

Introduction

- INSUPen Pro® is a reusable pen that can deliver insulin doses from 1 unit (0.01 mL) to 60 units (0.60 mL) in increments of 1 unit (0.01mL) with insulin preparations of 100IU/mL.
- INSUPen Pro® is available in green colour.
- INSUPen Pro® to be used only with Prefilled 3 mL (Insulin products 100 IU/mL) cartridges of Biocon's **Insugen-R Refil®, Insugen-N Refil®, Insugen-30/70 Refil®, Insugen-50/50 Refil® & Basalog Refil®** as prescribed by your health care professional.
- Read the entire user guide thoroughly before using your new INSUPen Pro® even if you have used other similar delivery systems before. Follow the instructions carefully while using your INSUPen Pro®. Failure to do so may result in delivery of an incorrect dose of insulin.
- Do not use your INSUPen Pro® if any part appears broken or damaged.

A. General information

Pen information

- INSUPen Pro® should be handled with care. Do not drop it and avoid knocking it against hard surfaces.
- INSUPen Pro® has no user serviceable parts. Do not try to repair a faulty pen.
- Visually impaired people can use INSUPen Pro® only with the help from someone who is able to follow the instructions completely.
- To minimise the risk of transmission of infectious diseases, your INSUPen Pro® should not be shared with anyone else.
- It is recommended to carry an additional INSUPen Pro® and insulin of the same type(s) you use, in case your existing INSUPen Pro® is lost or damaged. Do not change your type of insulin without consulting your healthcare professional.
- Your INSUPen Pro® is designed to be used for 3 years but not later than the expiry date mentioned on the pen carton. Dispose the pen as directed by your health care professional when this time has passed, even if it seems to be in good working condition.
- Refer to **Taking Care of INSUPen Pro®** in this userguide for more information.

Needle information

- The direction regarding needle handling are not intended to replace instructions from healthcare professionals, institutional policies and local policies.
- Needles are available in different lengths and gauges. Ask your healthcare professional to determine which needle is best for you.
- INSUPen Pro® is recommended for use with sterile disposable hypodermic needles (4 mm, 32 G) manufactured by Becton Dickinson & Company (BD) and Ypsomed
- Use new sterile needles for each injection.

Cartridge information

- Do not change your insulin type without taking medical advice.
- Read and follow the instructions provided with Biocon's 3 mL insulin cartridges (referred to as cartridge henceforth in this document).

B. Ensuring a clean, safe injection

- Wash your hands with soap and water before handling the pen.
- Select a location for injection as recommended by your healthcare professional.
- Always store the pen with the pen cap attached.

C. Getting started (first use)

Check for the following:

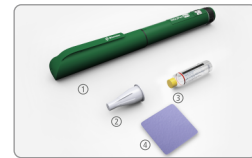
- The box is sealed.
- The pen is new and undamaged.
- Pen expiry date provided on the carton.
- Bring the insulin cartridge to room temperature prior to inserting into cartridge holder.

Make sure you have the following items:

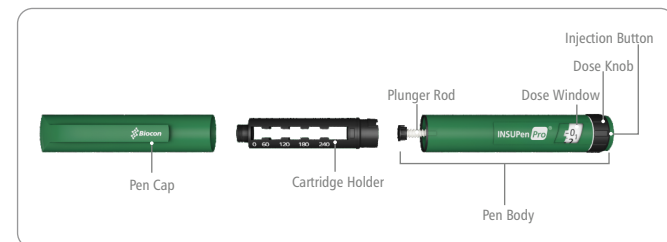
- INSUPen Pro®
- New pen needle

3. Insugen® or Basalog® cartridge

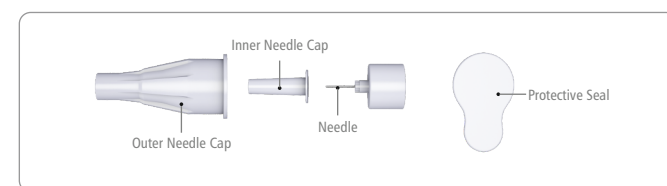
4. 2 Alcohol swabs



Parts of INSUPen Pro®



Needle assembly

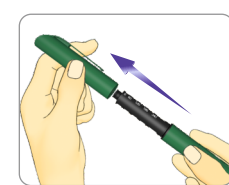


Cartridge



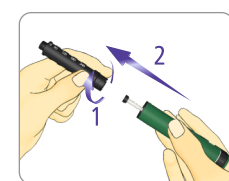
D. Inserting a new cartridge

Step 1: Remove the cap



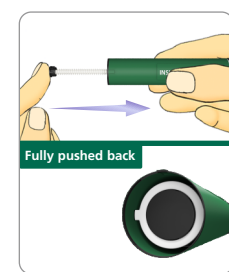
Take INSUPen Pro® out of the case. Pull off the pen cap.

