

HumaPen SAVVIO® INSULIN DELIVERY MEDICAL DEVICE INSTRUCTIONS FOR USE

For Single Patient Use Only

www.lilly.ca



INTRODUCTION

Intended Use: **HumaPen SAVVIO®** is a reusable insulin pen intended for the self-injection of insulin available in Lilly 3 mL cartridges using disposable pen needles (sold separately).

Intended Users: The intended users of HumaPen Savvio are those prescribed Lilly 3 mL insulin cartridges, including adults, adolescents and children who are capable of self-injection, or adult caregivers who administer insulin to others.

Contraindications: There are no known contraindications for HumaPen Savvio.

HumaPen SAVVIO® is designed for ease of use. You can give yourself multiple doses from one Lilly 3 mL insulin cartridge (100 units/mL). You can inject from 1 to 60 units of insulin in each injection. You can dial your dose one unit at a time. If you dial the wrong dose, you can correct the dose without wasting any insulin.



For more information on HumaPen SAVVIO and Lilly insulin, please visit our website at www.lilly.ca

Read these instructions completely and follow the directions carefully before using the pen. Failure to follow the instructions may result in the wrong insulin dose being delivered.

Do not share your pen with other people, even if the needle has been changed. Do not reuse or share needles with other people. You may give an infection to them or get an infection from them.



If any of the parts of your pen appear broken or damaged, DO NOT USE. Contact your healthcare professional or Lilly at 1-888-545-5972 for a replacement pen.

HumaPen SAVVIO is not recommended for the blind or visually impaired without the assistance of a sighted individual trained to use it.

Always carry a spare insulin delivery device in case your pen is lost or damaged.

IMPORTANT NOTES

- Your healthcare professional has prescribed the type of insulin best for you. Any changes in insulin should be made only under medical supervision.

	<ul style="list-style-type: none">• HumaPen SAVVIO is for use only with Lilly 3 mL insulin cartridges.• Do not use other brands of insulin cartridges.• Before each injection, read the cartridge label and be sure the pen contains the correct Lilly 3 mL insulin cartridge.
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- The color of the pen is not intended to indicate insulin type.

INSERT THE CARTRIDGE

- Read and follow the instructions provided in your Lilly 3 mL insulin cartridge Consumer Information Leaflet.
- Check to make sure the insulin cartridge is not cracked or broken and your insulin is not expired before inserting the insulin cartridge into your pen.
- Check the cartridge label for the type of insulin and appearance before each injection.

ATTACH NEEDLE

- HumaPen SAVVIO is recommended for use with Becton, Dickinson and Company (BD) pen needles.
- Use a new needle for each injection. This will help ensure sterility. It will also help prevent leakage of insulin, keep out air bubbles, and reduce needle clogs.
- The directions regarding needle handling are not intended to replace local, healthcare professional, or institutional policies.

PRIME THE PEN

- Prime every time. The pen must be primed until you see insulin at the needle tip before each injection to make sure the pen is ready to dose.
- If you do not prime, you may get the wrong dose.

INJECT THE DOSE

- HumaPen SAVVIO will not allow you to dial more than the number of units left in the cartridge.
- Do not push down on the injection button while dialing your dose.

	<ul style="list-style-type: none">• Do not attempt to inject your insulin by turning the dose knob. You will NOT receive your insulin by turning the dose knob. You must PUSH the injection button straight in for the dose to be delivered.• Do not attempt to change the dose while injecting.
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- You may see a drop of insulin at the needle tip. This is normal and it does not affect the dose you just received.

CARE AND STORAGE

- Remove the needle after every use. Do not store the pen with the needle attached.
- Keep your HumaPen SAVVIO, Lilly 3 mL insulin cartridges, and needles out of the reach and sight of children.
- Keep the pen away from dust .

-  Keep dry.
-  Keep away from sunlight.
-  Temperature limit.
- Store pen between -40°C (-40°F) and 70°C (158°F) without the insulin cartridge.
- Wipe the pen cap, pen body, and case with a damp cloth to clean them.
- Do not use alcohol, hydrogen peroxide, or bleach on the pen body or dose window. Also, do not cover in liquid, as this could damage the pen.
-  Do not apply lubrication such as oil, as this could damage the pen.
- Keep the pen away from extreme hot or cold temperature, after the Lilly 3 mL insulin cartridge is inserted.
- Refer to insulin cartridge Consumer Information Leaflet for complete insulin storage instructions.

REPLACEMENT AND DISPOSAL OF PEN

Do not use your pen for more than 6 years after the first use or past the use-by (expiration) date on the carton.

The expired pen may be discarded in your household trash after you have removed the needle.

