attaching and changing the needle.
6. Check the cartridge inserted into the injection pen for air bubbles. If bubbles are present, remove them as instructed in the injection pen directions.
7. **Follow the injection pen directions for performing the Safety Test or Priming.**
8. Set the injection pen to the correct ADMELOG dose as instructed in the injection pen directions.
9. To avoid tissue damage, injection sites can be rotated so that the same site is not used more than approximately once a month, this will reduce the risk of skin shrinking or thickening or lumps at the site.
   - **Do not inject where the skin has pits, is thickened, or has lumps.**
   - **Do not inject where the skin is tender, bruised, scaly or hard, or into scars or damaged skin.**
10. Cleanse the skin with alcohol where the injection is to be made.
11. Pinch and hold the skin and insert the needle attached to the injection pen as instructed by your doctor or diabetes educator.
12. To inject ADMELOG, follow the directions for the injection pen.
13. Slowly count to 10 before removing the needle from the injection site and gently apply pressure for several seconds. DO NOT RUB THE AREA.
14. Remove the needle from the injection pen immediately after each injection as instructed in the directions for the injection pen. Dispose of the needle appropriately. Do not reuse the needle.

Hypo- or hyperglycemia can result from injecting insulin in the wrong site or incorrectly. Hypoglycemia can result from injection directly into a blood vessel and if not recognized or treated may be followed by hyperglycemia since there was no deposition for long-term absorption.

Usual dose:

Your doctor has told you which insulin to use, how much, and when and how often to inject it. Because each patient's case of diabetes is different, this schedule has been individualized for you.

Your usual ADMELOG dose may be affected by changes in your food, activity, or work schedule. Carefully follow your doctor's instructions to allow for these changes. Other things that may affect your ADMELOG dose are illness, pregnancy, medication, exercise and travel.

Overdose:

Hypoglycemia (too little glucose in the blood) is one of the most frequent adverse events experienced by insulin users. It can be brought about by:

1. Missing or delaying meals
2. Taking too much insulin
3. Exercising or working more than usual
4. An infection or illness (especially with diarrhea or vomiting)
5. A change in the body's need for insulin
6. Diseases of the adrenal, pituitary, or thyroid gland, or progression of kidney or liver disease

7. Interactions with other drugs that lower blood glucose, such as oral hypoglycemics, salicylates, sulfa antibiotics, and certain antidepressants
8. Consumption of alcoholic beverages

Dietary Implications:
If a usual meal cannot be obtained at the appropriate time, then to avoid hypoglycemia, you should take the amount of carbohydrate prescribed for this meal in the form of orange juice, syrup, candy, or bread and milk, without changing your insulin dosage. If it becomes necessary to omit a meal on account of nausea and vomiting, you should test your blood sugar level and notify your doctor.

Mild to moderate hypoglycemia may be treated by eating foods or drinks that contain sugar. Patients should always carry a quick source of sugar, such as candy mints or glucose tablets.

More severe hypoglycemia may require the assistance of another person. Patients who are unable to take sugar orally or who are unconscious should be treated with intravenous administration of glucose at a medical facility or should be given an injection of glucagon (either intramuscular or subcutaneous). The patient should be given oral carbohydrates as soon as consciousness is recovered.

If you think you have taken too much ADMELOG, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

What are possible side effects from using ADMELOG?
These are not all the possible side effects you may feel when taking ADMELOG. If you experience any side effects not listed here, contact your healthcare professional. Please also see Serious Warnings and Precautions.

Hypoglycemia:
One of the most frequent adverse events experienced by insulin users is hypoglycemia (see To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ADMELOG.).

Diabetic Acidosis and Coma:
Diabetic acidosis may develop if your body has too little insulin (this is the opposite of insulin reaction, which is the result of too much insulin in the blood). Diabetic acidosis may be brought on if you omit your insulin or take less than the doctor has prescribed, eat significantly more than your diet calls for, or develop a fever or infection. With acidosis, urine tests show a large amount of sugar and acetone.

The first symptoms of diabetic acidosis usually come on gradually, over a period of hours or days, and include a drowsy feeling, flushed face, thirst, and loss of appetite. Heavy breathing and a rapid pulse are more severe symptoms.

If uncorrected, loss of consciousness, coma, or death can result. Therefore, it is important that you obtain medical assistance immediately.

Injection Site Reactions:
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 (localized cutaneous amyloidosis). The insulin may not work very well if you inject into a lumpy area. If you notice either of these conditions, consult your healthcare professional as a sudden change of site may result in hypoglycemia. A change in your injection technique may help alleviate the problem.

Allergy to Insulin:
Patients occasionally experience redness, swelling, and itching at the site of injection of insulin. This condition, called local allergy, usually clears up in a few days to a few weeks. If you have local reactions, contact your doctor, who may recommend a change in the type or species of insulin.

