

### 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 BONTEO carton thoroughly. Follow the instructions carefully whenever using the BONTEO device.

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

**DO NOT** use the BONTEO device for more than 28 days. The BONTEO 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 BONTEO in the same day.

**DO NOT** attempt to transfer BONTEO from the device provided to syringe or any other device.

### BONTEO Device and Parts\*

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

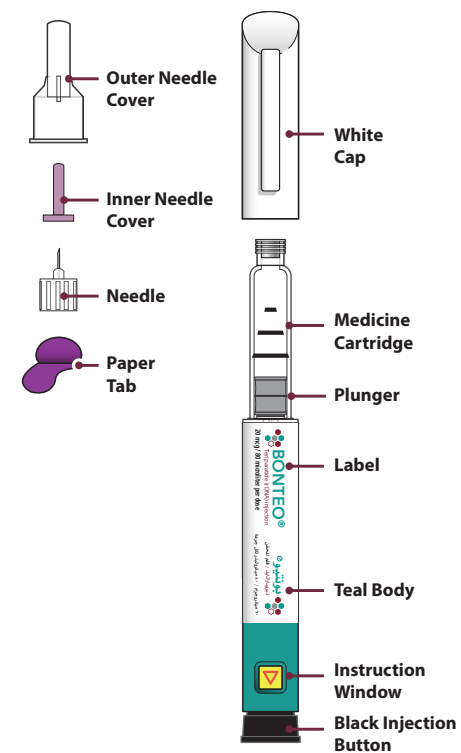


Figure A

## Prepare for Injection

### 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).

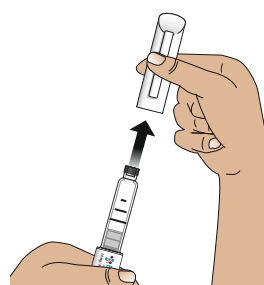


Figure B

### 2 Check Device, Device Label and Medication

- Check the device. **DO NOT** use the BONTEO 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).

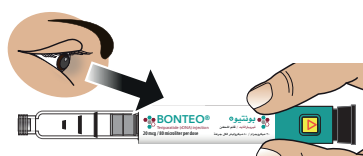


Figure C

### 3 Attach 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). **DO NOT** over-tighten the needle.

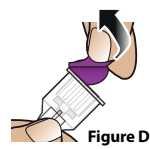


Figure D

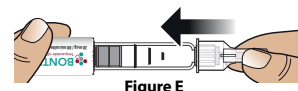


Figure E



Figure F

### 4 Remove Outer Needle Cover

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

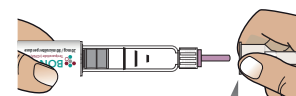


Figure G

### 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).

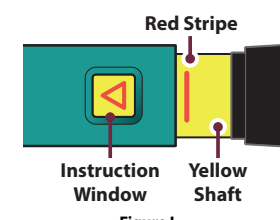


Figure I

### 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.

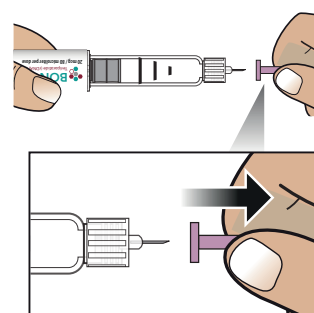


Figure J

### 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).
- 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). Once needle is removed from skin, take your thumb off the black injection button.

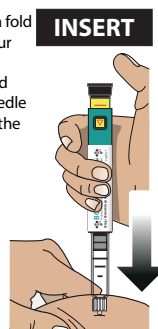


Figure K

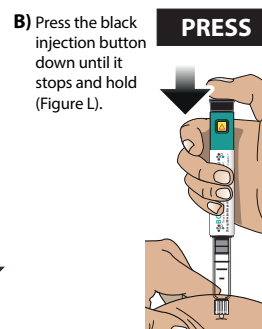


Figure L



Figure M

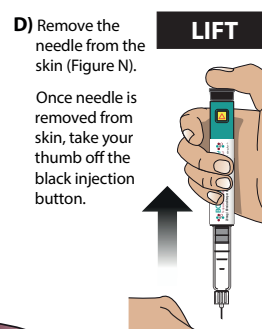


Figure N

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).

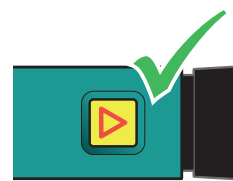


Figure O

### 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.

### 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.
- Unscrew the covered needle all the way by giving the large needle cover 3-5 counter-clockwise turns (Figure R). Pull the needle straight off (Figure S).
- Dispose of the needle into a puncture resistant container according to local regulations (Figure T). **DO NOT** reuse needle.



Figure P

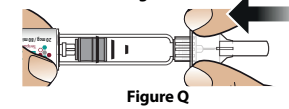


Figure Q

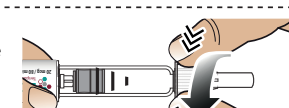


Figure R

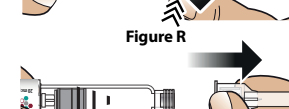


Figure S

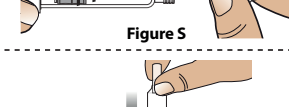


Figure T

### Disposal Information

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

### 10 Recap Device and Store

- Push white cap back on (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.

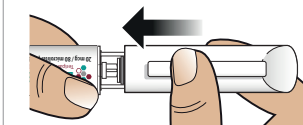


Figure U

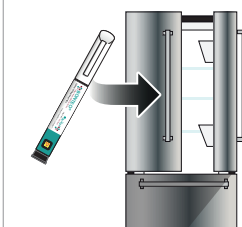


Figure V

## Troubleshooting

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

## Cleaning and Storage

### Cleaning Your BONTEO Delivery Device

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

### Storing Your BONTEO Delivery Device

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

## Other Important Notes

- The BONTEO delivery device contains 28 days of medicine.
- DO NOT** transfer BONTEO 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 BONTEO delivery device the right way.
- Check the BONTEO delivery device label to make sure you have the right medicine and that it has not expired.
- DO NOT** use the BONTEO delivery device if it looks damaged. Look at the BONTEO medicine in the cartridge. If the medicine is not clear and colorless, or if it has particles, do not use it. Call Pfenex 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 BONTEO 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 BONTEO delivery device and needles out of the reach of children.

## Disposal of Pen Needles and Delivery Device

Dispose of the BONTEO delivery device 28 days after first use.

1<sup>st</sup> Use Date: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

Throw Away After: \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

## Disposal Information

- 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