Contact your healthcare professional or Lilly for a new HumaPen SAVVIO.

If you have any questions or problems with your HumaPen SAVVIO, contact your healthcare professional or Lilly at 1-888-545-5972 for assistance.

Record the date your Pen was first used here: ___ / ___ / ___.

Record the Use-by date from your carton here: ___ / ___ / ___.

USE AS DIRECTED

HumaPen SAVVIO should only be used as described in this manual. The manufacturer will not be responsible for any problems with the device if these instructions are not followed. Failure to follow the instructions may result in the breakage of the pen and the wrong insulin dose being delivered.

FREQUENTLY ASKED QUESTIONS

QUESTIONS ABOUT INSERTING THE CARTRIDGE

1. Why doesn't the screw move out when there is no cartridge in the pen?

The screw may not move out when you push the injection button unless there is a cartridge in the pen. Once a cartridge is inserted, then the screw will move out when the injection button is pushed.

2. What should I do if I can't attach the cartridge holder to the pen body?

Check that the Lilly 3 mL insulin cartridge is correctly inserted into the cartridge holder. Then carefully line up the cartridge holder with the pen body and twist together until secure.

QUESTIONS ABOUT PRIMING THE PEN

1. Why is it important to prime before every injection?

- Priming helps to ensure that the pen and needle are working properly.
- Priming removes air that may collect in the needle or insulin cartridge during normal use.

If you do NOT prime, you may get the wrong insulin dose. Priming helps to ensure that the pen and needle are working properly. Once the pen is properly primed, insulin will flow from the needle. You may need to prime several times before you see insulin at the tip of the needle.

2. Why can it take several attempts to prime when a new cartridge is inserted?

There may be a gap between the screw and the cartridge plunger. Repeating the priming steps will move the screw out to touch the cartridge plunger. Once the end of the screw pushes the cartridge plunger out, insulin will flow from the needle.

3. Why should I prime until I see insulin at the tip of the needle?

Priming moves the screw into contact with the cartridge plunger and gets the air out of the cartridge.

- You may see insulin on the tip of the needle when you first attach it. This only shows that the needle is attached and not clogged. You must still prime the pen.
- You may also see no insulin at all when you are priming the pen. This may be because the screw is moving forward to close a gap between the screw and the cartridge plunger.
- Insulin will flow only when the pen is properly primed.
- If the injection button is hard to push, the needle may be clogged. Attach a new needle. Repeat the priming steps until insulin is seen at the needle tip.

If you are still unable to see insulin flow from the needle, **do NOT use** the pen. Contact your healthcare professional or Lilly at 1-888-545-5972 for assistance or to obtain a replacement.

4. What should I do if I have an air bubble in the cartridge?

Priming your pen will remove air. Point the pen up and tap the cartridge gently with your finger so any air bubbles can collect near the top. Repeat the priming steps until insulin is seen at the tip of the needle. A small air bubble may remain in the cartridge after completion of the priming steps. If you have properly primed the pen, this small air bubble will not affect your insulin dose.

QUESTIONS ABOUT INJECTING

1. What should I do if I dial a wrong dose (too high or too low)?

Turn the dose knob backward or forward to correct the dose before injecting.

2. What should I do if my full dose cannot be dialed?

If your dose is greater than the number of units left in the cartridge, you may either inject the amount remaining in your current cartridge and then use a new cartridge to complete your dose, OR inject the full dose with a new cartridge.

For example, if you need 31 units and only 25 units remain in the cartridge you will not be able to dial past 25. In this instance, you will need an additional 6 units.

Do not attempt to dial past this point. You may either:

- Inject the partial dose and then inject the remaining dose using a new cartridge.
- OR
- Inject the full dose with a new cartridge.

3. Why is it difficult to push the injection button when I try to inject?

- Your needle may be clogged. Try attaching a new needle, and then prime the pen.
- Place your thumb directly on top of the injection button so the dose knob can turn freely.
- Pushing the injection button down quickly may make the button harder to push. Pushing the button more slowly may make it easier.
- Using a larger diameter needle will make it easier to push the injection button during injection. Ask your healthcare professional which needle is best for you.

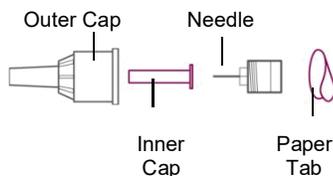
If none of the above steps resolves the problem, your pen may need to be replaced.

Your injection button may become harder to push if the inside of your pen gets dirty with insulin, food, drink, or other materials. Following the CARE AND STORAGE instructions should prevent this.