Step 2: Remove cartridge holder



Detach the cartridge holder by twisting and pulling gently away from the pen with a "click"

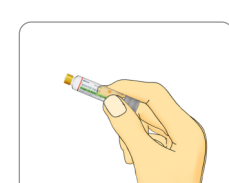
Step 3: Reset the plunger rod



Grip the pen body in one hand and gently push back the plunger rod with the other hand in to the injection mechanism section of the pen.

NOTE: Before inserting a new cartridge, make sure the plunger rod is fully pushed back.

Step 4: Check the cartridge



Remove the cartridge from the pack. Check that the cartridge is not cracked or broken. Ensure that you have the right type of insulin as prescribed by your healthcare professional.

! CAUTION

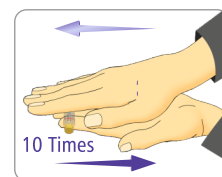
This pen is designed to hold only those cartridges that have Biocon's label. Do not use a cartridge if it is damaged. Check that the cartridge has not expired.

Do not use other brands of insulin cartridges with INSUPen Pro® (recommended for Biocon's cartridges only) to avoid inaccurate dosing.

For insulin solution (clear insulin) proceed directly to insert the cartridge as mentioned in Step 6.

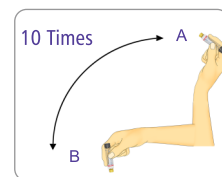
Only for insulin suspension (cloudy insulin) ensure to mix (resuspend) it as follows:

Step 5: Mix (Resuspend) cloudy insulin



Bring the cartridge to room temperature.

Roll the cartridge between your palms 10 times. These steps should be done with the cartridge in a flat (horizontal) position.

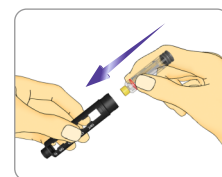


Hold the cartridge in your hand and then turn the cartridge up and down between positions A and B (ref. figure) so the glass bead moves from one end of the cartridge to the other.

Do this at least 10 times. Repeat step 5 until insulin looks uniformly white and cloudy.

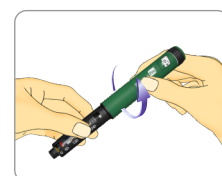
For further information refer to the instructions provided with Biocon's insulin cartridge.

Step 6: Insert the cartridge



Insert the cartridge into the cartridge holder with the metal end first.

Step 7: Fix the pen body



Twist the pen body back into the cartridge holder, this is attached properly when you again hear a "click".

E. Attaching a new needle

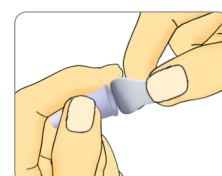
Step 8: Attach a new Needle



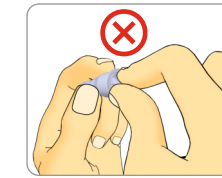
Wipe the front end of the cartridge with an alcohol swab.

! CAUTION

Always use a new sterile disposable hypodermic needle for each injection. Re-using a needle which is designed for single use will cause infection and contamination of drug. Use of a contaminated needle and drug can cause serious health issues. Also check the expiry date of needle on its protective seal, prior to use. Do not use an expired needle.

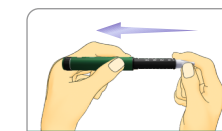


Remove the protective seal from the outer needle cap.



! CAUTION

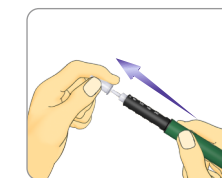
Do not attempt to pull out the needle by hand.



