

# HumaPen<sup>®</sup> SAVVIO<sup>™</sup> Insulin Delivery Device User Manual

www.lilly.ca

# INTRODUCTION

HumaPen<sup>®</sup> SAVVIO<sup>™</sup> is designed for ease of use. You can inject from 1 to 60 units of Lilly insulin from a Lilly 3 mL Cartridge (100 units/mL). You can dial your dose one unit at a time. If you dial too many units, you can correct the dose without wasting any insulin. For more information on HumaPen SAVVIO and Lilly insulin please visit our website www.lilly.ca

Read this manual completely and follow the directions carefully before using HumaPen SAVVIO. If you do not follow these directions completely, you may get too much or too little insulin

DO NOT SHARE YOUR PEN OR NEEDLES AS THIS MAY RISK TRANSMISSION OF INFECTIOUS AGENTS

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.

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

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

# **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. Always check the label text on the cartridge to make sure it is the correct insulin. The color of the

#### **INSERT THE CARTRIDGE**

HumaPen SAVVIO is for use only with Lilly 3 mL Insulin Cartridges. Do not use other brands of insulin cartridges.

Pen is not intended to indicate insulin type.

- Read and follow the instructions provided with your Lilly 3 mL Insulin Cartridge Consumer Information leaflet.
- · Before inserting the Insulin Cartridge, check to make sure the cartridge is not cracked or broken
- Before each injection, check the cartridge label for the type of insulin, expiration date, and appearance.

# ATTACH NEEDLE

- HumaPen SAVVIO is recommended for use with 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 to a stream of insulin before each injection to make sure the Pen is ready to dose
- If you do not prime, you may get too much or too little insulin.

#### INJECT THE DOSE

- · HumaPen SAVVIO will not allow you to dial more than the number of units left in the cartridge
- You must **PUSH** the Injection Button straight down for the dose to be delivered
- 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

# 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 too much or too little insulin 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.
- 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.

- 3. Why should I prime to a stream and why isn't the Pen ready for use if I see a drop of insulin on the Needle tip?
- You may see a drop of 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 to a stream
- You may also see no stream at all. This may be because the Screw is moving forward to close a gap between the Screw and the Cartridge Plunger
- If there is air in the cartridge, the insulin may sputter or drip until all the air is removed.
- Insulin will flow as a stream 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 a stream of insulin is seen. If you are still unable to see a stream of insulin out of 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 a stream of insulin is seen. 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)?

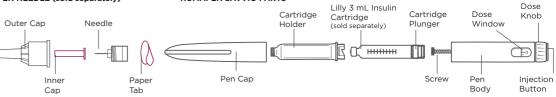
Turn the Dose Knob backward or forward to correct the dose before injecting.

# MAKE SURE YOU HAVE ALL YOUR PEN COMPONENTS.

(107)

PEN NEEDLE (sold separately)

HUMAPEN SAVVIO PARTS



Be sure to check your Insulin Cartridge for:

 Type of Insulin Expiration Date

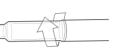
 Appearance Cracks or breakage

# **1. INSERT THE CARTRIDGE**





Twist Cartridge Holder to detach



FOR CLOUDY **INSULIN ONLY** Follow these instructions before each injection Roll the Pen gently 10 times. Invert the Pen gently 10 times. The insulin should

# **2. ATTACH NEEDLE**

Insert small end of 3 mL Insulin

Cartridge into the Cartridge Holder

If the Screw is out, use the Cartridge

Plunger to push it back

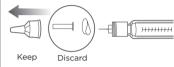
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Remove the Paper Tab and discard.

to remove the Needle after your injection. Pull off Inner Cap and discard.

Pull off Outer Cap and keep it



Push the Cartridge Holder and Pen Body

Twist the Cartridge Holder onto the Pen

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Body until you **feel a click** and it is

straight together.

secure

Point Pen up. Tap collect air at top. **CAUTION:** If no insulin stream is seen after several attempts, attach a new Needle, as the one on your

CAUTION: If you do not prime, you may get too much or too little insulin The pen is NOT properly primed if you only see a few drops of insulin.

Pen may be clogged.

# **4. INJECT THE DOSE**

Dial your dose. For example, 8 units is shown in the drawing below. If you dial too many units. you can correct the dose by dialing backwards

-8

Insert Needle into skin using injection technique recommended by your healthcare professional

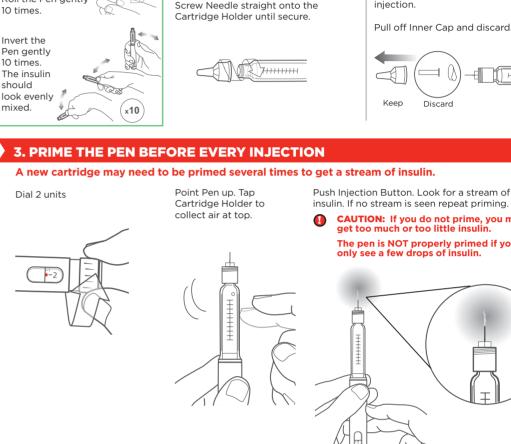
Place your thumb on the Injection Button and push firmly until the Injection Button stops.

To deliver the full dose, hold Injection Button in for **5 seconds**. Remove Needle from 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

5sec 1 ..... -0



**PUSH** the Injection Button straight in for the dose to be delivered.

- Do not attempt to change the dose while injecting
- 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 the Pen away from moisture, dust. extreme hot or cold temperatures, and direct sunlight.
- Do not store the Pen in a refrigerator.
- 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.
- Do not cover in liquid or apply lubrication such as oil, as this could damage the Pen.
- Refer to the Lilly 3 mL Insulin Cartridge Consumer Information leaflet for complete insulin storage instructions.

# REPLACEMENT

Your HumaPen SAVVIO has been designed to be used for up to 6 years after first use.

Contact your healthcare professional or Lilly for a new HumaPen SAVVIO when your Pen has been used for 6 years.

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:

DAY MONTH YEAR

#### 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. Attach a new Needle, and then prime the Pen.
- 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.

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

Contact your healthcare provider or Lilly at 1-888-545-5972.

# **5. STORE YOUR PEN**

Carefully replace the Outer Cap as instructed by your healthcare professional

To prevent air from entering the

with Needle attached.

cartridge, do not store the Pen

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While grasping Cartridge Holder, unscrew the capped Needle and dispose of as directed by your healthcare professional

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.

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> CE 0344

HumaPen SAVVIO meets the current dose accuracy and functional requirements of ISO 11608-1:2000 with Lilly 3 mL cartridges.

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