



INSTRUCTIONS FOR USE

ProStabilize™

(tirzepatide) injection, for subcutaneous use



2.5 mg / 0.5 mL single-dose pen

5 mg / 0.5 mL single-dose pen

7.5 mg / 0.5 mL single-dose pen

10 mg / 0.5 mL single-dose pen

12.5 mg / 0.5 mL single-dose pen

15 mg / 0.5 mL single-dose pen

* use 1 time each week

The information available here might not be the most recently approved version.

To access the most recently approved product information, you can either scan the QR code above or visit the following website:

<https://www.biohumanslabs.com/>

Important information you need to know before injecting ProStabilize

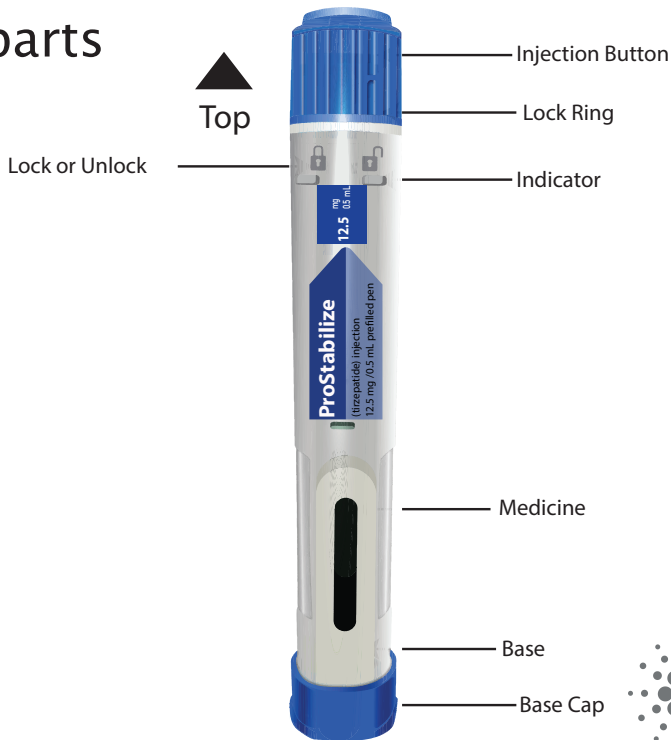
Read this package insert before using your ProStabilize Pen and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

Talk to your healthcare provider about how to inject ProStabilize the right way.

- * ProStabilize is a single-dose prefilled pen.
- * ProStabilize is used 1 time each week.
- * Inject under the skin (subcutaneously) only.
- * You or another person can inject into your stomach (abdomen) or thigh.
- * Another person can inject into the back of your upper arm.



Guide to parts



Preparing to inject ProStabilize

Remove the Pen from the refrigerator.

Leave the base cap on until you are ready to inject.

Check the Pen label to make sure you have the right medicine and dose, and that it has not expired.

Inspect the Pen to make sure that it is not damaged.

Make sure the medicine:

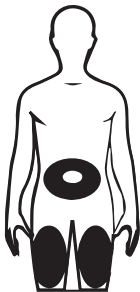
- is not frozen
- is colorless to slightly yellow or brown
- is not cloudy
- does not have particles

Wash your hands.

Expiration
date

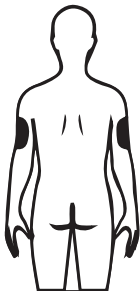


Choose your Injection site



Your healthcare provider can help you choose the injection site that is best for you.

You or another person can inject the medicine in your stomach (abdomen) or thigh.



Another person should give you the injection in the back of your upper arm.

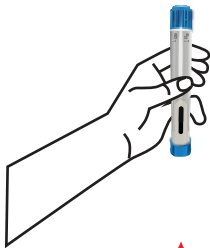
Change (rotate) your injection site each week.



Step

1

Pull off the Base cap



Base cap



Make sure the Pen is locked.

Do not unlock the Pen until you place the base on your skin and are ready to inject.

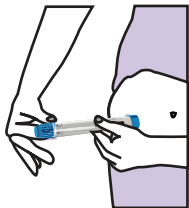
Pull the base cap straight off and throw it away in your household trash.