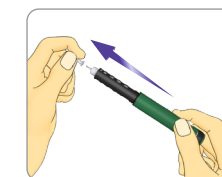
Attach the needle assembly firmly onto the cartridge holder. Keep the needle firm and straight while attaching.



The needle could bend/fall off if not kept straight while attaching.



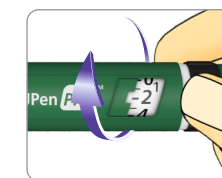
Remove the outer needle cap and save for later use in step 13.



Carefully pull off the inner needle cap and throw it away. You may see a droplet of insulin at the needle tip.

F. Priming (checking the insulin flow)

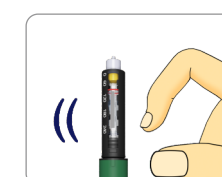
Step 9: Priming



Turn until you see '2' in the dose window.

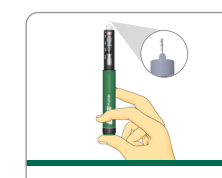
NOTE: If you turn the dose knob past the required dose of 2 units, simply turn it in the opposite direction to correct the dose.

Step 10: Removal of air bubbles



Hold INSUPen Pro® with the needle end pointing straight up.

Tap the cartridge holder gently with your finger to raise any air bubbles to the top of the insulin cartridge. There may be a few small air bubbles still seen.



With the needle pointing upwards, press the dose button in until it stops. The dose window should show '0'. You should see 2-3 drops of insulin come out of the needle tip. Priming is complete when 2-3 drops of insulin appear at the needle tip. If no insulin comes out of the needle repeat Step 10 upto a maximum of five times, until 2-3 drops of insulin are visible. If unable to achieve priming refer to FAQs (2 and 3) in this user guide for more information.

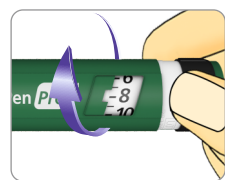
! CAUTION

It is important that you complete the priming step before preparing for each injection. It ensures dose accuracy, and shows that the needle is not blocked. If the injection button becomes hard to push, change the needle and try again.



G. Setting the dose

Step 11: Set the dose



Turn the dose knob to set the required dose. Doses with even numbers are indicated as digits against bold lines and doses with odd numbers are indicated by thin lines between the digits

CAUTION
When turning the dose knob to set the dose, be careful not to push the injection button, as insulin will come out.

Dose correction

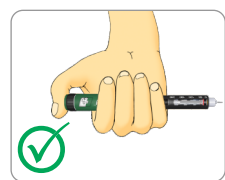
This step needs to be performed only if the dose has been set incorrectly prior to injection and a different dose is required. Refer to FAQs (5 and 6) in this user guide for more information.

NOTE:

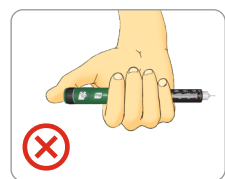
INSUPen Pro® can deliver up to 60 units in one injection. For more than 60 units, you will need two (or more) injections. The scale on the cartridge holder is only an indicator of the amount of insulin left in the cartridge.

H. Administering the injection

Step 12: Inject the dose

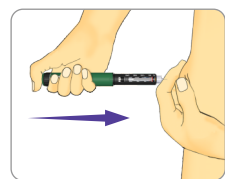


Wipe the skin with alcohol swab at the spot where you want to inject. Do not inject with the needle placed at an angle.



Holding injection button

Place your thumb on the injection button as shown, pressing sideways may result in an inaccurate dose.



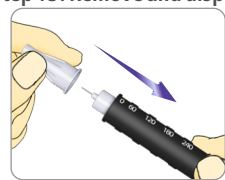
Insert the needle and follow the injection technique as advised by your healthcare professional.



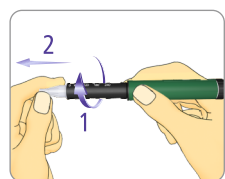
Press the injection button down slowly and firmly until you see a '0' in the dose window. Hold injection button down and count to 10 slowly (10 seconds) before withdrawing the needle from the skin.

CAUTION
If you do not keep the injection button pressed for 10 seconds after '0' has been displayed in the dose window, it could result in an inaccurate dose. You may also observe insulin coming out of the needle. Refer to FAQs (8) in this user guide for more information.

