All insulin products, including ADMELOG, cause a shift in potassium from the extracellular to intracellular space, possibly leading to hypokalemia. Untreated hypokalemia may cause respiratory paralysis, ventricular arrhythmia, and death. Monitor potassium levels in patients at risk for hypokalemia if indicated (e.g., patients using potassium-lowering medications, patients taking medications sensitive to serum potassium concentrations).

5.7 Fluid Retention and Heart Failure with Concomitant Use of PPAR-gamma Agonists

Thiazolidinediones (TZDs), which are peroxisome proliferator-activated receptor (PPAR)-gamma agonists, can cause dose-related fluid retention, particularly when used in combination with insulin. Fluid retention may lead to or exacerbate heart failure. Patients treated with insulin, including ADMELOG, and a PPAR-gamma agonist should be observed for signs and symptoms of heart failure. If heart failure develops, it should be managed according to current standards of care, and discontinuation or dose reduction of the PPAR-gamma agonist must be considered.

5.8 Hyperglycemia and Ketoacidosis Due to Insulin Pump Device Malfunction

Malfunction of the insulin pump or insulin infusion set or insulin degradation can rapidly lead to hyperglycemia and ketoacidosis. Prompt identification and correction of the cause of hyperglycemia or ketosis is necessary. Interim subcutaneous injections with ADMELOG may be required. Patients using continuous subcutaneous insulin infusion pump therapy must be trained to administer insulin by injection and have alternate insulin therapy available in case of pump failure *[see How Supplied/Storage and Handling (16.2) and Patient Counseling Information (17)]*.

6 ADVERSE REACTIONS

The following adverse reactions are also discussed elsewhere:

- Hypoglycemia *[see Warnings and Precautions (5.3)]*
- Hypersensitivity and allergic reactions *[see Warnings and Precautions (5.5)]*
- Hypokalemia *[see Warnings and Precautions (5.6)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Two clinical trials with ADMELOG were conducted: one in patients with type 1 diabetes and one in patients with type 2 diabetes *[see Clinical Studies (14)]*.

The data in Table 1 reflect the exposure of 252 patients with type 1 diabetes to ADMELOG with mean exposure duration of 49 weeks. The type 1 diabetes population had the following characteristics: Mean age was 43 years and mean duration of diabetes was 20 years. Fifty-nine percent were male, 80% were White, 6% were Black or African American and 7% were Hispanic. At baseline, the mean eGFR was 90 mL/min/1.73 m^2 and 49% of patients had eGFR ≥90 mL/min/1.73 m^2. The mean BMI was 26 kg/m^2. The mean HbA1c at baseline was 8.07%.

Two hundred fifty-three patients with type 2 diabetes were exposed to ADMELOG with mean exposure duration of 25 weeks. The type 2 diabetes population had the following characteristics: Mean age was 62 years and mean duration of diabetes was 17 years. Fifty-four percent were male, 90% were White, 6% were Black or African American and 17% were Hispanic. At baseline, the mean eGFR was 77 mL/min/1.73 m^2 and 27% of patients had eGFR ≥90 mL/min/1.73 m^2. The mean BMI was 32 kg/m^2. The mean HbA1c at baseline was 7.99%.

Common adverse reactions were defined as reactions occurring in ≥5% of the population studied.

Common adverse reactions (other than hypoglycemia) during a clinical trial in patients with type 1 diabetes mellitus are listed in Table 1. In a 26-week clinical trial in patients with type 2 diabetes mellitus, no adverse reactions (other than hypoglycemia) occurring in ≥5% of ADMELOG-treated patients (n=253) were observed.

Table 1: Adverse Reactions Occurring in ≥5% of ADMELOG-Treated Patients with Type 1 Diabetes in a 52-Week Trial

	ADMELOG + Insulin Glargine (100 units/mL), % (n=252)
Nasopharyngitis	13.1%
Upper respiratory tract infection	6.0%

Severe Hypoglycemia

Hypoglycemia is the most commonly observed adverse reaction in patients using insulin, including ADMELOG *[see Warnings and Precautions (5.3)]*. The rates of reported hypoglycemia depend on the definition of hypoglycemia used, diabetes type, insulin dose, intensity of glucose control, background therapies, and other intrinsic and extrinsic patient factors. For these reasons, comparing rates of hypoglycemia in clinical trials for ADMELOG with the incidence of hypoglycemia for other products may be misleading and also, may not be representative of hypoglycemia rates that will occur in clinical practice.

