
User Manual

FORTEO™

teriparatide (rDNA origin) injection

Prefilled Delivery Device

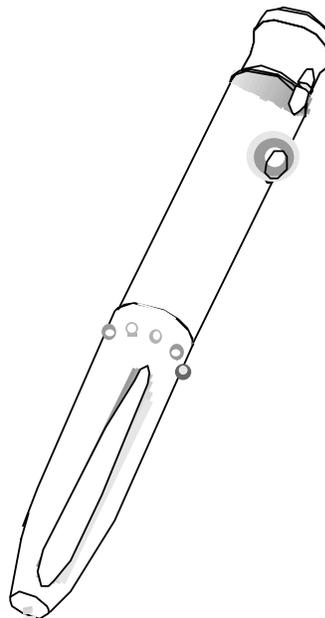
Instructions for Use

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

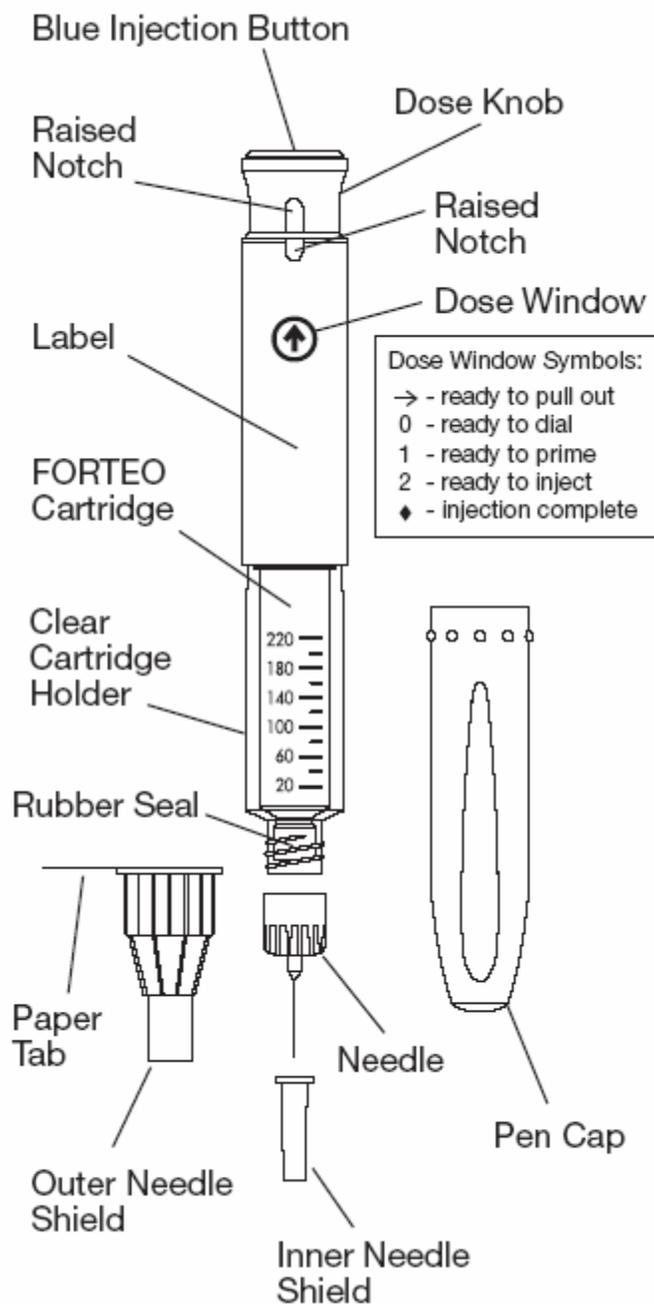
If you do not follow these instructions carefully, you may get the wrong FORTEO dose. Also, read the **Medication Guide** inside your FORTEO carton.

