**FORTEO™, teriparatide (rDNA origin) injection**

**Prefilled Delivery Device**

**User Manual**

**FORTEO™, teriparatide (rDNA origin) injection**

**Prefilled Delivery Device**

**Instructions for Use**

*Before using FORTEO, please read and follow these instructions carefully.*

If you do not follow these instructions carefully, you may get the wrong FORTEO dose. Also, read the Medication Guide inside your FORTEO carton.

**Pen Features**

- A prefilled, delivery device (pen) containing a 28-day supply of FORTEO, teriparatide (rDNA origin) injection
- Dose setting indication delivers the prescribed 20-mcg dose

**Pen Parts**

- Blue Injection Button
- Dose Knob
- Raised Notch
- Label
- FORTEO Cartridge
- Clear Cartridge Holder
- Rubber Seal
- Paper Tab
- Outer Needle Shield
- Inner Needle Shield
- Pen Cap

*Pen needles are sold separately and are available at your local pharmacy.

**Important Notes**

- A number of medicines come in pen delivery devices. Check the label on your pen before each use to make sure you are using your FORTEO pen.
- Wash your hands and prepare your skin using the under-the-skin (subcutaneous) injection method recommended by your health care professional.
- Use a new needle for each injection.
- Be sure the needle is firmly attached to the pen before "priming," setting (dialing) the dose, and injecting FORTEO.
- Do not share your pen.
- Keep your pen out of the reach of children.

**Pen Features**

- A number of medicines come in pen delivery devices. Check the label on your pen before each use to make sure you are using your FORTEO pen.
- Your FORTEO pen contains a cartridge, marked with lines and numbers to give you an idea of how much FORTEO is left in the pen. When the bottom of the plunger reaches the 0 mark, you should have your next FORTEO pen ready.
- Do not use these marks for measuring your dose. Use them only to tell when it is time to have a new pen ready.
- You can use your FORTEO for up to 28 days including the first injection from that pen. Throw away the FORTEO pen after 28 days, even if it is not completely empty. Throw away the pen as directed by your health care professional.
- To help you remember when to throw away your FORTEO pen, there is a place at the end of this user manual to mark the date when you first start to use your pen and the date (28 days later) when you need to throw away your pen.
- Do not store your FORTEO pen with the needle attached. Keeping the needle on may let FORTEO leak from the pen, and air bubbles can form in the cartridge.
- Throw away your used pen and needle as directed by your health care professional. Always use a puncture-resistant container to throw away the needle.
- The directions regarding needle handling are not intended to replace local, health care professional, or institutional policies.
- This pen 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 product.

**I. Preparing the Pen**

1. Wash your hands before preparing your pen for use.
2. Remove the FORTEO pen from the refrigerator.
3. Remove the pen cap by pulling it off.
4. A number of medicines come in pen delivery devices. Check the label on your pen before each use to make sure you are using your FORTEO pen.
5. Look at the FORTEO medicine in the cartridge. It should be clear and colorless, and it should not have particles in it. If it is not clear and colorless, or if it has particles, do not use it. Call Lilly toll free at 1-866-4FORTEO (1-866-436-7366) if you have any questions.
6. Use an alcohol swab to wipe the rubber seal on the end of the pen.

**II. Attaching the Needle**

This device can be used with Becton Dickinson and Company’s insulin pen needles.

1. Always use a new needle for each injection. Do not store the pen with the needle attached. Storing the pen with the needle attached may let FORTEO leak from the pen, and air bubbles can form in the cartridge.
2. Pull off the paper tab from the outer needle shield and throw the paper tab away.
3. Attach the capped needle to the end of the pen by pushing it on and turning it clockwise (to the right). Do not over-tighten the needle since it must be removed after the injection.

**III. Priming the Pen**

- Always use a new needle for each injection.
- The pen must be primed before every injection.
- You must prime the pen to make sure the medicine is flowing and that you are receiving the correct dose. Priming removes air bubbles that might affect the dose you get. Small air bubbles may collect in the FORTEO cartridge during normal use.
- Note: A small air bubble may stay in the cartridge when you finish the priming step. If you have properly primed the pen, this small air bubble will not harm you or affect your FORTEO dose.
- The very small amount of the prime dose does not affect the total supply of 28 days of therapy that the pen will deliver.

1. Turn the dose knob clockwise (to the right) until you see the arrow (>>) in the dose window and the raised notches on the pen and dose knob are in line.
2. With the arrow in the dose window and the notches in line, pull the dose knob out in the direction of the arrow until you see a “0” in the dose window.
3. Turn the dose knob clockwise (to the right) until you see the number “1” in the dose window. The “1” means “ready to prime.”
4. If you cannot dial to the number “1”, see the “Questions and Answers” section at the end of this manual.
5. Hold your pen with the needle pointing up. Tap the clear cartridge holder gently with your finger so any air bubbles collect near the top.
6. Using your thumb, if possible, push the blue injection button firmly and count e-1-2-3-4-5. You should see either a few drops or a tiny stream of FORTEO come out of the tip of the needle. If nothing comes out of the tip of the needle, repeat the “Priming the Pen” instructions. If after 2 additional tries you continue to have problems, contact Eli Lilly and Company at 1-866-4FORTEO (1-866-436-7366).
7. A diamond (>>) will appear centered in the dose window. This means that the priming is complete.
## IV. Setting the Dose

- The numbers in the dose window do not indicate the size of the dose. These numbers show the dosing steps (see Pen Parts diagram).