In the ADMELOG trials, severe hypoglycemia was defined as an event requiring assistance of another person to actively administer carbohydrate, glucagon, or other resuscitative actions. The incidence of severe hypoglycemia in patients receiving ADMELOG with type 1 diabetes mellitus and type 2 diabetes mellitus was 13.5% at 52 weeks and 2.4% at 26 weeks, respectively *[see Clinical Studies (14)]*.

Insulin Initiation and Intensification of Glucose Control

Intensification or rapid improvement in glucose control has been associated with a transitory, reversible ophthalmologic refraction disorder, worsening of diabetic retinopathy, and acute painful peripheral neuropathy. However, long-term glycemic control decreases the risk of diabetic retinopathy and neuropathy.

Lipodystrophy

Long-term use of insulin, including ADMELOG, can cause lipodystrophy at the site of repeated insulin injections or infusion. Lipodystrophy includes lipohypertrophy (thickening of adipose tissue) and lipoatrophy (thinning of adipose tissue), and may affect insulin absorption. Rotate

insulin injection or infusion sites within the same region to reduce the risk of lipodystrophy *[see Dosage and Administration (2.2)]*.

Weight Gain

Weight gain can occur with insulin therapy, including ADMELOG, and has been attributed to the anabolic effects of insulin and the decrease in glucosuria.

Peripheral Edema

Insulin, including ADMELOG, may cause sodium retention and edema, particularly if previously poor metabolic control is improved by intensified insulin therapy.

Adverse Reactions with Continuous Subcutaneous Insulin Infusion (CSII)

In a randomized, open-label crossover study in adult patients with type 1 diabetes treated over two 4-week periods, the incidence of infusion set occlusions (defined as failure to correct hyperglycemia [plasma glucose ≥300 mg/dL] by insulin bolus via insulin pump) in ADMELOG-treated patients (n=25) was evaluated. Infusion set occlusions were reported by 24% of patients.

In a randomized, 16-week, open-label, parallel design study of children and adolescents with type 1 diabetes, adverse event reports related to infusion-site reactions for another insulin lispro product, 100 units/mL, occurred in 21% of patients. The most frequently reported infusion site adverse events were infusion site erythema and infusion site reaction.

Allergic Reactions

Local allergy

As with any insulin therapy, patients taking ADMELOG may experience redness, swelling, or itching at the site of the injection. These minor reactions usually resolve in a few days to a few weeks, but in some occasions may require discontinuation of ADMELOG. In some instances, these reactions may be related to factors other than insulin, such as irritants in a skin cleansing agent or poor injection technique.

Systemic allergy

Severe, life-threatening, generalized allergy, including anaphylaxis, may occur with any insulin, including ADMELOG. Generalized allergy to insulin may cause whole body rash (including pruritus), dyspnea, wheezing, hypotension, tachycardia, or diaphoresis.

Localized reactions and generalized myalgias have been reported with injected metacresol, which is an excipient in ADMELOG *[see Contraindications (4)]*.

6.2 Immunogenicity

Consistent with the potentially immunogenic properties of protein and peptide pharmaceuticals, patients treated with ADMELOG may develop anti-insulin antibodies. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay and may be influenced by several factors such as assay methodology, sample handling, timing of sample collection, concomitant medication, and underlying disease. For these reasons, the incidence of antibodies to ADMELOG in the studies described below cannot be directly compared with the incidence of antibodies in other studies or to other products.

with renal impairment. Careful glucose monitoring and dose adjustments of insulin, including ADMELOG, may be necessary in patients with renal dysfunction.