Step 13: Remove and dispose needle



Carefully place the outer needle cap over the needle.



Unscrew the capped needle and dispose it as directed by your healthcare professional.

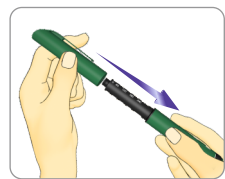


CAUTION
To discard used needles, follow local regulations in your country concerning the handling of potentially infectious materials.

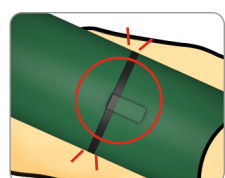
CAUTION
Do not attempt to remove the needle without the outer needle cap in place.

I. Storing INSUPen Pro®

Step 14: Storing INSUPen Pro®



Replace the pen cap.

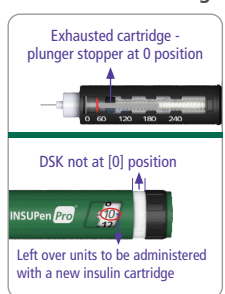


Align the body of the pen with the pen cap for safe storage.

Store INSUPen Pro® for your next use.

For more information refer Section M: Taking care of INSUPen Pro®

J. Last dose & Cartridge replacement

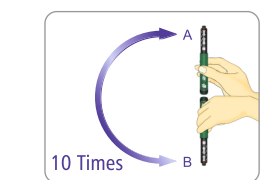
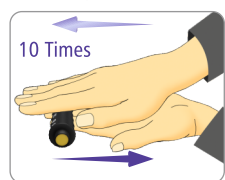


If the injection button stops during the injection and 0 is not indicated. **DO NOT TRY** to force the injection button down. This may happen due to non availability of Insulin in the cartridge. Replace the exhausted cartridge with a new Insulin cartridge of the same type you use and follow the steps from 1 to 14. Refer to FAQs (8) in this user guide for more information.

NOTE: Carry additional cartridge of the same Insulin type along with the pen to avoid delay in taking Insulin dose.

K. Instructions for repeat use

1. Pull off the pen cap.
2. For insulin solution (clear solution) repeat steps 8 to 14 to get your desired dose.
3. For insulin suspension (cloudy insulin) before every subsequent injection (repeat use) ensure that the cartridge containing an insulin suspension (cloudy insulin) is uniformly white and cloudy, when resuspended. Roll the pen between your palms 10 times. These steps should be done with the pen in a flat (horizontal) position.
Resuspend the cloudy insulin by holding the pen in your hand and turning it up and down between positions A & B (see Figure) so the glass bead moves from one end of the cartridge to the other with the insulin cartridge inside the cartridge holder.



Repeat steps 8 to 14 to get your desired dose.

L. Frequently Asked Questions (FAQs)

1. What do I do if air bubbles are present in the cartridge?
The presence of air bubbles can affect the amount of insulin delivered. A small air

bubble might remain in the container after tapping; this small air bubble will not affect your dose. Ensure that you remove the air bubbles as mentioned in Step 10 of the user guide.

2. What do I do if there are no drops visible while checking the insulin flow (priming)?

The needle may be blocked. Replace the needle and check for insulin flow. A few drops of insulin will appear as described in Section F: Priming (checking the insulin flow)

3. Why is it important to check the insulin flow and prime before every injection?

Priming ensures that the pen and needle are working properly. Once the pen is properly primed, insulin will flow from the needle. If you do not prime, you may not get the accurate amount of insulin.

4. Why can it take several attempts at priming before I see a drop of insulin with a new cartridge?

There may be a slight gap between the plunger rod and the plunger stopper. Repeating the priming steps will move the plunger rod into contact with the cartridge plunger stopper. Once in contact the plunger rod will push the cartridge plunger stopper forward, forcing insulin to flow through the needle.

5. What do I need to do if the set dose is higher than the desired dose?

Turn the dose knob to a lower number until the correct dose is set. Check on the dose window that the desired dose has been reached. Dose correction takes place without any drug loss. Ensure to do this before you press the injection button. Do not push the injection button while turning, as insulin will come out. The dose cannot be changed during injection.

6. What do I need to do if the set dose is lower than the desired dose?

Turn the dose knob to a higher number until the correct dose is set. Check on the dose window that the desired dose has been reached. Dose correction takes place without any drug loss. Ensure to do this before you press the injection button. Do not push the injection button while turning, as insulin will come out. The dose cannot be changed during injection.