Less common, but potentially more serious, is generalized allergy to insulin, which may cause rash over the whole body, shortness of breath, wheezing, reduction in blood pressure, fast pulse, or sweating. Severe cases of generalized allergy may be life threatening. If you think you are having a generalized allergic reaction to insulin, notify a doctor immediately. Your doctor may recommend skin testing, that is, injecting small doses of other insulins into the skin, in order to select the best insulin for you to use. Patients who have had severe generalized allergic reactions to insulin should be skin tested with each new preparation to be used before treatment with that preparation is started.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects
You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:
Prior to first use, ADMELOG insulin cartridges should be stored in a refrigerator between 2° and 8°C. Do not freeze. Do not expose to excessive heat or sunlight. The pen and cartridge of ADMELOG that you are currently using should not be refrigerated but should be kept as cool as possible (below 30°C) and away from direct heat and light. Do not use ADMELOG if it has been frozen. Cartridges in use, or not refrigerated, should be discarded after 28 days, even if they still contain ADMELOG.

Inspection of Cartridge:
ADMELOG should be clear and colourless. DO NOT USE a cartridge of ADMELOG if it appears cloudy, thickened, or slightly coloured, or if solid particles are visible. A cartridge that is not clear and colourless or that is cracked or broken should be returned to the place of purchase for exchange.

If you notice anything unusual in the appearance or effect of your insulin, consult your healthcare professional

DO NOT USE A CARTRIDGE OF ADMELOG AFTER THE EXPIRATION DATE STAMPED ON THE LABEL.

Dispose of used needles in a puncture-resistant container or as directed by your healthcare professional.

Dispose of used pens as instructed by your healthcare professional and without the needle attached.

Keep out of reach and sight of children.

If you want more information about ADMELOG:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website; (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html), Sanofi's website at http://www.sanofi.ca, or by calling 1-888-852-6887.

This leaflet was prepared by sanofi-aventis Canada Inc.

Last Revised: December 02, 2021

PATIENT MEDICATION INFORMATION - ADMELOG® SoloSTAR®

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

ADMELOG® SoloSTAR® (Pre-filled disposable pen) (*Ad-mah-log*)

Insulin lispro injection

Read this carefully before you start taking **ADMELOG** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ADMELOG**.

ADMELOG is a biosimilar biologic drug (biosimilar) to the reference biologic drug Humalog. A biosimilar is authorized based on its similarity to a reference biologic drug that was already authorized for sale.

Serious Warnings and Precautions

- Hypoglycemia or low blood sugar is the most common adverse effect experienced by insulin users. Blood glucose monitoring is recommended for all patients with diabetes. Uncorrected hypoglycemic or hyperglycemic reactions can cause loss of consciousness, coma or even death. Information on how to recognize these symptoms is provided below.
- This human insulin analogue differs from other insulins because it has a unique structure, a very quick onset of action and a short duration of activity. ADMELOG should be given within 15 minutes before a meal or when necessary shortly after a meal instead (within 20 minutes of the start of the meal). The short duration of action of ADMELOG means that if you have Type 1 diabetes you also need to use a longer acting insulin such as insulin NPH to give the best glucose control (except when using an insulin infusion pump).
- ADMELOG SoloSTAR should not be used if it is not water-clear and colourless or if it has formed a deposit of solid particles on the wall of the prefilled pen cartridge.
- Any change of insulin should be made cautiously and only under medical supervision. Changes in purity, strength, brand (manufacturer), type (regular, NPH, etc.), species (beef, pork, beef-pork, human), and/or method of manufacture (recombinant DNA versus animal-source insulin) may result in the need for a change in dosage.
- Patients taking ADMELOG may require a change in dosage from that used with other insulins. If an adjustment is needed, it may occur with the first dose or over a period of several weeks.

What is ADMELOG used for?
Insulin is a hormone produced by the pancreas, a large gland that lies near the stomach. This hormone is necessary for the body's correct use of food, especially sugar. Diabetes occurs when the pancreas does not make enough insulin to meet your body's needs.

To control your diabetes, your doctor has prescribed injections of insulin to keep your blood glucose at a near-normal level.

How does ADMELOG work?
Insulin lispro is a recombinant DNA sourced human insulin analogue. ADMELOG consists of zinc-insulin lispro crystals dissolved in a clear fluid. ADMELOG is used to control high blood sugar (glucose) in people with diabetes. ADMELOG takes effect more rapidly and has a shorter duration of activity as compared to regular insulin.

The rapid onset of activity requires ADMELOG to be given within 15 minutes before a meal. When necessary, ADMELOG may be given shortly after a meal instead (within 20 minutes of the start of the meal). The time course of action of any insulin may vary to some extent in different individuals or at different times in the same individual. As with all insulin preparations, the duration of action of ADMELOG is dependent on dose, site of injection, blood supply, temperature, and physical activity.

Proper control is important. Uncontrolled diabetes (hyperglycemia) over a long period of time can result in a number of serious problems such as blindness, kidney failure, poor circulation/heart attacks, strokes and/or nerve damage. These problems can be prevented or reduced by good diabetes management. This will require close and constant cooperation with your diabetes healthcare team including yourself, your doctor and your diabetes educators (nurses, dietitians, social workers, pharmacists and other healthcare professionals). Thus, you can lead an active, healthy and productive life by eating a balanced daily diet, exercising regularly, and taking your insulin injections as prescribed.

You have been instructed to test your blood and/or your urine regularly for glucose. If your blood tests consistently show above- or below-normal glucose levels or your urine tests consistently show the presence of glucose, your diabetes is not properly controlled, and you must let your doctor know.

