A Guide to Your Semglee® and Kirsty™ Insulin Injections

VIATRIS®

Welcome to your Semglee® and Kirsty™ insulin injections guide

What is insulin?

Insulin is a hormone produced by the body to control the amount of sugar (glucose) in the blood.[1] Without insulin, sugar builds up in the blood.[1] This can lead to serious health problems, such as heart disease, nerve damage, blindness, erectile dysfunction, kidney problems, and increased chances of amputation.[1,2]

For patients diagnosed with **type 1 diabetes,** the body is no longer able to produce insulin.[1] They will need to start on insulin therapy immediately and continue throughout their lives.[1,3]

For patients with **type 2 diabetes,** the body either produces an insufficient amount of insulin or is not able to use the insulin effectively.[1] A healthy lifestyle and medication supplemented with insulin therapy can effectively manage their blood sugar.[1]

Insulin can be administered with injections through **insulin pens, syringes or insulin pumps.**[4]

There are different types of insulin treatments based on their onset, peak, and duration of action.[5]

- **Rapid-acting insulin:**[5]
  This type of insulin medication starts taking effect within **30 minutes** after the injection. Its effect peaks at **1 hour** and lasts for **3 to 4 hours**. It must be injected **5 to 15 minutes before a meal.**
- **Long-acting insulin:**[5]
  Its onset of action starts at approximately **2 hours** after injection and peaks at **4 to 6 hours.**
  Its effect lasts for up to **24 hours.** It must be injected **once daily.**

What is a biosimilar?

A biosimilar is a biologic drug that is highly similar to a biologic drug that was already authorized for sale.[6] No expected clinically meaningful differences exist in efficacy and safety between a biosimilar and the already authorized biologic.[6]

Biosimilar medicines have to be reviewed and authorized for sale by Health Canada to ensure they offer the same confidence in quality, efficacy, and safety profile as the reference medicine.[6] The testing and authorization process for new biosimilar medicines is thorough, so you can be confident that the medicine you are using meets the highest standards.[6]

Health Canada ensures the safety of biosimilars by requiring manufacturers to follow additional post-authorization surveillance procedures such as:[6]

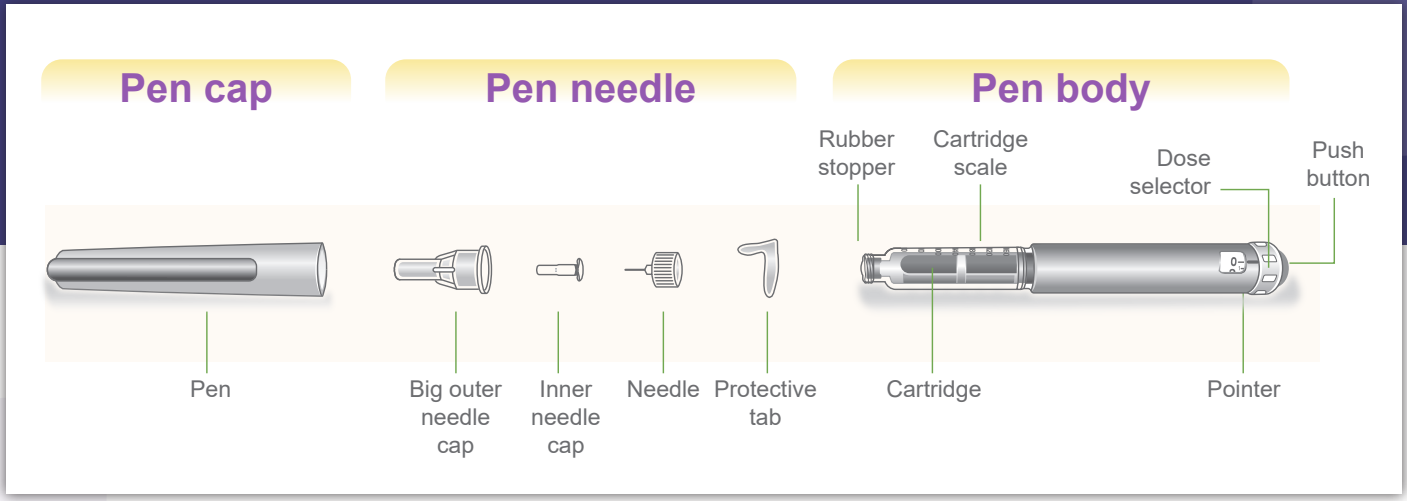
- monitoring and reporting side-effects
- performing periodic benefit-risk analyses of drug effects
- notifications regarding any new safety information
- requesting authorization for any major changes

Biosimilars can offer an effective, safe, and less costly alternative to already available medicines.[6,7]

Since initial treatments have not worked for you, you have been prescribed insulins

Your doctor may also suggest other medicines or treatments to address certain symptoms.

Your Semglee® and Kirsty™ insulins will be provided to you in disposable prefilled autoinjector pens.



