

Teriparatide Injection User Manual



Storage Information

Always store the device in the refrigerator with the white cap on. **DO NOT** store the device with a needle attached. The device can be stored in the refrigerator after first use for **28 days**. Dispose device after 28 days of use.

IMPORTANT INFORMATION

DO NOT start the administration procedure until you have read the Medication Guide and this User Manual contained in your teriparatide injection carton thoroughly. Follow the instructions carefully whenever using the teriparatide injection device.

DO NOT share your teriparatide injection device or needles with anyone else. Infection or disease can be spread from one person to another.

DO NOT use the teriparatide injection device for more than 28 days. The teriparatide injection device contains 28 days of medicine. After 28 days of use dispose of this device even if it is not completely empty.

DO NOT inject more than one dose of teriparatide injection in the same day.

DO NOT attempt to transfer teriparatide injection from the device provided to syringe or any other device.

Teriparatide Injection Device and Parts

Needles not included. Becton, Dickinson and Company pen needles from 29 to 31 gauge are recommended for use with this device.

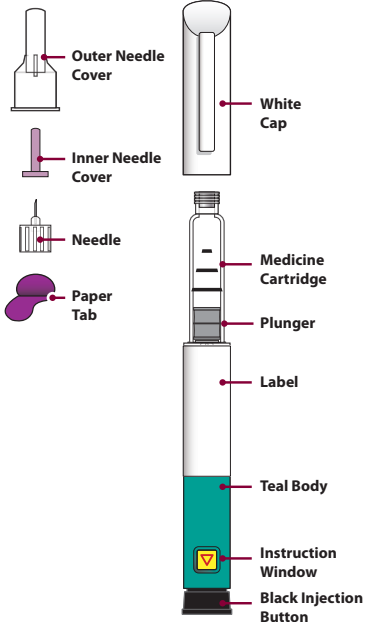


Figure A

1 Prepare Site and Remove the White Cap

- Wash hands prior to use.
- Prepare the injection site (thigh or abdomen) as recommended by your healthcare provider.
- Remove the white cap by pulling it straight off of the device (Figure B).

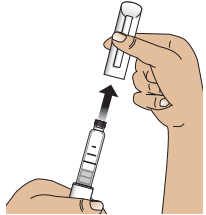


Figure B

2 Check Device, Device Label and Medication

- Check the device. **DO NOT** use the teriparatide injection device if it is damaged.
- Check the label on the device. **DO NOT** use if the device contains the incorrect medication or if the medication has expired (Figure C).
- Check the medication cartridge. The liquid medication should be clear and colorless. **DO NOT** use the medication if it is cloudy, colored, or has floating particles (Figure C).

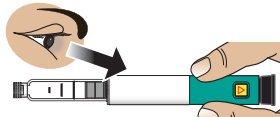


Figure C

3 Attach New Needle

- Peel off the paper tab (Figure D).
- Push the needle **straight** onto medicine cartridge. Screw on needle clockwise until firmly attached (Figure E and Figure F).

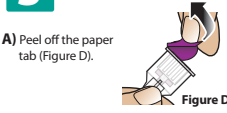


Figure D

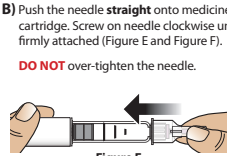


Figure E



Figure F

4 Remove Outer Needle Cover

Pull off large outer needle cover (Figure G), and **save it for later** (see Step 9).



Figure G

5 Set Dose

Pull out the black injection button until it stops (Figure H).

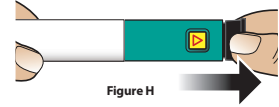


Figure H

Check to make sure red stripe shows. Additionally, the instruction window will show an arrow pointing towards the needle end of the device (Figure I).

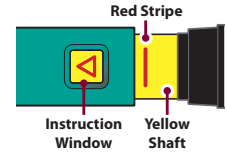


Figure I

Troubleshooting

If the device does not set fully or if you cannot pull back on the black injection button refer to [Troubleshooting Problem E](#) on the back page.

Administer Injection

6 Remove Inner Needle Cover

- Pull off small inner needle protector and throw it away (Figure J).
- CAUTION:** The needle will be exposed.