What are the ingredients in ADMELOG?
Medicinal ingredient: Human Insulin Analogue

Non-medicinal ingredients: m-Cresol [3.15 mg/ml]; Glycerol; Dibasic sodium phosphate; Water for injections; Zinc oxide.

Hydrochloric acid and sodium hydroxide may be used to adjust pH to 7.0 – 7.8.

ADMELOG comes in the following dosage forms:
ADMELOG is a sterile solution containing insulin lispro injection. It is available in: 3 mL disposable prefilled SoloSTAR injection pen.

ADMELOG is also available in:
- 10 mL vial
- 3 mL cartridge (for use only with JuniorSTAR and AllStar PRO reusable pens)

Always keep an extra supply of ADMELOG i.e. a spare prefilled pen on hand. Always wear identification to indicate that you have diabetes so that appropriate treatment can be given if complications occur away from home.

When you receive your insulin from the pharmacy, always check to see that:
1. The name ADMELOG appears on the carton and prefilled pen label.
2. The carton and prefilled pen label is correct for your type of insulin.
3. The expiration date on the package will allow you to use the insulin before that date.

Do not use ADMELOG if:
- Your blood sugar is too low (hypoglycemia). After treating your low blood sugar, follow your healthcare professional 's instructions on the use of ADMELOG.
- You are allergic to anything in ADMELOG. A complete list of ingredients in ADMELOG is provided above.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ADMELOG. Talk about any health conditions or problems you may have, including if you:
- have trouble with your kidneys or liver, your doctor may decide to alter your insulin dose.
- drink alcohol (including wine and beer): watch for signs of hypoglycemia and never drink alcohol on an empty stomach.

- exercise more than usual or if you want to change your usual diet. Exercise may lower your body's need for insulin during and for some time after the activity. Exercise may also speed up the effect of an insulin dose, especially if the exercise involves the area of injection site.
- are ill. Illness, especially with nausea and vomiting, may cause your insulin requirements to change. Even if you are not eating, you will still require insulin. You and your doctor should establish a sick day plan for you to use in case of illness. When you are sick, test your blood/urine frequently.
- are travelling across more than 2 time zones. You should consult your doctor concerning adjustments in your insulin schedule.
- are pregnant. ADMELOG can be used in pregnancy if clinically indicated. Data on a large number of pregnancies exposed to insulin lispro (100 U/mL) do not indicate any adverse effect of ADMELOG on pregnancy or on the health of the foetus/newborn. Good control of diabetes is especially important for you and your unborn baby. Pregnancy may make managing your diabetes more difficult. If you are planning to have a baby, are pregnant, or are nursing a baby, consult your doctor.
- use other medicines. Many medicines affect the way glucose works in your body and this may influence your insulin dose. Medicines that may affect your insulin treatment are noted in the following sections. Talk to your doctor or pharmacist if you take, or change any other medicines, even those not prescribed.
- if you develop 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 healthcare professional if you are currently injecting into a lumpy area before you start injecting in a different area. A sudden change of site may result in hypoglycemia. Your healthcare professional may tell you to check your blood sugar more closely, and to adjust your insulin or your other antidiabetic medications dose.

Other warnings you should know about:
DO NOT USE ANY OTHER INSULIN EXCEPT ON YOUR DOCTOR'S ADVICE AND DIRECTION.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with ADMELOG:
Insulin requirements may be increased if you are taking other drugs with hyperglycemic activity, such as oral contraceptives (for example, birth control pills, injections and patches), corticosteroids, or thyroid replacement therapy. Insulin requirements may be decreased in the presence of agents such as oral antidiabetic agents, salicylates (aspirin), sulfa antibiotics, certain antidepressants (monoamine oxidase inhibitors), beta-blockers, alcohol, ACE inhibitors and angiotensin II receptor blockers. Always discuss any medications you are taking with your doctor.

The use of thiazolidinediones (such as rosiglitazone and pioglitazone), alone or in combination with other antidiabetic agents (including insulin), has been associated with heart failure and swelling of the lower extremities. Please contact your physician immediately if you develop symptoms of shortness of breath, fatigue, exercise intolerance, or swelling of the lower extremities while you are on these agents.

How to take ADMELOG:
Read the detailed Instructions for Use that come with your ADMELOG SoloSTAR disposable prefilled pen. Use ADMELOG exactly as your healthcare professional tells you to. Your healthcare professional should tell you how much ADMELOG to use and when to use it.

- Check your insulin label each time you give your injection to make sure you are using the correct insulin;
- ADMELOG comes in a SoloSTAR disposable prefilled pen that you must use to take your ADMELOG. The dose counter on your pen shows your dose of ADMELOG. **Do not** make any dose changes unless your healthcare professional tells you to;
- ADMELOG is injected under your skin (subcutaneously);
- Change (rotate) your injection sites within the area you chose with each dose;
- **Do not** inject ADMELOG into your vein (intravenously);
- **Keep ADMELOG and all medicines out of the reach of children.**

ADMELOG is a clear solution and looks like some long-acting insulins. Always check for the name of the insulin on your carton and your ADMELOG SoloSTAR pen label when you pick it up from the pharmacy to make sure it is the same as what your doctor recommended.