Patients with hepatic impairment

Type 2 diabetic patients with impaired hepatic function showed no effect on the pharmacokinetics of another insulin lispro product, 100 units/mL, as compared to patients with no hepatic dysfunction. However, some studies with human insulin have shown increased circulating levels of insulin in patients with liver failure. Careful glucose monitoring and dose adjustments of insulin, including ADMELOG, may be necessary in patients with hepatic dysfunction.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Standard 2-year carcinogenicity studies in animals have not been performed. In Fischer 344 rats, a 12-month repeat-dose toxicity study was conducted with insulin lispro at subcutaneous doses of 20 and 200 units/kg/day (approximately 3 and 32 times the human subcutaneous dose of 1 unit/kg/day, based on units/body surface area). Insulin lispro did not produce important target organ toxicity including mammary tumors at any dose.

Insulin lispro was not mutagenic in the following genetic toxicity assays: bacterial mutation, unscheduled DNA synthesis, mouse lymphoma, chromosomal aberration, and micronucleus assays.

Male fertility was not compromised when male rats given subcutaneous insulin lispro injections of 5 and 20 units/kg/day (0.8 and 3 times the human subcutaneous dose of 1 unit/kg/day, based on units/body surface area) for 6 months were mated with untreated female rats. In a combined fertility, perinatal, and postnatal study in male and female rats given 1, 5, and 20 units/kg/day subcutaneously (0.16, 0.8, and 3 times the human subcutaneous dose of 1 unit/kg/day, based on units/body surface area), mating and fertility were not adversely affected in either gender at any dose.

14 CLINICAL STUDIES

14.1 Overview of Clinical Studies

The safety and effectiveness of ADMELOG have been established based on adequate and well controlled studies of ADMELOG in adult patients with type 1 and type 2 diabetes mellitus, and based on adequate and well controlled studies of another insulin lispro product, 100 units/mL, in adult and pediatric patients 3 years of age and older with type 1 diabetes mellitus and adult patients with type 2 diabetes mellitus.

The safety and effectiveness of ADMELOG were studied in 507 adult patients with type 1 diabetes and 505 adult patients with type 2 diabetes.

The safety and effectiveness of another insulin lispro product, 100 units/mL, were studied in 1,087 adult and pediatric patients with type 1 diabetes and in 722 adult patients with type 2 diabetes.

100 units/mL (n=81), compared with regular human insulin, 100 units/mL (n=86). This other insulin lispro product was administered by subcutaneous injection immediately prior to meals and regular human insulin was administered 30 to 45 minutes before meals. Human insulin extended zinc suspension was administered once or twice daily as the basal insulin. There was a 2 to 4-week run-in period with regular human insulin and human insulin extended zinc suspension before randomization.

The mean age of these subjects was 31 years (range 12 to 70 years), and 47% were male. The population was 97% White.

Table 4: Type 1 Diabetes Mellitus – Adults and Pediatric Patients 12 Years of Age and Older – Mean Change in HbA1c% (another insulin lispro product, 100 units/mL, versus regular human insulin, 100 units/mL)

Treatment Duration **Treatment in Combination with:**	**12 Months** **Human Insulin Extended Zinc**	
	Another Insulin Lispro Product	**Regular Human Insulin**
N	81	86
Baseline HbA1c (%)*	8.2 ± 1.4	8.3 ± 1.7
Change from baseline HbA1c (%)[a]	-0.1 ± 0.9	0.1 ± 1.1
Treatment difference in HbA1c mean (95% confidence interval)	0.4 (0.0; 0.8)	

* Values are Mean ± SD.

Another Insulin Lispro Product, 100 units/mL: Studies in Pediatric Patients 3 Years of Age and Older

An 8-month, crossover study of pediatric patients with type 1 diabetes (n=463), aged 9 to 19 years, compared two subcutaneous multiple-dose treatment regimens: another insulin lispro product, 100 units/mL, or regular human insulin, 100 units/mL, both administered with NPH human insulin isophane suspension as the basal insulin. Insulin lispro achieved glycemic control comparable to regular human insulin, as measured by HbA1c (see Table 5).