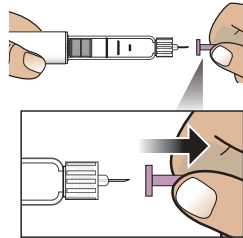


Figure J

7 Inject Dose

- Gently hold a fold of skin on your thigh or abdomen and insert the needle straight into the folded skin (Figure K).
- Press the black injection button down until it stops and hold (Figure L).



Figure K



Figure L

- Hold it in and count to 5 slowly. You must wait until the count of 5 to make sure the full dose has been delivered (Figure M).
- Remove the needle from the skin (Figure N).

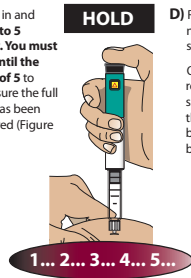


Figure M

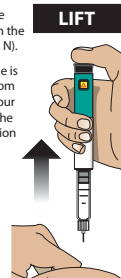


Figure N

Note: You may not see the plunger moving. To confirm that your dose has been delivered, see Step 8.

8 Confirm Dose

Check to make sure the black injection button is all the way down. The instruction window will show an arrow pointing towards the black button.

If the yellow shaft does not show, you have finished the injection steps the right way (Figure O).



Figure O

Important
You should **not** see any of the yellow shaft. If you do and have already injected the medicine, **do not** inject yourself a second time in the same day.

Instead, **you must reset the device.**
Refer to [Troubleshooting Problem A](#) on the back page for more information.

After Injection

9 Remove Needle and Dispose

- Put the large outer needle cover on the needle by scooping it up and pressing it on (Figure P and Figure Q). Do not try to put the needle cover back on with your hands.

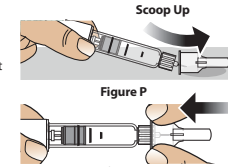


Figure P

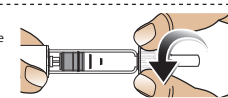


Figure Q

- Unscrew the covered needle all the way by giving the large needle cover 3-5 counter-clockwise turns (Figure R).

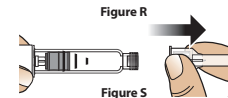


Figure R

Pull the needle straight off (Figure S).

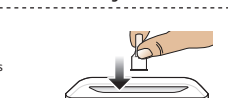


Figure S

- Dispose of the needle into a puncture resistant container according to local regulations (Figure T).

DO NOT reuse needle.

Disposal Information

For more information about how to correctly dispose of the needle refer to the Disposal Information section on the back page.

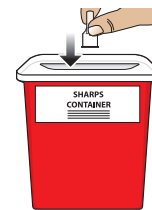


Figure T

10 Recap Device and Store

- Push white cap back on (Figure U).

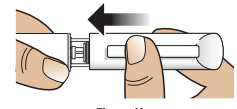


Figure U

- Always store the device in the refrigerator with the white cap on right after use (Figure V). **DO NOT** store the device with a needle attached.

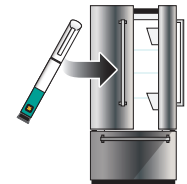
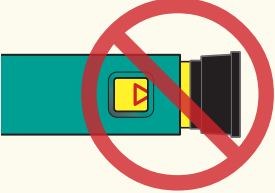