CAREFULLY FOLLOW THE DIRECTIONS SUPPLIED BY YOUR HEALTH PROFESSIONAL ON THE CORRECT USE OF YOUR ADMELOG SoloSTAR PEN TO:

- **HELP AVOID CONTAMINATION AND POSSIBLE INFECTION**
- **OBTAIN AN ACCURATE DOSE**

× The injection pen is for single patient use. Do not share it with anyone including other family members. Do not use on multiple patients.
×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.

The dose counter of the pen shows the number of units of ADMELOG to be injected.

As with all insulins, if patients are blind or have poor eyesight and cannot read the dose counter on the pen, they should get help from a person with good eyesight who is trained to use the insulin device.

Do not re-use the needle. A new sterile needle must be attached before each injection. Re-use of needles may increase the risk of blocked needles which may cause inaccurate dose delivery. Using a new sterile needle for each injection also minimizes the risk of contamination and infection.

Carefully read the "ADMELOG SoloSTAR pre-filled pen Instructions for Use" included in the package and use the pen as described. If you do not follow all of these instructions, you may get too much or too little insulin.

Injection Procedure

1. **Take the new pen out of the fridge at least 1 hour before you inject.** Make sure the insulin is at room temperature to minimize local irritation at the injection site; cold insulin is more painful to inject.
2. **Check the name and expiration date on the label of your pen.** To avoid medication errors between ADMELOG and other insulins, check the label on your ADMELOG SoloSTAR pen to make sure you have the correct insulin before every injection. Never use your pen after the expiration date.
3. **Check that the insulin is clear.** ADMELOG should be a clear and colorless solution with no visible particles. Do not use the pen if you notice anything unusual in the appearance of the solution.
4. **Wash your hands.**

5. **It is not necessary to shake or rotate the ADMELOG SoloSTAR pen before use.**
6. **Always attach a new needle.** Follow the ADMELOG SoloSTAR Instructions for Use for attaching and changing the needle.
7. **Pull off the protective cap and set it aside for later.**
8. **Do a safety test.** Always do a safety test before each injection to ensure your pen and needle are working correctly and to make sure that you get the correct insulin dose.
    - You may see air bubbles in the insulin – this is normal, they will not harm you.
9. **Select the correct dose.** Follow the steps included in your ADMELOG SoloSTAR Instructions for Use to ensure the correct dose of ADMELOG is selected.
    - Never select a dose or press the injection button without a needle attached – this may damage your pen.
10. **Choose a place to inject – upper arms, stomach, buttock or thighs.** Injection sites within an injection area (abdomen, thigh, buttock or upper arm) must be rotated from one injection to the next as instructed by your healthcare professional. This will reduce the risk of skin shrinking or thickening or lumps at the site;
    - **Do not** inject where the skin has pits, is thickened, or has lumps;
    - **Do not** inject where the skin is tender, bruised, scaly or hard, or into scars or damaged skin.
11. **Cleanse the skin with alcohol where the injection is to be made.**
12. **Push the needle into your skin as shown by your health professional.** Do not touch the injection button yet.
13. **Place your thumb on the injection button – press all the way in and hold.** Do not press at an angle, your thumb could block the dose selector from turning.
14. **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. DO NOT RUB THE AREA.
15. **Remove the needle immediately after each injection.** Follow the steps included in your ADMELOG SoloSTAR Instructions for Use – do not re-use the needle.
    - Always take care when handling needles – this is to prevent injury and cross-infection. Never put the inner needle cap back on.
16. **Dispose of your needle appropriately.** Throw away the used needle in a puncture-resistant container or as instructed by your health professional or local authority.
17. **Put the pen cap back on.** Do not put the pen back in the fridge.

Hypo- or hyperglycemia can result from injecting insulin in the wrong site or incorrectly. Hypoglycemia can result from injection directly into a blood vessel and if not recognized or treated may be followed by hyperglycemia since there was no deposition for long-term absorption.

Usual dose:
Your doctor has told you which insulin to use, how much, and when and how often to inject it. Because each patient's case of diabetes is different, this schedule has been individualized for you.

Your usual ADMELOG dose may be affected by changes in your food, activity, or work schedule. Carefully follow your doctor's instructions to allow for these changes. Other things that may affect your ADMELOG dose are illness, pregnancy, medication, exercise and travel.

Overdose:
Hypoglycemia (too little glucose in the blood) is one of the most frequent adverse events experienced by insulin users. It can be brought about by:

1. Missing or delaying meals
2. Taking too much insulin
3. Exercising or working more than usual

4. An infection or illness (especially with diarrhea or vomiting)
5. A change in the body's need for insulin
6. Diseases of the adrenal, pituitary, or thyroid gland, or progression of kidney or liver disease
7. Interactions with other drugs that lower blood glucose, such as oral hypoglycemics, salicylates, sulfa antibiotics, and certain antidepressants
8. Consumption of alcoholic beverages

Dietary Implications:
If a usual meal cannot be obtained at the appropriate time, then to avoid hypoglycemia, you should take the amount of carbohydrate prescribed for this meal in the form of orange juice, syrup, candy, or bread and milk, without changing your insulin dosage. If it becomes necessary to omit a meal on account of nausea and vomiting, you should test your blood sugar level and notify your doctor.