Table 5: Type 1 Diabetes Mellitus – Pediatric Patients 9 Years of Age and Older – Mean Change in HbA1c (%) (another insulin lispro product, 100 units/mL, versus regular human insulin, 100 units/mL)

	Baseline	Another Insulin Lispro Product + NPH	Regular Human Insulin + NPH
HbA1c (%)*	8.6 ± 1.5	8.7 ± 1.5	8.7 ± 1.6
Change from baseline HbA1c (%)*	-	0.1 ± 1.1	0.1 ± 1.3

* Values are Mean ± SD.

In a 9-month, crossover study of pediatric patients with type 1 diabetes mellitus (n=60), aged 3 to 11 years, compared three subcutaneous injection regimens: another insulin lispro product, 100 units/mL, administered immediately before meals, this same insulin lispro product, 100 units/mL, administered immediately after meals and regular human insulin, 100 units/mL administered 30 minutes before meals resulted in similar glycemic control, as measured by HbA1c, regardless of treatment group.

14.3 Type 1 Diabetes Mellitus – Continuous Subcutaneous Infusion

Another Insulin Lispro Product, 100 units/mL: Studies in Adult and Pediatric Patients 15 Years of Age and Older

To evaluate the administration of another insulin lispro product, 100 units/mL, as a subcutaneous infusion via external insulin pumps, two open-label, crossover studies were performed in patients with type 1 diabetes mellitus.

One study involved 39 patients, ages 19 to 58 years, treated for 24 weeks with another insulin lispro product, 100 units/mL, or regular human insulin 100 units/mL. After 12 weeks of treatment, the mean HbA1c values decreased from 7.8% to 7.2% in patients treated with another insulin lispro, and from 7.8% to 7.5% in the regular human insulin-treated patients.

Another study involved 60 patients (mean age 39, range 15 to 58 years) treated for 24 weeks with either another insulin lispro product, 100 units/mL, or buffered regular human insulin, 100 units/mL. After 12 weeks of treatment, the mean HbA1c values decreased from 7.7% to 7.4% in patients treated with insulin lispro, and remained unchanged from 7.7% in the buffered regular human insulin-treated patients.

Another Insulin Lispro Product, 100 units/mL: Study in Pediatric Patients 4 Years of Age and Older

A randomized, 16-week, open-label, parallel design, study of pediatric patients with type 1 diabetes mellitus (n=298), aged 4 to 18 years, compared two subcutaneous infusion regimens administered via an external insulin pump: insulin aspart, 100 units/mL (n=198), or another insulin lispro product, 100 units/mL (n=100). These two treatments resulted in comparable changes from baseline in HbA1c after 16 weeks of treatment (see Table 6).

			temperature
3 mL single patient use SoloStar prefilled pen	28 days	Until expiration date	28 days **Do not refrigerate**.

Use in an External Insulin Pump

Insulin in the reservoir should be discarded after 7 days. However, as with other external insulin pumps, the infusion set should be replaced and a new infusion set insertion site should be selected at least every 3 days.

Diluted ADMELOG for Subcutaneous Injection

Diluted ADMELOG may remain in patient use for up to 24 hours when stored in a refrigerator (36°F-46°F [2°C-8°C]) or for up to 4 hours when stored at room temperature (86°F [30°C]). Do not dilute ADMELOG used in an external insulin pump.

16.3 Preparation and Handling

Diluted ADMELOG for Subcutaneous Injection

ADMELOG may be diluted with sterile 0.9% sodium chloride for subcutaneous injection. Diluting one part ADMELOG to one part 0.9% sodium chloride will yield a concentration one-half that of ADMELOG (equivalent to U-50).

16.4 Admixture for Intravenous Administration

Infusion bags prepared with ADMELOG are stable when stored in a refrigerator (36°F-46°F [2°C-8°C]) for 24 hours or may be used at room temperature for up to 4 hours *[see Dosage and Administration (2.2)]*.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information and Instructions for Use).

Never Share an ADMELOG SoloStar Prefilled Pen or Syringe Between Patients

Advise patients that they must never share an ADMELOG SoloStar pen with another person, even if the needle is changed. Advise patients using ADMELOG vials not to share needles or syringes with another person. Sharing poses a risk for transmission of blood-borne pathogens.