Some patients may have their injection given by a doctor or nurse, and other patients may choose to inject themselves once they have been shown how to do it.

Note: Pen does not include disposable needle.

Semglee® and Kirsty™ Prefilled Autoinjector Pen Containing 100 units/mL (U-100) insulin[8,9]

IMPORTANT

Please check the patient medication information for further details.
Read the patient medication information carefully before you start taking biosimilar insulin and each time you get a refill. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about biosimilar insulin.

INSTRUCTIONS FOR USE

Read the following instructions carefully before using your prefilled pen and each time you get another pen. If you do not follow the instructions carefully, you may get too little or too much insulin, which can lead to too-high or too-low blood sugar levels.

Do not use the pen without proper training from your doctor, pharmacist or nurse. This pen is not recommended for use by the blind or visually impaired without the help of someone trained to use it. Get help from a person with good eyesight who is trained to use the prefilled pen.

Your insulin pen is a prefilled dial-a–dose device. You can select doses from 1 to 80 units in increments of 1 unit.

It is good to always carry a spare insulin pen in case yours is lost or damaged.

Your insulin pen is for you only. Do not share or reuse any part of your pen. Each time, before you use a pen, check that the device has not been tampered with. If it has, do not use that pen and take another one.

Required supplies

- Single-use, prefilled pen
- Sterile disposable hypodermic needle compatible with this pen
- Alcohol wipes
- Sharps disposal container

Step 1: Prepare your pen

A) Inspect the pen. Check the label on the pen to make sure:
  - It is the correct insulin type.
  - The expiration date has not passed.

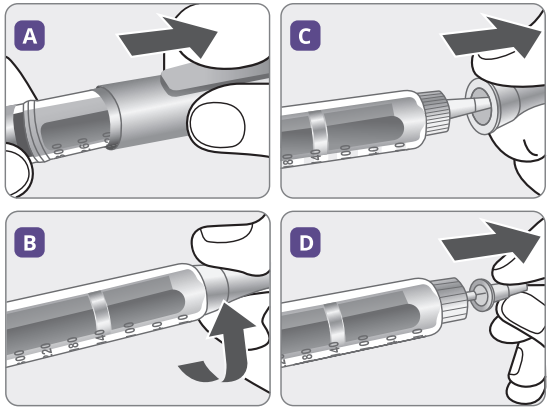
B) Pull off the pen cap. Wipe the rubber stopper with an alcohol swab.

C) Remove the paper tab from a new disposable needle. Screw the needle straight and tightly onto your prefilled pen. Trying to attach the outer needle cap sideways may bend or damage the needle. Pull off the big outer needle cap and keep it for later.

D) Carefully pull off the inner needle cap and throw it away.

IMPORTANT

Always use a new needle for each injection. This reduces the risk of contamination, infection, leakage of insulin, blocked needles, and inaccurate dosing. Be careful not to bend or damage the needle before use.



Step 2: Prime your pen needle

Prior to each injection, small amounts of air may collect in the cartridge during normal use. To avoid injection of air and ensure proper dosing:

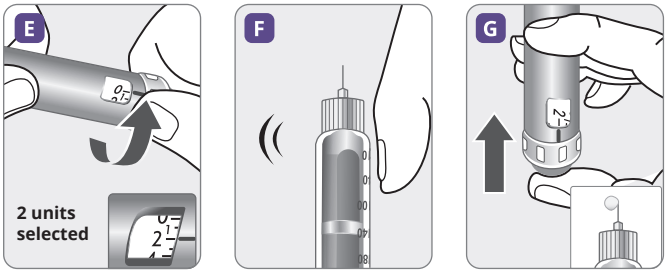
E) Turn the dose knob to 2 dose units. You will hear a "click" for each unit turned.

F) Hold your prefilled pen with the needle pointing upward and tap the cartridge gently with your finger to help any large air bubble to move to the top of the cartridge. Small bubbles may still be visible. This is normal.

G) Keeping the needle upward, press the push-button all the way in. The dose selector returns to 0. A drop of insulin should appear at the needle tip. If not, change the needle and repeat the procedure no more than 6 times. If a drop of insulin still does not appear, the pen is defective, and you must use a new one.

IMPORTANT

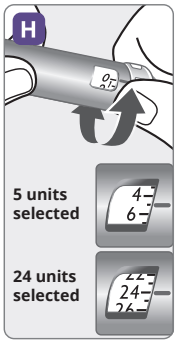
Always make sure that a drop appears at the needle tip before you inject. This ensures that the insulin flows. If a drop does not appear, this may indicate a blocked or damaged needle.



Step 3: Select your dose

Check that the dose window shows "0".

H) Turn the dose selector to the number of units you need to inject. The dose can be corrected either up or down by turning the dose selector in either direction until the correct dose lines up with the pointer. As you turn the dose knob to set your dose, the plunger will extend out and you will hear a "click" at each unit dialed. When turning the dose selector, be careful not to push the push-button as insulin will come out. You cannot select a dose larger than the number of units left in the cartridge.