Mild to moderate hypoglycemia may be treated by eating foods or drinks that contain sugar. Patients should always carry a quick source of sugar, such as candy mints or glucose tablets.

More severe hypoglycemia may require the assistance of another person. Patients who are unable to take sugar orally or who are unconscious should be treated with intravenous administration of glucose at a medical facility or should be given an injection of glucagon (either intramuscular or subcutaneous). The patient should be given oral carbohydrates as soon as consciousness is recovered.

If you think you have taken too much ADMELOG, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

What are possible side effects from using ADMELOG?
These are not all the possible side effects you may feel when taking ADMELOG. If you experience any side effects not listed here, contact your healthcare professional. Please also see Warnings and Precautions.

Hypoglycemia:
One of the most frequent adverse events experienced by insulin users is hypoglycemia (see To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ADMELOG.).

Diabetic Acidosis and Coma:
Diabetic acidosis may develop if your body has too little insulin (this is the opposite of insulin reaction, which is the result of too much insulin in the blood). Diabetic acidosis may be brought on if you omit your insulin or take less than the doctor has prescribed, eat significantly more than your diet calls for, or develop a fever or infection. With acidosis, urine tests show a large amount of sugar and acetone.

The first symptoms of diabetic acidosis usually come on gradually, over a period of hours or days, and include a drowsy feeling, flushed face, thirst, and loss of appetite. Heavy breathing and a rapid pulse are more severe symptoms.

If uncorrected, loss of consciousness, coma, or death can result. Therefore, it is important that you obtain medical assistance immediately.

Injection Site Reactions:
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 (localized cutaneous amyloidosis). The insulin may not work very well if you inject into a lumpy area. If you notice either of these conditions, consult your healthcare professional as a sudden change

of site may result in hypoglycemia. A change in your injection technique may help alleviate the problem.

Allergy to Insulin:
Patients occasionally experience redness, swelling, and itching at the site of injection of insulin. This condition, called local allergy, usually clears up in a few days to a few weeks. If you have local reactions, contact your doctor, who may recommend a change in the type or species of insulin.

Less common, but potentially more serious, is generalized allergy to insulin, which may cause rash over the whole body, shortness of breath, wheezing, reduction in blood pressure, fast pulse, or sweating. Severe cases of generalized allergy may be life threatening. If you think you are having a generalized allergic reaction to insulin, notify a doctor immediately. Your doctor may recommend skin testing, that is, injecting small doses of other insulins into the skin, in order to select the best insulin for you to use. Patients who have had severe generalized allergic reactions to insulin should be skin tested with each new preparation to be used before treatment with that preparation is started.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects
You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:
Prior to first use, the ADMELOG SoloSTAR prefilled pen should be stored in a refrigerator between 2° and 8°C. Do not freeze. Do not expose to excessive heat or sunlight. The ADMELOG SoloSTAR prefilled pen that you are currently using should not be refrigerated but should be kept as cool as possible (below 30°C) and away from direct heat and light. Do not use ADMELOG SoloSTAR if it has been frozen. Prefilled pens in use, or not refrigerated, should be discarded after 28 days, even if they still contain ADMELOG.

Inspection of the prefilled pen:
ADMELOG should be clear and colourless. DO NOT USE ADMELOG SoloSTAR if the liquid appears cloudy, thickened, or slightly coloured, or if solid particles are visible. A prefilled pen cartridge that is not clear and colourless or that is cracked or broken should be returned to the place of purchase for exchange.

If you notice anything unusual in the appearance or effect of your insulin, consult your healthcare professional

DO NOT USE ADMELOG SOLOSTAR AFTER THE EXPIRATION DATE STAMPED ON THE LABEL.

Dispose of used needles in a puncture-resistant container or as directed by your healthcare professional.

Dispose of used pens as instructed by your healthcare professional and without the needle attached

Keep out of reach and sight of children.

If you want more information about ADMELOG:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); Sanofi's website at http://www.sanofi.ca, or by calling 1-888-852-6887.

This leaflet was prepared by sanofi-aventis Canada Inc.

Last Revised: December 02, 2021

ADMELOG® 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.
✗ **Never use a syringe to remove insulin from your pen.**
✓ Always perform a safety test.
✓ Always carry a spare pen and spare needles in case they got lost or stop working.

Learn to inject

- Talk with your healthcare professional about how to inject, before using your pen.
- This pen is not recommended for use by people who are blind or have visual impairments without the assistance of a person trained in the proper use of the product.
- 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.

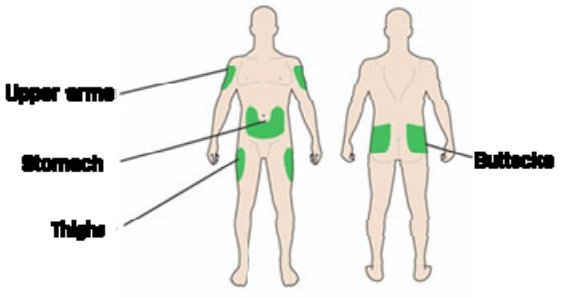
Need help?