Hypoglycemia

Instruct patients on self-management procedures including glucose monitoring, proper injection technique, and management of hypoglycemia and hyperglycemia, especially at initiation of ADMELOG therapy. Instruct patients on handling of special situations such as intercurrent conditions (illness, stress, or emotional disturbances), an inadequate or skipped insulin dose, inadvertent administration of an increased insulin dose, inadequate food intake, and skipped meals. Instruct patients on the management of hypoglycemia.

Inform patients that their ability to concentrate and react may be impaired as a result of hypoglycemia. Advise patients who have frequent hypoglycemia or reduced or absent warning

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Approved: December 2017

Instructions for Use

ADMELOG® SoloStar® (ad-mah-log)
(insulin lispro injection) for subcutaneous use
3 mL disposable prefilled pen (100 Units/mL, U-100)

Read this first

Do not share your ADMELOG SoloStar pen with other people, even if the needle has been changed. You may give other people a serious infection, or get a serious infection from them.

ADMELOG SoloStar should not be used by people who are blind or have severe vision problems without the help of a person who has good eyesight and who is trained to use the ADMELOG SoloStar the right way.

ADMELOG SoloStar is a disposable prefilled pen used to inject ADMELOG. Each ADMELOG SoloStar has 300 units of insulin which can be used for multiple injections. You can select doses from 1 to 80 units in steps of 1 unit. The pen plunger moves with each dose. The plunger will only move to the end of the cartridge when 300 units of insulin have been given.

Important information

- **Do not** use your pen if it is damaged or if you are not sure that it is working properly.
- **Do not** use a syringe to remove insulin from your pen.
- **Do not reuse needles.** If you do, you might get the wrong dose of ADMELOG and/or increase the chance of getting an infection.
- Always perform a safety test (see **Step 3**).
- Always carry a spare pen and spare needles in case they got lost or stop working.

Learn to inject

- Talk with your healthcare provider 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.
- 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.

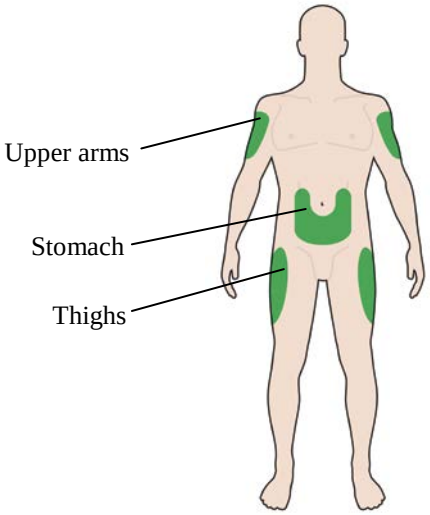
Need help?

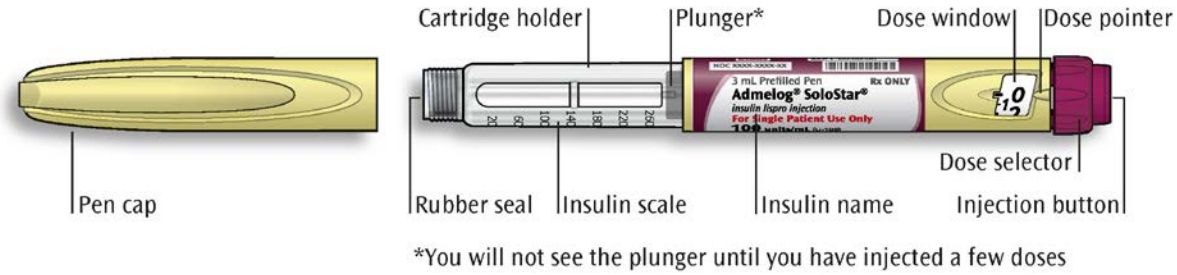
If you have any questions about your pen or about diabetes, ask your healthcare provider, or go to **www.Admelog.com** or call sanofi-aventis at **1-800-633-1610**.

Extra items you will need:

- a new sterile needle (see **Step 2**).
- an alcohol swab.
- a puncture-resistant container for used needles and pens. (See **“Throwing your pen away”**).