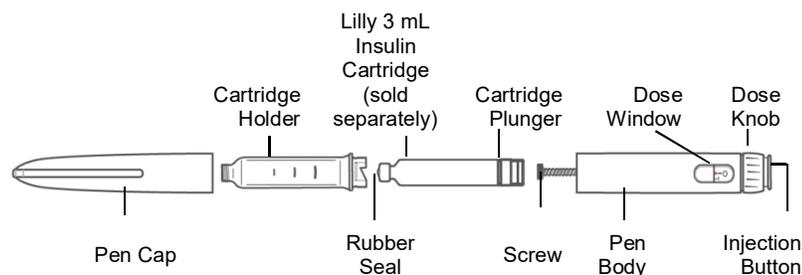
If you have any questions or problems with your HumaPen SAVVIO, contact your healthcare professional or Lilly at 1-888-545-5972 for assistance.

MAKE SURE YOU HAVE ALL YOUR PEN COMPONENTS.

PEN NEEDLE (sold separately)



HUMAPEN SAVVIO PARTS



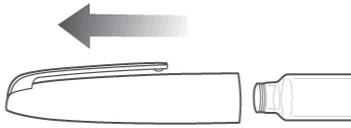
Be sure to check your Insulin Cartridge for:

- Type of Insulin
- Expiration Date

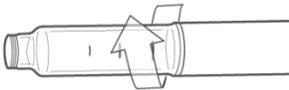
- Appearance
- Cracks or breakage

1. INSERT THE CARTRIDGE

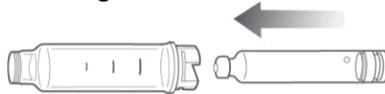
Pull off pen cap and set aside.



Twist cartridge holder to detach.



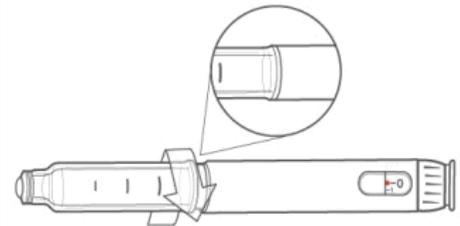
Insert small end of Lilly 3 mL insulin cartridge into the cartridge holder.



If the screw is out, use the cartridge plunger to push it back.



Push the cartridge holder and pen body straight together. Twist the cartridge holder onto the pen body until you feel a click and it is secure.



Wipe the small rubber seal on the end of the cartridge with an alcohol swab.

2. ATTACH NEEDLE

FOR CLOUDY MIXTURE INSULIN ONLY

Follow these instructions before each injection.



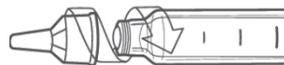
Roll the pen gently 10 times.

Invert the pen gently 10 times. The insulin should look evenly mixed.



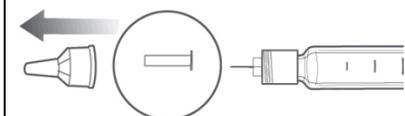
Remove the paper tab and discard.

Screw needle straight onto the cartridge holder until secure.



Pull off the outer cap. Save the outer cap to remove the needle after your injection.

Pull off the inner cap and throw it away.

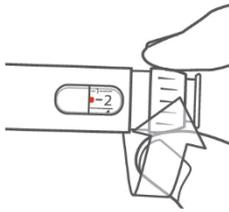


Keep Discard

3. PRIME THE PEN BEFORE EVERY INJECTION

A new cartridge may need to be primed several times before you see insulin at the needle tip.

Dial 2 units

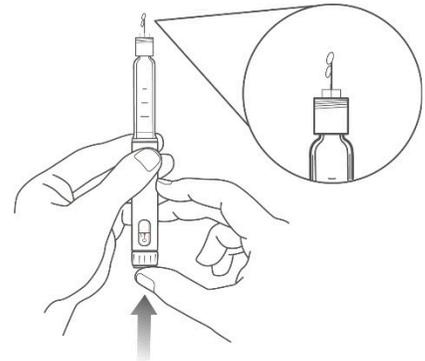


Point pen up. Tap cartridge to collect air at the top for removal.



Push injection button and hold for 5 seconds. Look for insulin at the tip of the needle. If no insulin is seen repeat priming.

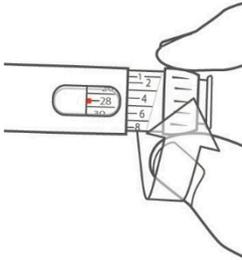
! If you do not prime, you may get the wrong dose.



! If no insulin is seen after several attempts, the needle on your pen may be clogged. Attach a new needle and repeat the priming steps.