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



FORTEO, teriparatide (rDNA origin) injection

Pen Parts*

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

FORTEO, teriparatide (rDNA origin) injection

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.
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FORTEO, teriparatide (rDNA origin) injection

Important Notes (Continued)

- Keep your pen out of the reach of children.
 - 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.
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FORTEO, teriparatide (rDNA origin) injection

Important Notes

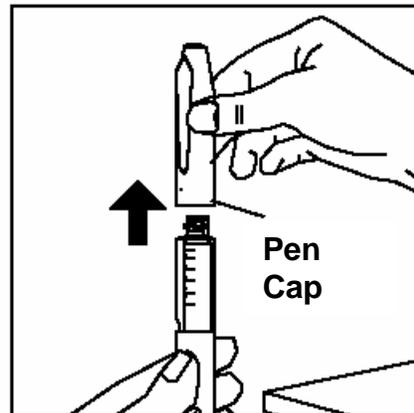
(Continued)

- 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.
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FORTEO, teriparatide (rDNA origin) injection

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.

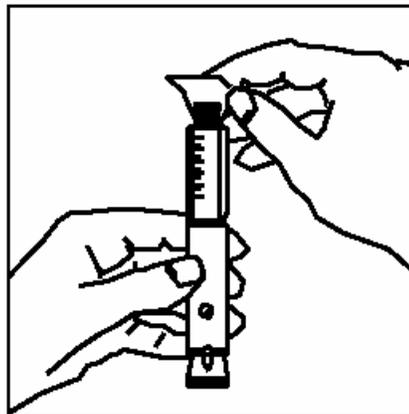


4. A number of medicines come in pen delivery devices. Check the label on your pen before each use to make sure you are using your FORTEO pen.
 5. Look at the FORTEO medicine in the cartridge. It should be clear and colorless, and it should not have particles in it. If it is not clear and colorless, 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.
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FORTEO, teriparatide (rDNA origin) injection

I. Preparing the Pen (Continued)

6. Use an alcohol swab to wipe the rubber seal on the end of the pen.

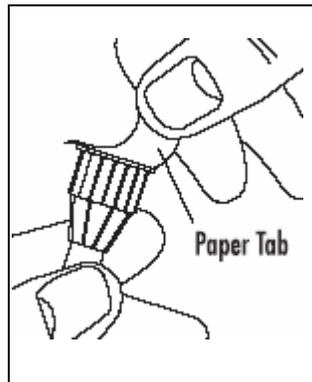


FORTEO, teriparatide (rDNA origin) injection

II. Attaching the Needle

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

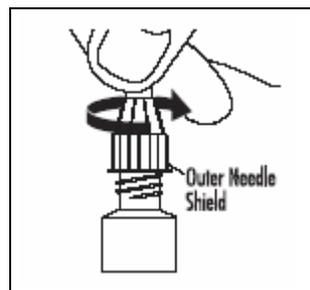
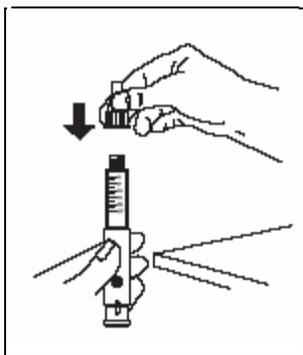
1. Always use a new needle for each injection. Do not store the pen with the needle attached. Storing the pen with the needle attached may let FORTEO leak from the pen, and air bubbles can form in the cartridge.
2. Pull off the paper tab from the outer needle shield and throw the paper tab away.



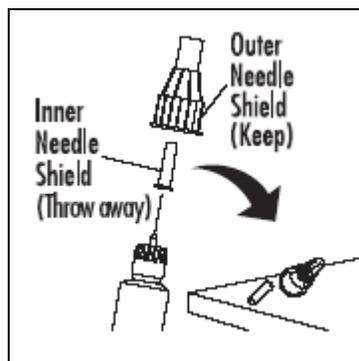
FORTEO, teriparatide (rDNA origin) injection

II. Attaching the Needle (Continued)

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.