If you have any questions about your pen or about diabetes, ask your healthcare professional, go to **www.sanofi.ca** or call sanofi-aventis at **1-888-852-6887.**

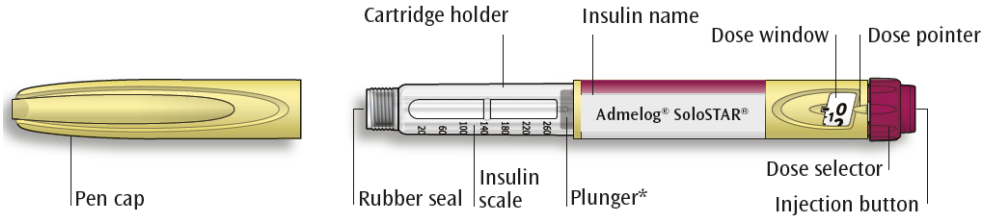
Extra items you will need:

- a new sterile needle (see STEP 2).
- an alcohol swab
- a puncture resistant container for used needles and pens.

Places to inject



Get to know your pen



*You will not see the plunger until you have injected a few doses

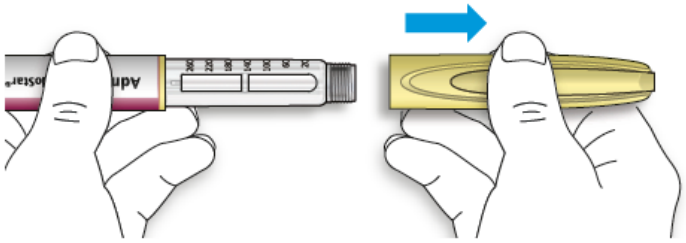
STEP 1: Check your pen

✓ Take a new pen out of the refrigerator at least 1 hour before you inject. Cold insulin is more painful to inject.

1A Check the name and expiration date on the label of your pen.

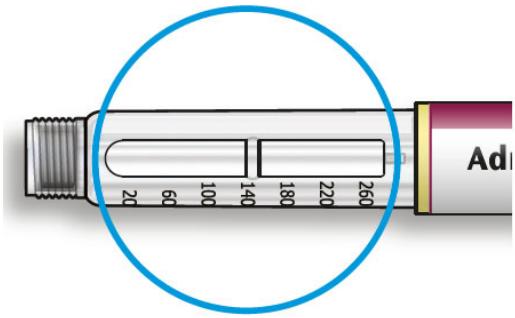
- Make sure you have the correct insulin.
- Never use your pen after the expiration date.

1B Pull off the pen cap.

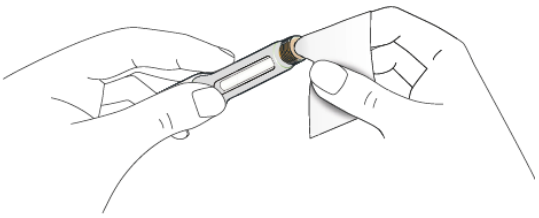


1C Check that the insulin is clear.

- Do not use the pen if the insulin looks cloudy, colored or contains particles.



1D Wipe the rubber seal with an alcohol swab.



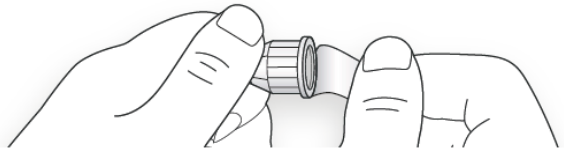
ⓘ If you have other injector pens

- Making sure you have the correct medicine is especially important if you have other injector pens.

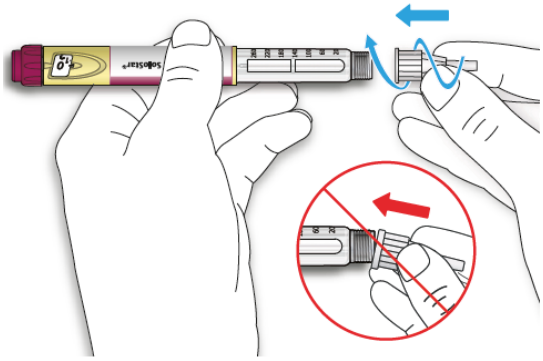
STEP 2: Attach a new needle

- ✓ Do not reuse needles. Always use a new sterile needle for each injection. This helps stop blocked needles, contamination and infection.
- ✓ Always use needles from Becton Dickinson (such as BD Ultra-Fine®), Ypsomed (such as Clickfine®) or Owen Mumford (such as Unifine® Pentips®)

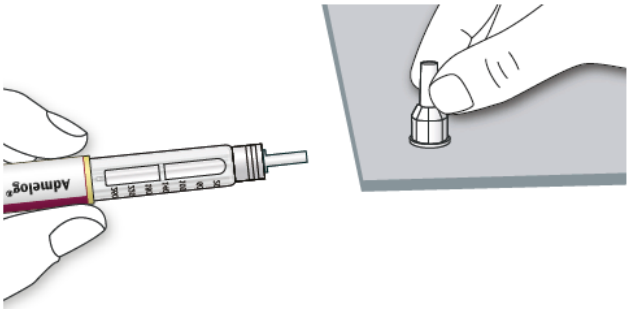
2A Take a new needle and peel off the protective seal.



