PA 9291 FSAMP

User Manual FORTEOTM

teriparatide (rDNA origin) injection Prefilled Delivery Device



Instructions for Use

Before using FORTEO, please read and follow these instructions

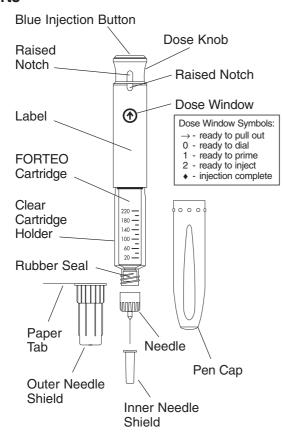
If you do not follow these instructions carefully, you may get the wrong FORTEO dose. Also, read the Medication Guide inside your FORTEO carton.

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*



*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.

FORTEO™, teriparatide (rDNA origin) injection

- · Store your FORTEO pens in the refrigerator at all times, but not in a freezer. Do not let your FORTEO pen freeze. See the "Medication Guide" for complete storage information.
- 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 100 mark, about 2/3 (two-thirds) of the FORTEO has been used. When the bottom of the plunger reaches the 60 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 FÓRTEO 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 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.



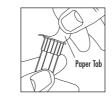
- 4. A number of medicines come in pen delivery devices. Check the label on your pen before each use to make sure you are using your FORTEO pen.
- 5. Look at the FORTEO medicine in the cartridge. It should be clear and colorless, and it should not have particles in it. If it is not clear and colorless, or if it has particles, do not use it. Call Lilly toll free at 1-866-4FORTEO (1-866-436-7836) 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.



Attac to th push clock not o since after the injection.





FORTEO™, teriparatide (rDNA origin) injection

4. Hold the pen with the needle pointing up and remove the outer needle shield. Keep the outer needle shield because you will need it to remove the needle after the injection is



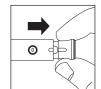
5. Pull off the inner needle shield and throw it away.

III. Priming the Pen

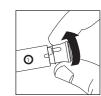
- · Always use a new needle for every injection.
- The pen must be primed before every injection.
- You must prime the pen to make sure the medicine is flowing and that you are receiving the correct dose. Priming removes air bubbles that might affect the dose you get. Small air bubbles may collect in 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 (\rightarrow) 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.



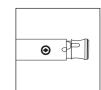
3. Turn the dose knob clockwise (to the right) until you see the number "1" in the dose window. The "1" means "ready to prime."



- 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 in the blue injection button all the way and keep pressing. Continue to hold the blue injection button firmly and count s-I-o-w-I-y to 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 (1-866-436-7836).



diamond (♦) will appear centered in the lose window. This means that the priming is complete



ch the capped needle ne end of the pen by ning it on and turning it kwise (to the right). Do over-tighten the needle	1	Outer Needle	7. A do
over-tighten the needle e it must be removed		Outer Needle Shield	

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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 (→) 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.



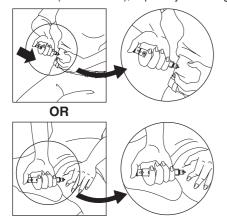
3. Turn the dose knob clockwise (to the right) past the "1" until you see the number "2" in the dose window. When the "2" appears, you have set the 20-mcg dose and the pen is "ready to inject."



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.



Ask your health care professional for more instructions about injection technique and changing sites (rotation).

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.



- Continue to hold down the blue injection button firmly and count s-l-o-w-l-y
 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 (*) 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 (→) 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.





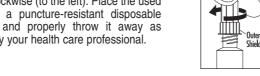
FORTEO™, teriparatide (rDNA origin) injection

VI. After an Injection

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

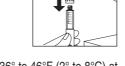


2. Remove the capped needle by turning it counterclockwise (to the left). Place the used needle in a puncture-resistant disposable container and properly throw it away as directed by your health care professional.



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 s-l-o-w-l-y 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.

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

The dose knob cannot be reset (turned) to the arrow (→) at the end of a dose.

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

- 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 s-I-o-w-I-y to 5. Then turn the dose knob clockwise until the arrow (→) 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.

Dose dialed and injection button pushed in without the needle attached

Action

To get an accurate dose, you must:

- 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 (♦) or arrow (→) in the dose window.
- 3) Prime the pen. (See III. Priming the Pen.)

FORTEO™, teriparatide (rDNA origin) injection

Problem

FORTEO does not come out of the needle.

Action

- To get an accurate dose, you must:
- 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 (♦) or arrow (→) in the dose window.
- 3) Prime the pen. (See III. Priming the Pen.)

Problem

Wrong dose (prime or injection dose) dialed.

• If you have not pushed in the injection button, simply turn the dose knob counterclockwise (to the left) or clockwise (to the right) to correct the dose.

• If you have injected FORTEO, you did not get your correct dose. Call your health care professional for instructions

Problem

Not sure how much FORTEO remains in the cartridge

Action

Hold the pen with the needle end pointing down. The scale on the clear cartridge holder shows an estimate of the amount of FORTEO left. These numbers should not be used to measure a FORTEO dose or the number of days left. (To understand these numbers, see Important Notes.)

Problem

A dose cannot be dialed. (You do not see the number in the dose window when setting

Action

The pen will not let you dial a prime (1) or an injection (2) dose if there is not enough FORTEO left in the cartridge. If the dose cannot be dialed, use a new pen for your FORTEO dose

Problem

You see an "x" in the dose window.

Action

If you see an "x" in the dose window, your pen is broken. Do not attempt to use the pen. Use a new pen for your next FORTEO dose. Contact Eli Lilly and Company at 1-866-4FORTEO (1-866-436-7836).

Problem

A small amount of FORTEO is in the cartridge, but a dose cannot be dialed.

The pen design prevents the cartridge from being completely emptied. A small amount of FORTEO will always stay in the cartridge.

Problem

You cannot push in the injection button all the way when priming the pen or injecting a dose.

1) If nothing is coming out of the needle, check if the needle is properly attached or is clogged. Follow instructions above under "FORTEO does not come out of the

2) If you are sure FORTEO is coming out of the needle, push in the injection button more slowly to reduce the effort needed and keep pressing the injection button until it is pushed in all the way.

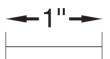
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or additional information call -866-4FORTEO (1-866-436-7836)
lanufactured by Lilly France S.A.S. -67640 Fegersheim, France or Eli Lilly and Company dianapolis, IN 46285, USA

Literature revised October 20, 2003

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Control No.:

Read User Manual before injecting NDC 0002-8971-01 MS8971

FORTEO

teriparatide (rDNA origin) injection
750 mcg/3 mL
Multidose prefilled delivery device
28 daily subcutaneous doses, 20 mcg/day
Do NOT transfer contents to a syringe
Throw away 28 days after first use
REFRIGERATE - DO NOT FREEZE

Manufactured by Lilly France S.A.S., F-67640 Fegersheim, France for Eli Lilly and Company, Indianapolis, IN 46285, USA

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