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 finished.



5. Pull off the inner needle shield and throw it away.
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FORTEO, teriparatide (rDNA origin) injection

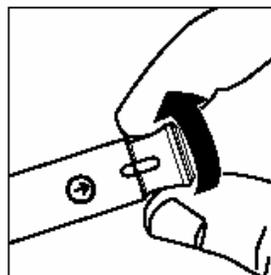
III. Priming the Pen

- **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.
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FORTEO, teriparatide (rDNA origin) injection

III. Priming the Pen (Continued)

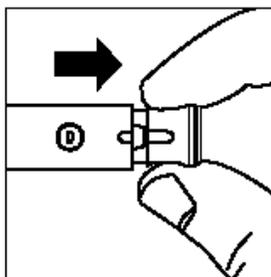
- **Note:** A small air bubble may stay in the cartridge when you finish the priming step. If you have properly primed the pen, this small air bubble will not harm you or affect your FORTEO dose.
 - The very small amount of the prime dose does not affect the total supply of 28 days of therapy that the 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.



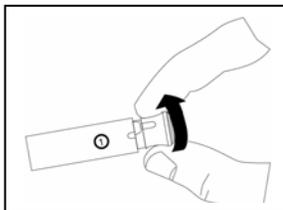
FORTEO, teriparatide (rDNA origin) injection

III. Priming the Pen (Continued)

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.**”

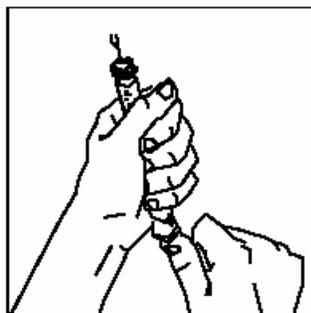


4. If you cannot dial to the number “1”, see the “Questions and Answers” section at the end of this manual.
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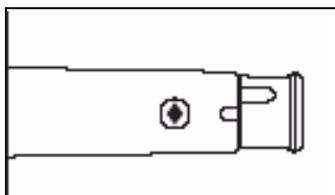
FORTEO, teriparatide (rDNA origin) injection

III. Priming the Pen (Continued)

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-l-o-w-l-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).



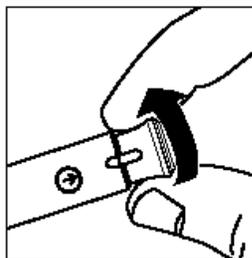
7. A diamond (◆) will appear centered in the dose window. This means that the priming is complete.



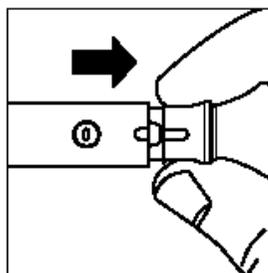
FORTEO, teriparatide (rDNA origin) injection

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.



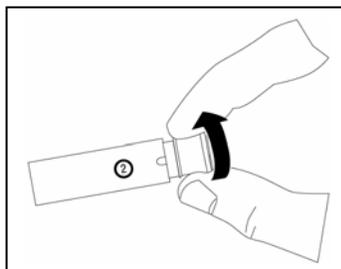
2. With the arrow (→) in the dose window and the notches in line, pull the dose knob out in the direction of the arrow until you see a "0" in the dose window.



FORTEO, teriparatide (rDNA origin) injection

IV. Setting the Dose (Continued)

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.”**

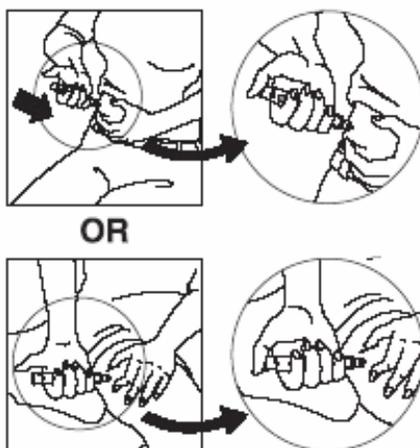


4. If you cannot dial to the number “2,” see the “Questions and Answers” section at the end of this manual.
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FORTEO, teriparatide (rDNA origin) injection

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.