4. INJECT THE DOSE

Turn dose knob to your desired dose.
Example: 28 units shown in the drawing below.



! If you dial too many units, you can correct the dose by dialing backwards.

Note: The pen will not allow you to dial more than the number of units left in the cartridge.

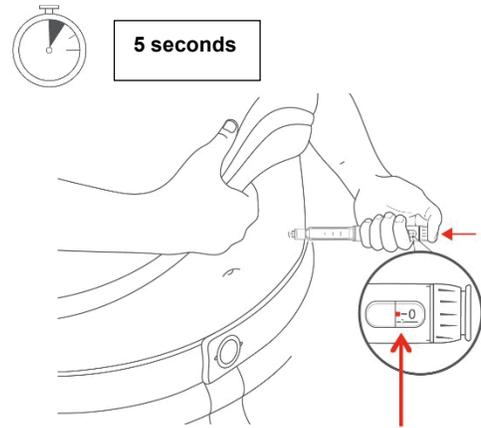
! The dose knob clicks as you turn it. **DO NOT** dial your dose by counting clicks because you may dial the wrong dose.

Insert needle into skin using the injection technique recommended by your healthcare professional.

! Place your thumb on the injection button and then **slowly** and firmly push the injection button until it stops moving.

Continue to hold the button for **5 seconds** then remove the needle from your skin.

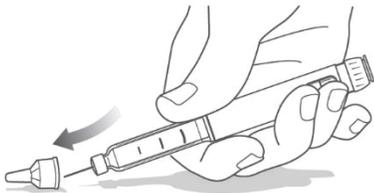
Note: After removal check to make sure you see **0** in the dose window to confirm you received the complete dose. If you are not sure you injected your full dose, **do not inject another dose.** Contact your healthcare provider or Lilly at 1-888-545-5972.



5. STORE YOUR PEN

 Carefully replace the outer needle cap as instructed by your healthcare professional.

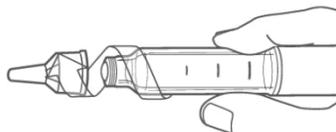
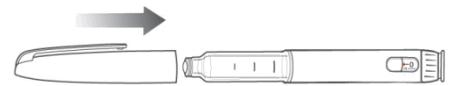
Note: To prevent air from entering the cartridge, do not store the pen with needle attached.



While grasping cartridge holder, unscrew the capped needle.

-  Put used needles in a sharps container or a hard plastic container with a secure lid. Do not throw needles directly into your household trash.
- Do not recycle the filled sharps container.
- Ask your healthcare provider about options to dispose of the sharps container properly. You can also check the Canadian Diabetes Association website at www.diabetes.ca for information on sharps disposal.
- The directions regarding needle handling are not intended to replace local, healthcare provider, or institutional policies.

Replace the pen cap.



 If you have any questions or problems with your HumaPen SAVVIO, contact your healthcare professional or Lilly at 1-888-545-5972.

Report all **MEDICAL DEVICE COMPLAINTS** or **UNDESIRABLE SIDE EFFECTS**, including **SUSPECTED SERIOUS INCIDENTS**, to Eli Lilly and Company at 1-888-545-5972.

You are also encouraged to report all **UNDESIRABLE SIDE EFFECTS**, including **SUSPECTED SERIOUS INCIDENTS**, to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

Importer/Distributor:
Eli Lilly Canada Inc.
130 King Street West, P.O. Box 73, Toronto, Ontario
M5X 1B1



Eli Lilly and Company
Pharmaceutical Delivery Systems
Lilly Corporate Center
Indianapolis, IN 46285, USA

CE
0344

HumaPen SAVVIO meets the dose accuracy and functional requirements of ISO 11608-1 with Lilly 3 mL cartridges.

Non-harmonized Symbol Glossary¹

	Patient information website
	Medical device ²
	Single patient – multiple use ²

¹ Glossary includes non-harmonized symbols used in the labeling.

² Symbols used on the carton.

International Organization for Standards (ISO) Symbol Glossary¹

	Caution ²
	Keep dry ³
	<u>Temperature limit</u> ³
	<u>Consult instructions for use</u> ⁴
	<u>Manufacturer</u> ³
	<u>Catalogue number</u> ⁴
	<u>Batch code</u> ⁴
	<u>Use-by date</u> ⁴

¹ Glossary includes only ISO symbols used in the labelling.

² ISO Symbol used only on the pen user manual (UM).

³ ISO Symbol used on both the pen user manual (UM) and carton

⁴ ISO Symbol used only on the carton

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HPSAV-0005-CA-IFU-20200720

Revision date: July 20, 2020