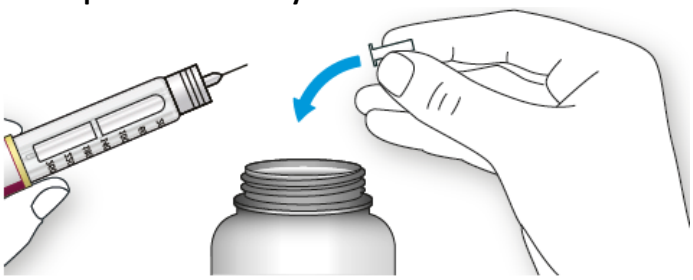
2B Keep the needle straight and screw it onto the pen until fixed. Do not overtighten.



2C Pull off the outer needle cap. Keep this for later.



2D Pull off the inner needle cap and throw away.



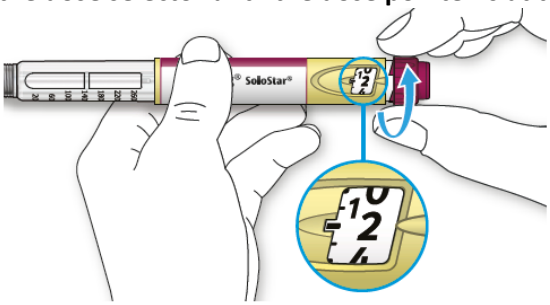
ⓘ Handling needles

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

STEP 3: Do a safety test

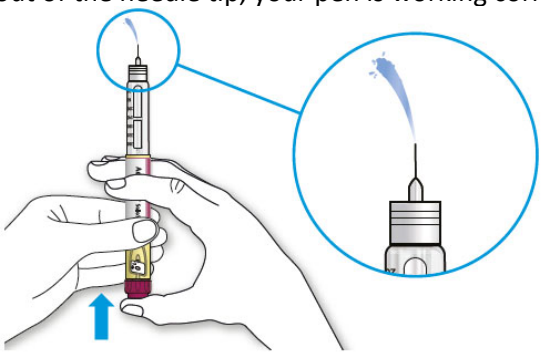
✓ Always do a safety test before each injection – this is to:
✓ Check your pen and the needle are working properly.
✓ Make sure that you get the correct insulin dose.

3A Select 2 units by turning the dose selector until the dose pointer is at the 2 mark.



3B Press the injection button all the way in.

- When insulin comes out of the needle tip, your pen is working correctly.



3C Repeat this step if no insulin appears:

- **If you are using a new pen for the first time**, you may need to repeat this step **up to 3 times** before seeing insulin.
- **For all injections**, 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.

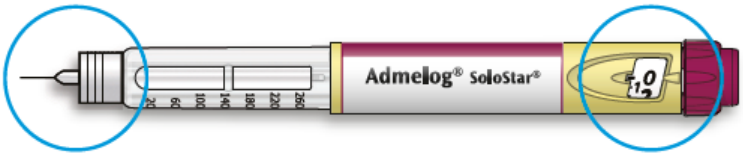
If you see air bubbles

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

STEP 4: Select the dose

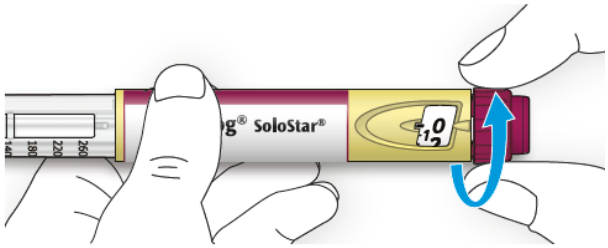
✗ Never select a dose or press the injection button without a needle attached. This may damage your pen.

4A Make sure a needle is attached and the dose is set to "0".



4B Turn the dose selector until the dose pointer lines up with your dose.

- Always check the number in the dose window to make sure you dialed the correct 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. If you use a new pen, perform a safety test (see STEP 3).



How to read the dose window

Even numbers are shown in line with the dose pointer:

20 units selected

Odd numbers are shown as a line between even numbers:

21 units selected

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.

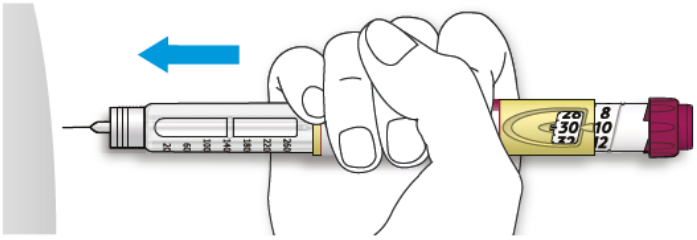
STEP 5: Inject your dose

✗ If you find it hard to press the injection button in, do not force it as this may break your pen. See the ⓘ section below for help.

5A Choose a place to inject as shown in the picture labelled "Places to inject".