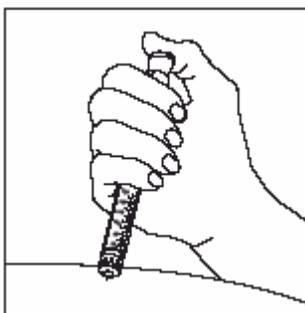


Ask your health care professional for more instructions about injection technique and changing sites (rotation).

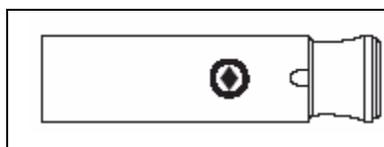
FORTEO, teriparatide (rDNA origin) injection

V. Injecting the Dose (Continued)

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 **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.



FORTEO, teriparatide (rDNA origin) injection

V. Injecting the Dose (Continued)

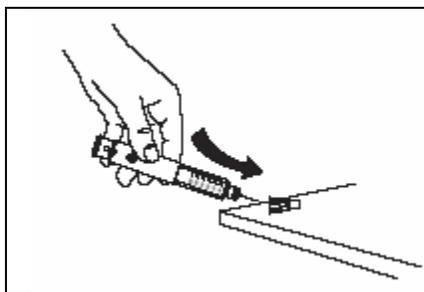
6. Reset the pen for tomorrow's dose by turning the dose knob clockwise (to the right) until you see the arrow (→) in the dose window and the raised notches on the pen and dose knob are in line. If you cannot turn the dose knob, your full dose has not been delivered. See the "Questions and Answers" section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



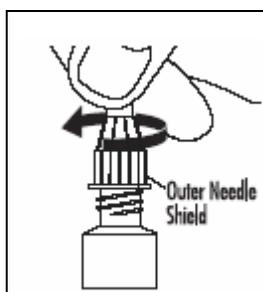
FORTEO, teriparatide (rDNA origin) injection

VI. After an Injection

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



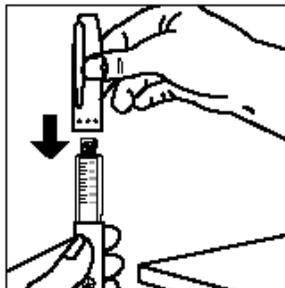
2. Remove the capped needle by turning it counterclockwise (to the left). Place the used needle in a puncture-resistant disposable container and properly throw it away as directed by your health care professional.



FORTEO, teriparatide (rDNA origin) injection

VI. After an Injection (Continued)

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.

FORTEO, teriparatide (rDNA origin) injection

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.
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FORTEO, teriparatide (rDNA origin) injection

Questions and Answers (Continued)

Problem

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

OR

The dose knob cannot be reset (turned) to the arrow (→) 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 **s-l-o-w-l-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.
-

FORTEO, teriparatide (rDNA origin) injection

Questions and Answers (Continued)

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

Problem

FORTEO does not come out of the needle.

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

FORTEO, teriparatide (rDNA origin) injection

Questions and Answers (Continued)

Problem

Wrong dose (prime or injection dose) dialed.

Action

- 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.

OR

- 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.)**

FORTEO, teriparatide (rDNA origin) injection

Questions and Answers (Continued)

Problem

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

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).

FORTEO, teriparatide (rDNA origin) injection

Questions and Answers (Continued)

Problem

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

Action

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.

Action

- 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 needle."
 - 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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FORTEO, teriparatide (rDNA origin) injection

1st use date ___/___/___

Throw away after ___/___/___

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

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Indianapolis, IN 46285, USA

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