Places to inject





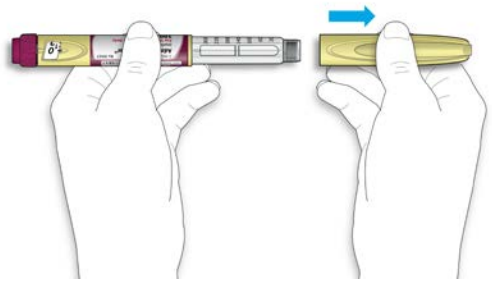
Step 1: Check your pen

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.
- **Do not** use your pen after the expiration date.

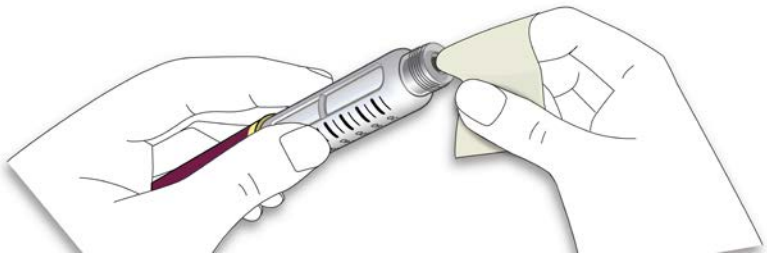
1B Pull off the pen cap.



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.



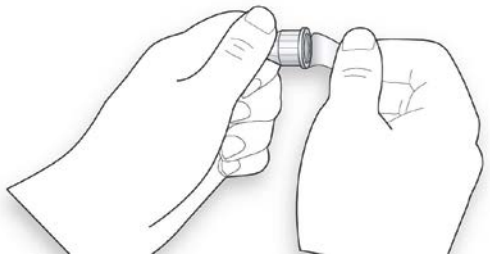
If you have other injector pens:

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

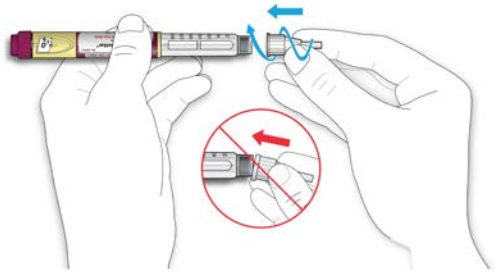
Step 2: Attach a new needle

- **Do not** reuse needles. Always use a new sterile needle for each injection. This helps stop blocked needles, contamination, and infection.
- Only use needles* that are compatible for use with ADMELOG SoloStar, e.g. needles from BD (such as BD Ultra-Fine®), Ypsomed (such as Clickfine®), Owen Mumford (such as Unifine® Pentips®).

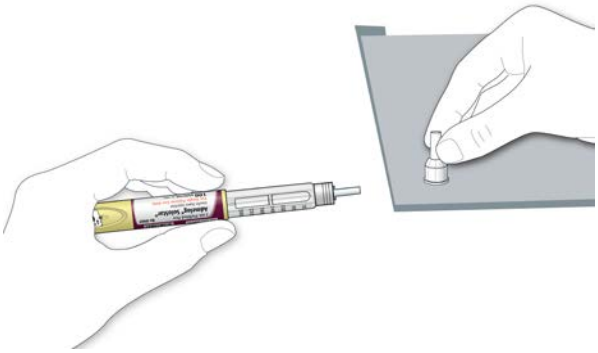
2A Take a new needle and peel off the protective seal.



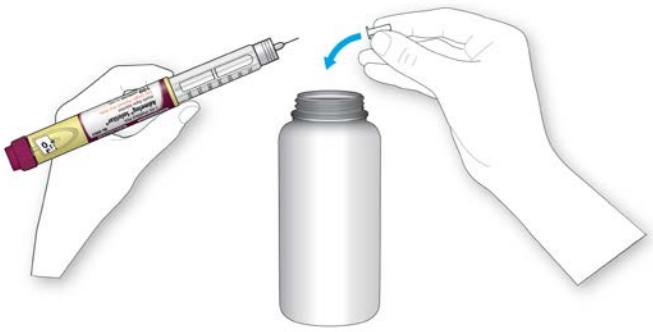
2B Keep the needle straight and screw it onto the pen until fixed. Do not over-tighten.



