

Lyxumia™

Instructions Leaflet

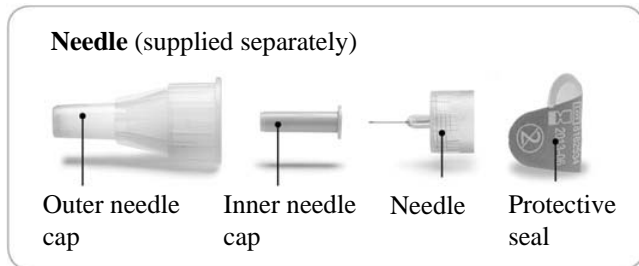
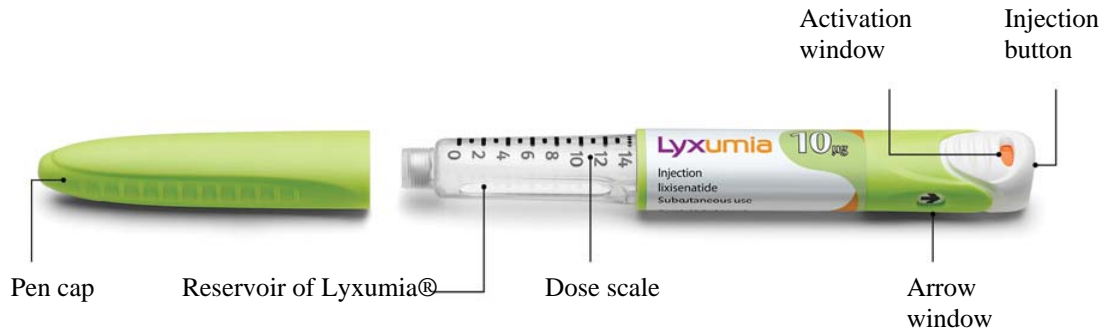
Lyxumia™ is provided in a prefilled pen for injection. Talk with your healthcare professional about proper injection technique before using Lyxumia™.

If you are not able to follow all the instructions completely on your own, (e.g. if you are blind or have severe vision problems) use Lyxumia™ Pen only if you have help from a person who is able to follow the instructions.

Keep this leaflet for future reference.

If you have any questions about Lyxumia™ or about diabetes, ask your healthcare provider.

About Your Lyxumia® Pen



Black plunger
The plunger will advance along the dose scale after each injection.



Important information for use of Lyxumia™ Pen

- Only inject one dose per day.
- This pen is only for one person's use. Do not share it with anyone else.
- If you are giving an injection to another person or if your injection is given by another person, special care must be taken to avoid accidental needle injury and transfer of infection.
- Always check the label to ensure you have the correct Lyxumia™ 10 mcg Pen and it has not passed the expiry date. Using the wrong medication may result in unwanted changes in blood sugar that could be harmful to your health.
- Each Lyxumia™ Pen contains 14 pre-set doses. There is no need to measure the required dose.
- Check the appearance of the Lyxumia™ reservoir. The liquid must be clear, colourless and free of particles. If not, do not use this Lyxumia™ Pen.
- Always use a new sterile needle for each injection. This helps prevent contamination or potential needle blockage.
- Only use needles that have been approved for use with Lyxumia™
- Always have a spare Lyxumia™ Pen in case your pen is lost or damaged.
- Do not attempt to extract liquid from the Lyxumia™ reservoir using a syringe.
- Once your Lyxumia™ Pen is activated it can be used for up to 14 days (see Storage).

Activation of the Pen

You must activate your Lyxumia™ Pen before you use it for the first time, to make sure that it is working correctly and that the dose for your first injection is correct.

When you activate your Lyxumia™ Pen, do not inject the liquid into your body. Instead, get a suitable container to catch the excess liquid for disposal.

The activation process must be done only once, before first use of each new Lyxumia™ Pen.

Do not repeat the activation process before each injection or you will not obtain 14 doses from your

The images below show what your Lyxumia™ Pen looks like before and after activation.

New Pen

The pen requires activation before injecting your first dose from it.

Not activated

(Orange window)



Activated Pen

The pen is activated and ready for injections. The window remains white. **Do not repeat** activation.

Ready for injections
(White window)



NEW PEN ACTIVATION

Only follow this section when the activation window is orange. Activate your new Lyxumia™ Pen only once.

A new pen will display an orange colour in the activation window.



Step 1 : Pull off cap and check pen

Check that the activation window is orange



Check the liquid. It should be clear, colourless and free of particles. If not, do not use.

In a new pen the black plunger will not be visible against the dose scale

Step 2 Attach needle and remove needle caps

Wipe the rubber seal (on the end of the cartridge) with alcohol swab.



Remove protective seal from the outer needle cap

Line up the needle with the Pen and keep it straight as you screw it firmly onto the Pen.



Take care not to stick yourself when the needle is exposed.
Pull off the outer needle cap and keep it to remove the needle later.
Pull off the inner needle cap and throw it away.

Step 3 Pull injection button and check arrow



Check that the arrow is pointing towards the injection button.

Pull the injection button out fully.



Check that the arrow is now pointing towards the needle.