Do not put the base cap back on—this could damage the needle.

Do not touch the needle.

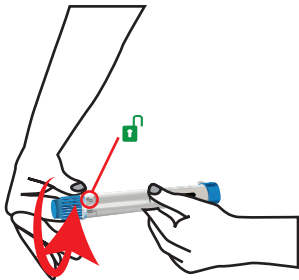


Step
2 Place Base on skin,
Then unlock



Place the base flat against your skin at the injection site.

Step
3



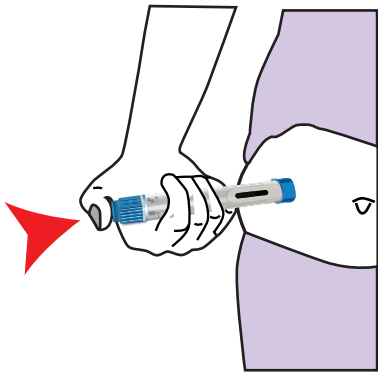
Unlock by turning the lock ring.



Step
4

Press and hold up to 10 seconds

Press and hold the
injection button for up to 10 seconds.



Listen for :

- * First click = injection started
- * Second click = injection completed

After your injection, place the used
Pen in a sharps container.



Disposing of your used Pen

* Put your used Pen in a sharps disposal container right away after use.

Do not throw away (dispose of) Pens in your household trash.

If you do not have a sharps disposal container, you may use a household container that is:

- made of a heavy-duty plastic,
- can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
- upright and stable during use,
- leak-resistant, and
- properly labeled to warn of hazardous waste inside the container.

* When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be local laws about how you should throw away used needles and syringes.

* Do not recycle your used sharps disposal container.



Storage and handling

- * Store your Pen in the refrigerator between 2°C to 8°C (36°F to 46°F).
- * You may store your Pen unrefrigerated in the original carton at temperatures below 30°C [86°F] for up to 21 days.
- * Do not freeze your Pen. If the Pen has been frozen, throw the Pen away and use a new Pen.
- * Store your Pen in the original carton to protect your Pen from light.
- * Handle the pen carefully. If you drop the Pen on a hard surface, do not use it. Use a new Pen for your injection.
- * Keep ProStabilize Pen and all medicines out of the reach of children.



Commonly asked questions

Q. What if I see air bubbles in my Pen?

A. Air bubbles are normal.

Q. What if my Pen is not at room temperature?

A. It is not necessary to warm the Pen to room temperature.

Q. What if i unlock the Pen and press the injection button before pulling off the base cap?

A. Do not remove the base cap. Throw away the Pen and get a new Pen.

Q. What if there is a drop of liquid on the tip of the needle when I remove the base cap?

A. A drop of liquid on the tip of the needle is normal. Do not touch the needle.

Q. Do i need to hold the injection button down until the injection is complete?

A. This is not necessary, but it may help you keep the Pen steady against your skin.



Q. I heard more than 2 clicks during my injection—2 loud clicks and 1 soft one. Did I get my complete injection?

A. Some people may hear a soft click right before the second loud click. That is the normal operation of the Pen. Do not remove the Pen from your skin until you hear the second loud click.

Q. I am not sure if my Pen worked the right way?

A. Check to see if you have received your dose. Your dose was delivered the right way if the gray plunger is visible. Also, see Step 4 of the instructions.

A. If you do not see the base cap, contact your healthcare provider for further instructions. Until then, store your Pen safely to avoid an accidental needle stick.

Q. What if there is a drop of liquid or blood on my skin after my injection?

A. This is normal. Press a cotton ball or gauze over the injection site. Do not rub the injection site.



Other information

« If you have vision problems, do not use your Pen without help from a person trained to use the ProStabilize Pen.

Where to learn more

« If you have questions or problems with your ProStabilize Pen, call your healthcare provider.



Manufactured, packaged and released:

Bio Human Laboratories, Germany, European Union

Marketing Authorization Holder:

Bio Human Laboratories, Germany, European Union

Revised: July 2023

THIS IS A MEDICAMENT

- A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