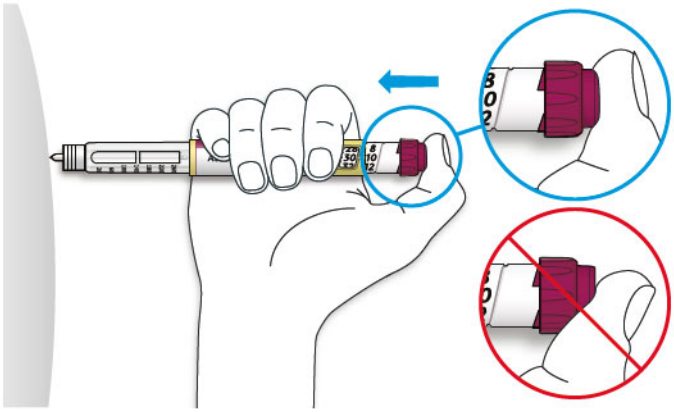
5B Push the needle into your skin as shown by your healthcare professional.

- Do not touch the injection button yet.



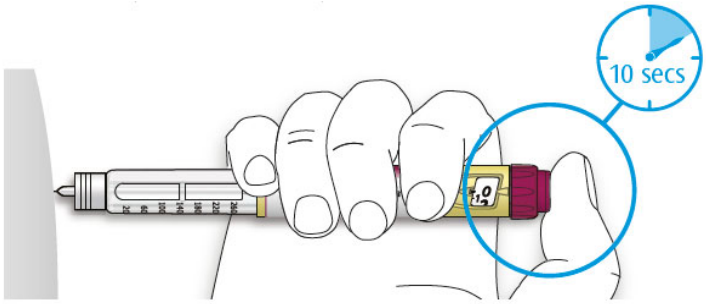
5C Place your thumb on the injection button. Then press all the way in and hold.

- Do not press at an angle – your thumb could block the dose selector from turning.



5D 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.



5E After holding and slowly counting to 10, release the injection button. Then remove the needle from your skin.

ⓘ **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

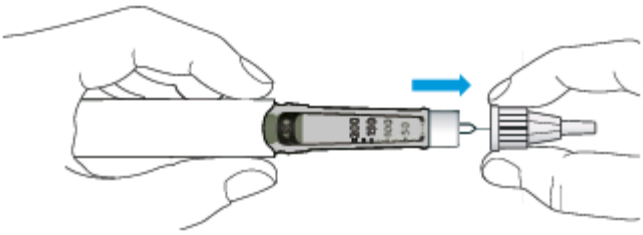
✓ Take care when handling needles – this is to prevent needle injury and cross-infection.

✗ Never put the inner needle cap back on.

6A Grip the widest part of the outer needle cap. Keep the needle straight and guide it into the outer needle cap back

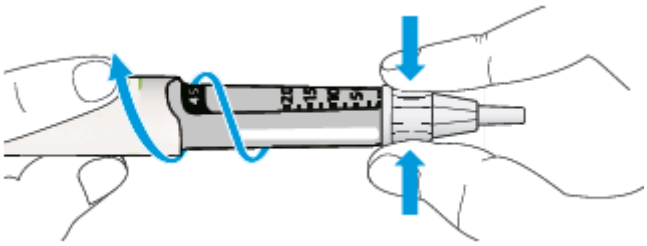
Then push firmly on.

- The needle can puncture the cap if it is recapped at an angle.

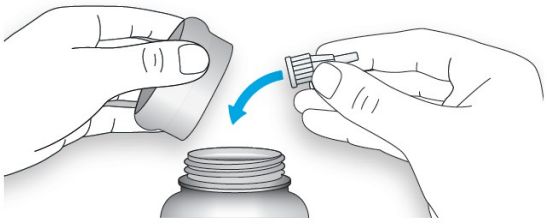


6B Grip and squeeze the widest part of the outer needle cap. Turn your pen several times with your other hand to remove the needle.

- Try again if the needle does not come off the first time.

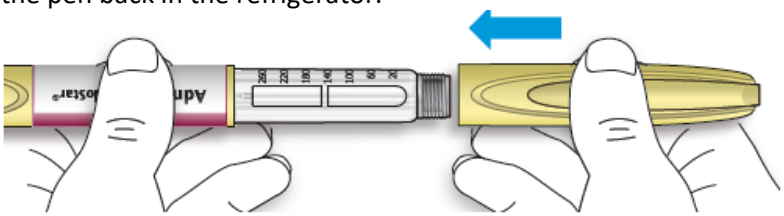


6C Throw away the used needle in a puncture resistant container, or as told by your healthcare professional or local authority.



6D Put the pen cap back on.

- Do not put the pen back in the refrigerator.



Use by

- Only use your pen for up to 4 weeks after its first use.

How to store your pen

Before first use

- Keep new pens in a refrigerator at **2°C to 8°C**.
- Do not freeze.

After first use

- Keep your pen at room temperature (15-30°C)
- Never put your pen back in the refrigerator.
- Never store your pen with the needle attached.
- Store your pen with the pen cap on.
- Keep your pen away from heat or light.
- **Keep this pen out of the sight and reach of children.**

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 fix 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 clean, damp cloth (water only). Do not soak, wash or lubricate your pen – this may damage it.

Throwing your pen away

- Remove the needle before throwing your pen away.
- Throw away your used pen as told by your healthcare professional or local authority.

Last Revised: December 02, 2021

Distributed by: sanofi-aventis Canada Inc.