IMPORTANT

Always use the dose selector and the pointer to see how many units you have selected before injecting the insulin.

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

Step 4: Inject

Select the injection site as explained to you by your healthcare professional, clean with a new alcohol wipe, and let your skin dry before you inject your dose. Your insulin can be injected under the skin (subcutaneously) of your stomach area, buttocks, upper legs (thighs), or upper arms. For each injection, change (rotate) your injection site within the area of skin that you use. Do not use the same injection site for each injection.

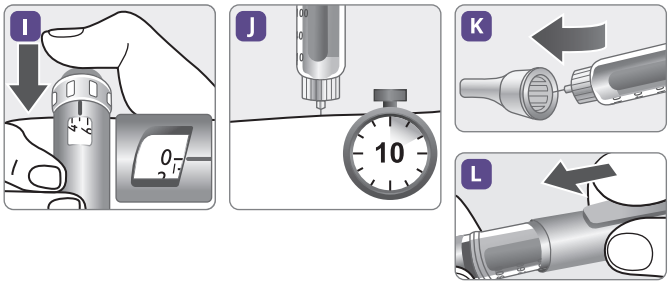
I) Push the needle straight into the skin as shown by your healthcare professional. Inject the dose by pressing the push-button all the way in until 0 lines up with the pointer. The dose knob will turn and you will hear "clicks" as you press down. Be careful only to push the push-button when injecting. Turning the dose selector will not inject insulin.

J) Hold the injection button on the end down for 10 seconds after the dose window shows "0" to make sure all of the insulin is injected. Withdraw the needle from the skin and release the pressure on the push-button. Always make sure that the dose selector returns to 0 after the injection. If the dose selector stops before it returns to 0, the full dose has not been delivered, which may result in a too-high blood sugar level.

Step 5: After your injection

K) Take the outer needle cap that you had saved, hold it at the widest part, and carefully cover the needle without touching it. Once the needle is covered, push the cap on and unscrew the needle. Safely remove the needle from your prefilled pen after each use. Dispose of needle in a suitable Sharps container.

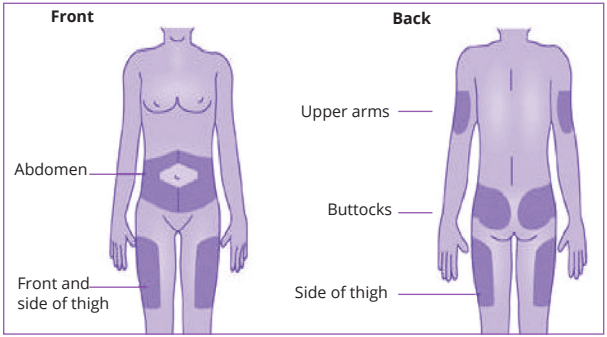
L) Put the pen cap on the prefilled pen. Store the pen at room temperature (under 30°C). Do not store the pen with a used needle attached.



Reminders

- Always carry an extra insulin prefilled pen
- Always handle your prefilled pen with care.
- Always use a new sterile disposable needle for each injection
- Do not soak or wash your pen using any of the following:
    - Alcohol
    - Hydrogen peroxide
    - Bleach
    - Or any other liquids
- Clean the exterior of your prefilled pen by wiping it with a medicinal swab
- Do not refill your prefilled pen
- Once your pen is empty it must be disposed of properly

Injection Diary



You can use this chart to keep track of your treatment.

You should rotate and change your injection site each time.[8–10] Stay at least 1 inch from a previous site used.[10] If you are injecting into the abdomen, do not use the area within 2 inches of belly button.[10] You can put any relevant notes that you would like to share with your physician or nurse.

SITE	DATE	TIME

HbA_{1c} Monitoring Table

Current HbA_{1c} level: _____ **Date:** _____

Target HbA_{1c} level: _____

Date	1	2	3	4

Self-Management Plan

	Your Goal	Actions	Confidence (1–10)	Result and Date	Result and Date	Result and Date	Result and Date	Result and Date	Result and Date	Result and Date
Blood sugar (glucose) HbA_{1c}										
Total cholesterol										
HDL-C										
LDL-C										
Triglycerides										
Weight										
BMI										
Blood Pressure										
Other										
Date										

Your Record

My target pre-meal blood glucose range (mmol/l): _____

My target post-meal blood glucose range (mmol/l): _____

Date	Blood Glucose Level (mmol/L)								Insulin Dose (units)				Special events/ comments
	Before Breakfast 	2 Hours After Breakfast 	Before Lunch 	2 Hours After Lunch 	Before Dinner 	2 Hours After Dinner 	Before Bed 	During the Night 	Breakfast 	Lunch 	Dinner 	Bedtime 	

Notes

Notes

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/adverse-reaction-reporting.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.

Please read carefully the instructions on the leaflet contained within the package/on the label.

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