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



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



Handling needles:

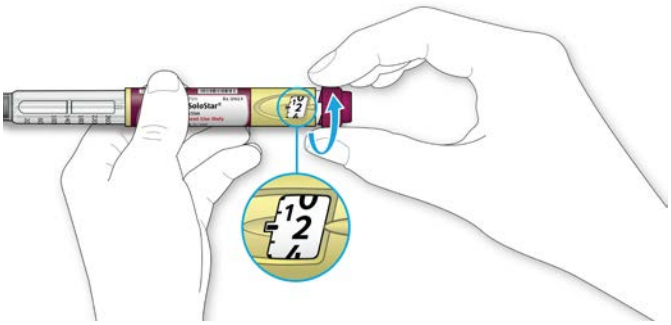
- Take care when handling needles to prevent needle-stick injury and cross-infection.

Step 3: Do a safety test

Always do a safety test before each injection to:

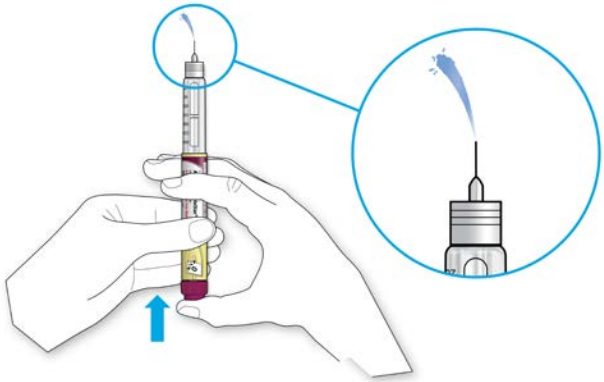
- Check your pen and the needle to make sure they are working properly.
- Make sure that you get the correct insulin dose.

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.



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.
- **Do not** 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

Do not 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.

- 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.

How to read the dose window

Even numbers are shown in line with 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 1 dose.
- You can see roughly how many units of insulin are left by looking at where the plunger is on the insulin scale.

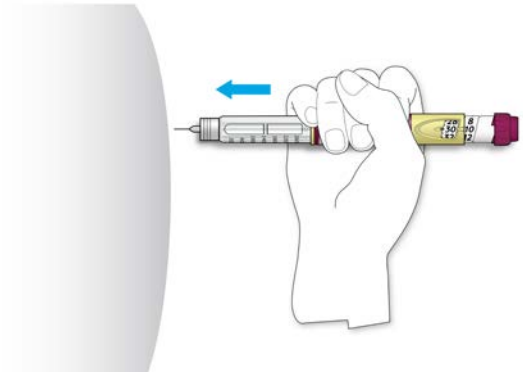
Step 5: Inject your dose

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 above.

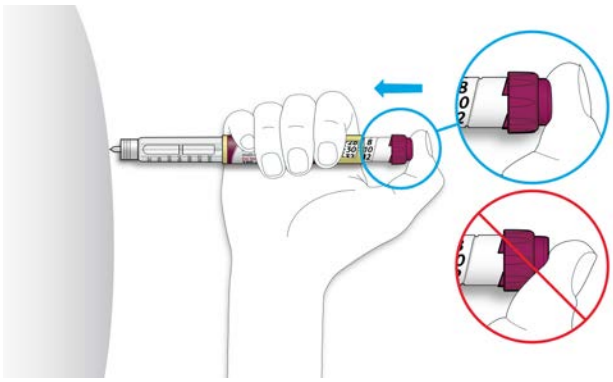
5B Push the needle into your skin as shown by your healthcare provider.

- Do not touch the injection button yet.