1. Turn the dose knob clockwise (to the right) until you see the arrow (\(\rightarrow\)) in the dose window and the raised notches on the pen and dose knob are in line.

2. With the arrow (\(\rightarrow\)) in the dose window and the notches in line, pull the dose knob out in the direction of the arrow until you see a “0” in the dose window.

3. Turn the dose knob clockwise (to the right) past the “1” until you see the number “2” in the dose window. When the “2” appears, you have set the 20-mcg dose and the pen is “ready to inject.”

4. If you cannot dial to the number “2,” see the “Questions and Answers” section at the end of this manual.

## V. Injecting the Dose

- The number “2” in the dose window means the dose is “ready to inject.”

Make injections just below the surface of the skin (the subcutaneous tissue).

1. Prepare your skin for the injection as instructed by your health care professional.

2. Lightly hold a fold of skin as shown below, and push the needle straight into your skin. The skin may need to be pinched up to avoid a deep injection into a muscle (intramuscular), especially in the thigh area.

3. Make sure you can still see the number “2” in the dose window. Inject the FORTEO by using your thumb, if possible, to push in the blue injection button all the way.

4. Continue to hold down the blue injection button firmly and count \(\text{slowly}\) to 5 to ensure that the FORTEO has been completely injected into the skin. Remove the needle from your skin when you finish counting.

5. When the injection is complete, you must see a diamond (\(\Box\)) centered in the dose window. The diamond tells you the injection button has been pushed in all the way and your full dose has been injected.

6. Reset the pen for tomorrow’s dose by turning the dose knob clockwise (to the right) until you see the arrow (\(\rightarrow\)) in the dose window and the raised notches on the pen and dose knob are in line. If you cannot turn the dose knob, your full dose has not been delivered. See the “Questions and Answers” section at the end of this manual.

## VI. After an Injection

1. Carefully replace the outer needle shield as instructed by your health care professional.

2. Remove the capped needle by turning it counterclockwise (to the left). Place the used needle in a puncture-resistant disposable container and properly throw it away as directed by your health care professional.

3. Replace the cap on the pen.

4. Store your FORTEO pen in the refrigerator at 36° to 46°F (2° to 8°C) at all times. You should inject FORTEO right after you take the pen out of the refrigerator. Put the pen back into the refrigerator right after use.

You can use your FORTEO pen for up to 28 days including the first injection from the pen. After 28 days, throw away the FORTEO pen, even if it is not completely empty. Throw away the pen as directed by your health care professional.

Never share a FORTEO pen.

Do not freeze the FORTEO pen. Do not use FORTEO if it has been frozen.

Do not use the FORTEO pen after the expiration date printed on the carton and pen label.

Do not store or throw away the pen with a needle attached.

### Questions and Answers

#### Problem

The dose knob cannot be turned.

**Action**

- a. Make sure that the needle is properly attached to the pen.
- b. Hold the pen with needle down and use your thumb to push in the blue injection button all the way. Continue holding the blue injection button in firmly and count \(\text{slowly}\) to 5. You should see FORTEO coming out of the needle, and you should now be able to turn the dose knob. If you still cannot turn the dose knob, contact Eli Lilly and Company at 1-866-4FORTEO (1-866-436-7836) for further instructions.

#### Problem

A diamond (\(\Box\)) cannot be seen in the center of the dose window at the end of a dose.

**Action**

- If you cannot see a diamond centered in the dose window after you have given yourself an injection, or the dose knob cannot be reset to the arrow in the dose window, a complete dose was not delivered because the injection button was not pushed down all the way. Don’t worry—simply follow the instructions below to reset the pen.
  - a. Hold the pen with needle down and use your thumb to push in the blue injection button all the way. Continue holding the blue injection button in firmly and count \(\text{slowly}\) to 5. Then turn the dose knob clockwise until the arrow (\(\rightarrow\)) appears in the dose window and the raised notches on the pen and dose knob are in line. This resets the pen for tomorrow’s dose. To avoid this problem during future injections, hold down the injection button more firmly and count to 5 more slowly. If you still cannot turn the dose knob, contact Eli Lilly and Company at 1-866-4FORTEO (1-866-436-7836) for further instructions.
  - b. If you have difficulty completing the dose and resetting the pen for several days in a row, contact Eli Lilly and Company for further instructions.

#### Problem

Dose dialed and injection button pushed in without the needle attached.

**Action**

- To get an accurate dose, you must:
  - 1) Attach a new needle.
  - 2) Push in the injection button all the way (even if you see a “0” in the dose window) until you see a diamond (\(\Box\)) or arrow (\(\rightarrow\)) in the dose window.
  - 3) Prime the pen. (See III. Priming the Pen.)

For additional information call 1-866-4FORTEO (1-866-436-7836)

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