Step 4 Press and hold Injection Button to Activate Pen



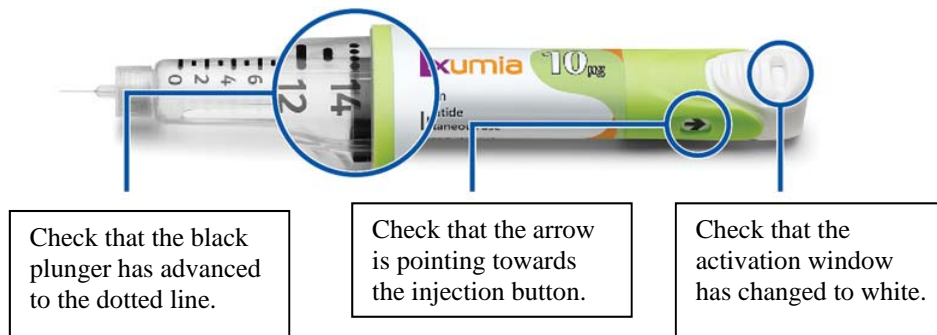
Point the needle into a suitable container (e.g. paper cup or tissue) that will catch the excess liquid for disposal.

Push the injection button all the way in.

You may feel or hear a “click”.

Keep the injection button pressed in and slowly count to 5 in order to expel the last drops. **Do not repeat activation** for this pen.

Step 5 Check that pen is activated



If these things do not occur, do not use this pen.

This pen is now activated. Do not repeat activation for this pen.

Continue directly to Step C for your first dose.

You **do not** need to replace the needle between activation and your first injection.

DAILY USE OF PEN

Only follow this section when the activation window is white. Inject only one dose each day.



Step A: Pull of cap and check pen



Check the liquid. It should be clear, colourless and free of particles. If not, do not use.
Check the number of doses in the pen as indicated by the black plunger.
Check the label on your pen to make sure you have the correct medication.
Confirm that the activation window is white. If it is orange, go to *New Pen Activation*.

Step B : Attach new needle and remove needle caps



Remove protective seal from the outer needle cap.

Wipe the rubber seal (on the end of the cartridge) with alcohol swab.

Line up the needle with the Pen and keep it straight as you screw it firmly onto the Pen.



Take care not to stick yourself when the needle is exposed.

Pull off the outer needle cap and keep it to remove the needle later. Pull off the inner needle cap and throw it away.

Always use a **new sterile needle** for each injection.

Step C : Pull injection button and check arrow



Check that the arrow is pointing towards the injection button.
Pull the injection button out fully.



Check that the arrow is pointing towards the needle.
The pen is now ready to inject.

Step D : Press and hold injection button to inject the dose



Grasp a fold of skin and insert the needle (see injection sites).

Press the injection button all the way in. You may feel or hear a “click”.

Keep the injection button pressed in and slowly count to 5 to get the full dose.

Your dose has now been delivered. Only inject **one dose each day**.

Step E: Check plunger



The black plunger should have advanced along the dose scale
(In the **example** above the dose scale shows that there are 13 injections left)

Step F Remove and discard needle after each injection



Place outer needle cap on a flat surface. Guide the needle into the outer needle cap.
Put the outer needle cap back on.



Squeeze the outer needle cap to grip the needle and use it to unscrew the needle from the pen.

Dispose of the needle in a puncture resistant container or as instructed by your healthcare professional.



Replace the pen cap

Repeat all steps in *Section Daily use of Pen* for your next daily injections.

Discard a used pen 14 days after activation, even if there is some medicine left.

Storage

General Information

- Keep your Lyxumia™ Pen in a safe place out of the reach and sight of children.
- Protect your Lyxumia™ Pen from dust and dirt.
- Replace the pen cap after each use in order to protect from light.
- Activate your new pen just before you use it the first time.

Before activation:

Store your unused Lyxumia™ Pens in the refrigerator (2 to 8°C; 36 to 46 °F). Do not freeze Lyxumia™ Pens and do not use Lyxumia™ if it has been frozen.

After activation:

Store Lyxumia™ below 30°C (86°F). Do not refrigerate Lyxumia™ once it has been activated. Do not store your Lyxumia™ Pen with the needle attached.

Once Lyxumia™ Pen is activated it can be used for up to 14 days. Discard a used Lyxumia™ Pen after 14 days, even if there is some medicine left in the pen.

Replace the pen cap after each use in order to protect from light.

Table of activation and disposal

Pen	Date of activation	Date to Discard
1		
2		
3		
4		
5		
6		

Maintenance

- Your Lyxumia™ Pen should be handled with care.
- You can clean the outside of your Lyxumia™ Pen by wiping it with a damp cloth.
- Do not soak, wash or lubricate your Lyxumia™ Pen as this may damage it.
- If you are concerned that your Lyxumia™ Pen may be damaged, do not use it. Obtain a new one. Do not repair the pen.

Disposal



The Lyxumia® Pen is empty when the black plunger has reached '0' on the dose scale

The injection button cannot be pulled out when the pen is empty

- Replace the pen cap before disposing of your Lyxumia™ Pen.

- Discard your Lyxumia™ Pen as required by your local authority.

Manufactured by:

M/s Sanofi-Aventis Deutschland GmbH, Industriepark Höchst, 65926 Frankfurt am Main, Germany.

Imported & Marketed in India by: Sanofi-Synthelabo (India) Ltd.,

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