7. What should I do if the dose knob stops rotating before it reaches the required number of units during dose setting?

This is because you are trying to select dose larger than 60 units.

8. What do I do if the injection button stops during the injection and 0 is not indicated after an injection?

This means that you have not received the selected dose of insulin. Do not try to force the injection button down.

There may be several reasons for such an incident:

- This may be because of not having sufficient insulin available in the cartridge
Example: If 20 units are required and insulin left in the cartridge is 10 units. Pen dose knob can be dialled to 20 units & during injection dose knob stops at 10 unit. Then insert a new cartridge and follow steps 1 to 13 to deliver another 10 units from the new cartridge, so that in total you receive 20 units.
- During the injection you may have not pressed the injection button for long enough. Ensure that you press the injection button for 10 seconds as directed. Pressing on the edge of the dose button can lead to injection blockage.
- Your needle may be blocked. Change the needle and check the insulin flow (prime) as described in Section F: Priming (checking the insulin flow). Select the number of remaining units you need to complete your previous dose and inject as described in Section H: Administering the injection.
- If the step above does not work then it is possible that the cartridge is blocked. In this case, use a new cartridge.

9. Why can I not dial the dose to use the small amount of insulin that remains in my cartridge?

INSUPen Pro® is designed to deliver at least 300 units of insulin. INSUPen Pro® design prevents the cartridge from being completely emptied because the small amount of insulin that remains in the cartridge cannot be delivered.

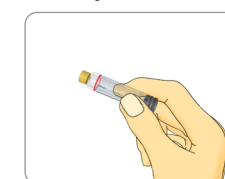
M. Taking care of INSUPen Pro®

Storage and Handling

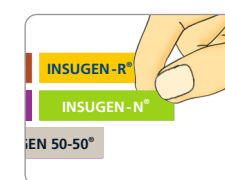
- Keep INSUPen Pro® away from moisture, dust, direct sunlight and places where the temperature may get too high or low.

- When a cartridge is inserted in INSUPen Pro®, store your INSUPen Pro® as mentioned in the package insert that comes with the cartridge.
- It is recommended to keep your INSUPen Pro® in the pen case supplied.
- Remove the needle after every use. Do not store the pen with the needle attached as this will help ensure sterility. Pen cap will help in prevention of leakage of insulin, keep out air bubbles and reduce needle clogs.
- Do not use alcohol, hydrogen peroxide, bleach or any other solvent to clean the pen. Also, do not apply lubrication such as oil, as this could damage the pen.
- Keep/store INSUPen Pro® out of reach and sight of children.
- Always use a new sterile disposable hypodermic needle for each injection.
- As a precautionary measure, always carry a spare INSUPen Pro® in case your pen is lost or damaged.
- Your pen is designed to work accurately and safely. It must be handled with care. Avoid dropping the pen, as this may cause cartridge breakage or damage the pen.
- Do not share your pen with others. This pen is intended and recommended for use by one person only.
- Clean the outside of your pen by wiping it with a damp cloth.
- Duration of use of the pen not more than 3 years from the date of purchase and within the expiry date

N. Mark your INSUPen Pro® with different types of insulin label stickers



Step i: Select the sticker according to the type of insulin (Insugen® or Basalog® cartridge) you have been prescribed.



Step ii: Peel off the sticker.



Step iii: Paste the sticker on the cartridge holder of INSUPen Pro®. Continue with the steps as mentioned.



Pen designed and manufactured for Biocon Limited by: Ypsomed AG, Switzerland

Marketed by:
Biocon Biologics India Limited
Biocon House, Semicon Park,
Electronics City, Phase - II,
Bengaluru - 560 100, India.

® - Registered trademark

For single patient use only

In case of any query about the usage of INSUPen Pro® or any general queries regarding services or essentials of diabetes, Call Toll Free number 1800-425-7667 timing is between 8 am to 10 pm.

In case of any adverse event related to Biocon Products, call Toll Free Number : 1800-102-9465 or visit our website www.biocon.com and fill voluntary reporting form available under "Report Adverse Events / Side Effects and Product Complaints" and send the duly filled form to us at DrugSafety@biocon.com.