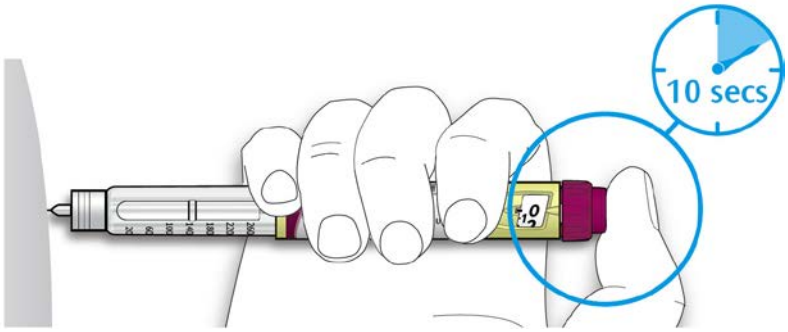
5C Place your thumb on the injection button. Then press all the way in and hold.

- **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.
- **Do not** use a syringe to remove insulin from your pen.

Step 6: Remove the needle

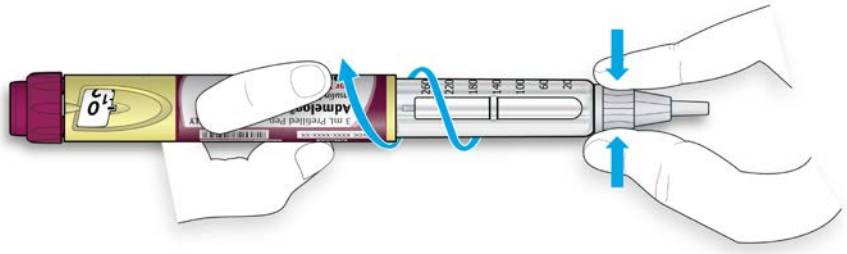
- Take care when handling needles to prevent needle-stick injury and cross-infection.
- **Do not** put the inner needle cap back on.

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

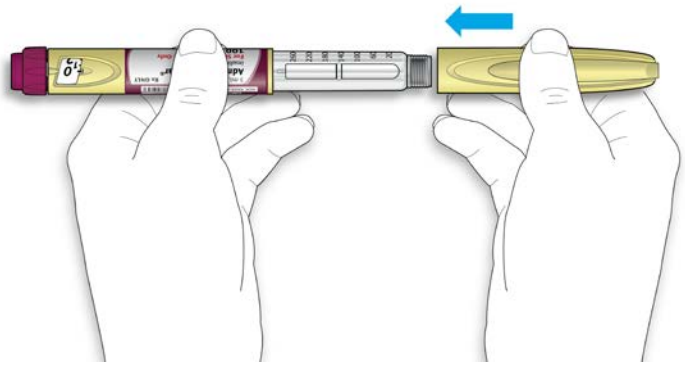
- Try again if the needle does not come off the first time.



6C Throw away the used needle in a puncture-resistant container (see "**Throwing your pen away"** at the end of this Instructions for Use).

6D Put your pen cap back on.

- Do not put the pen back in the refrigerator.



How to store your pen

Before first use

- Keep new pens in the refrigerator between **36°F to 46°F (2°C to 8°C)**.
- **Do not** freeze. **Do not** use ADMELOG if it has been frozen.

After first use

- Keep your pen at room temperature **below 86°F (30°C)**.
- Keep your pen away from heat or light.
- Store your pen with the pen cap on.
- **Do not** put your pen back in the refrigerator.
- **Do not** store your pen with the needle attached.
- **Keep out of the reach of children.**
- Only use your pen for **up to 28 days** after its first use. Throw away the ADMELOG SoloStar pen you are using after 28 day, even if it still has insulin left in it.

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 damp cloth (water only). **Do not** soak, wash or lubricate your pen. This may damage it.

Throwing your pen away

- Put the used ADMELOG SoloStar pen in a FDA-cleared sharps disposal container right away after use. **Do not** throw away (dispose of) the ADMELOG SoloStar pen in your household trash.
- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
  - made of a heavy-duty plastic,
  - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
  - upright and stable during use,
  - leak-resistant, and

- properly labeled to warn of hazardous waste inside the container.
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: http://www.fda.gov/safesharpsdisposal.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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A SANOFI COMPANY

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