Figure V

See Reverse Side for More Information

Troubleshooting

| Problem | Solution |
|--|---|
| <p>A The yellow shaft is still showing after I push in the black injection button. How do I reset my teriparatide injection delivery device?</p>  | <p>To reset the teriparatide injection delivery device, follow the steps below:</p> <ol style="list-style-type: none"> 1) If you have already injected, DO NOT inject yourself a second time on the same day. 2) Remove the needle and dispose in a sharps container according to local regulations. 3) Attach a new needle, pull off the large needle cover and save it. 4) Pull off the inner needle cover and throw away. 5) Point the needle down into an empty container. Push in the black injection button until it stops. Hold it in and slowly count to five. You may see a small stream or drop of fluid. When you have finished, the black injection button should be all the way in. 6) If you still see the yellow shaft showing, contact Alvogon, Inc. (see Contact Information below and to the right) or your healthcare provider. 7) Remove the needle and dispose in a sharps container according to local regulations. Push the white cap back on, and put your teriparatide injection delivery device in the refrigerator. <p>You can prevent this problem by always using a NEW needle for each injection, and by pushing the black injection button all the way in and slowly counting to five.</p> |
| <p>B How can I tell if my teriparatide injection delivery device works?</p> | <p>The black injection button should be all the way in to show that the full dose of medicine has been injected from the teriparatide injection delivery device. Use a new needle every time you inject to be sure your teriparatide injection delivery device will work properly.</p> |
| <p>C I see an air bubble in my teriparatide injection delivery device.</p> | <p>A small air bubble will not affect your dose and it will not harm you. You can continue to take your dose as usual.</p> |
| <p>D I cannot get the needle off.</p> | <ol style="list-style-type: none"> 1) Put the large needle cover on the needle. 2) Use the large needle cover to unscrew the needle. 3) Unscrew the needle all the way by giving the large needle cover 3 to 5 counter-clockwise turns. 4) If you still cannot get the needle off, ask someone to help you. |
| <p>E What should I do if I have difficulty pulling out the black injection button?</p> | <p>Change to a new teriparatide injection delivery device to take your dose as instructed by your healthcare provider.</p> <p>When the black injection button becomes hard to pull out, this means there is not enough medicine in your teriparatide injection delivery device for another dose. You may still see some medicine left in the cartridge.</p> |

Disposal Information

Put your used needles in a FDA-cleared sharps disposal container right away after use.

DO NOT throw away (dispose of) loose needles in your household trash.

If you do not have a FDA-cleared sharps disposal container, you may use a 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
- 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 state or local laws about how you should throw away used needles.

For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.

DO NOT dispose of your used sharps disposal container in your household trash unless your community guidelines permit this.

DO NOT recycle your used sharps disposal container.

Cleaning and Storage

Cleaning Your Teriparatide Injection Delivery Device

- Wipe the outside of the teriparatide injection delivery device with a damp cloth.
- Do not place the teriparatide injection delivery device in water, or wash or clean it with any liquid.

Storing Your Teriparatide Injection Delivery Device

- After each use, refrigerate the teriparatide injection delivery device right away. Read and follow the instructions in the Medication Guide section "How should I store teriparatide injection?"
- **DO NOT** store the teriparatide injection delivery device with a needle attached. Doing this may cause air bubbles to form in the medicine cartridge.
- Store the teriparatide injection delivery device with the white cap on.
- **DO NOT** freeze teriparatide injection. If the teriparatide injection delivery device has been frozen, throw the device away and use a new teriparatide injection delivery device. If the teriparatide injection delivery device has been left out of the refrigerator, do not throw the delivery device away. Place the delivery device back in the refrigerator and call Alvogon, Inc. (see Contact Information below).

Other Important Notes

- The teriparatide injection delivery device contains 28 days of medicine.
- **DO NOT** transfer teriparatide injection to a syringe. This may result in you taking the wrong dose of medicine.
- Read and follow the instructions in the User Manual so that you use your teriparatide injection delivery device the right way.
- Check the teriparatide injection delivery device label to make sure you have the right medicine and that it has not expired.
- **DO NOT** use the teriparatide injection delivery device if it looks damaged. Look at the teriparatide injection medicine in the cartridge. If the medicine is not clear and colorless, or if it has particles, do not use it. Call Alvogon, Inc. if you notice any of these (see Contact Information below).
- Use a new needle for each injection.
- During injection, you may hear one or more clicks – this is normal.
- The teriparatide injection delivery device is not recommended for use by the blind or by those who have vision problems without help from a person trained in the proper use of the device.
- Keep your teriparatide injection delivery device and needles out of the reach of children.

Disposal of Pen Needles and Delivery Device

Disposal of Pen Needles and the Teriparatide Injection Delivery Device

- Before throwing away the teriparatide injection delivery device, be sure to remove the pen needle.
- Throw away your teriparatide injection delivery device and used needles as instructed by your healthcare provider, local or state laws, or institutional policies.

Dispose of the teriparatide injection delivery device 28 days after first use.

1st Use Date: _____ / _____ / _____

Throw Away After: _____ / _____ / _____

Contact Information

If you have questions, need help or for more information with your teriparatide injection delivery device, contact Alvogon, Inc. at 1-866-770-3024 or your healthcare provider.

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