

PA 9291 FSAMP

User Manual

FORTEO™

teriparatide (rDNA origin) injection
Prefilled Delivery Device

Lilly

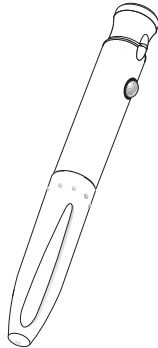
Instructions for Use

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

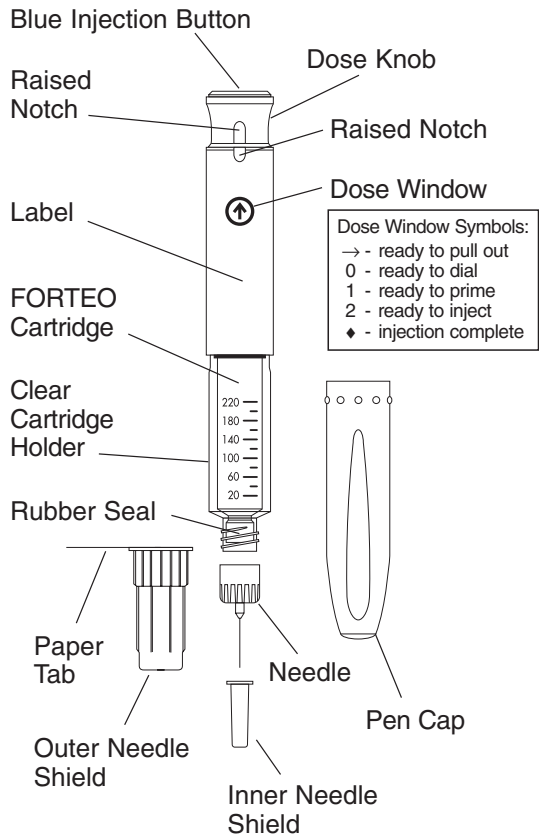
If you do not follow these instructions carefully, you may get the wrong FORTEO dose. Also, read the **Medication Guide** inside your FORTEO carton.

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*



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

Important Notes

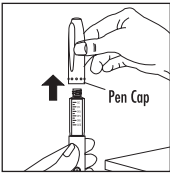
- A number of medicines come in pen delivery devices. Check the label on your pen before each use to make sure you are using your FORTEO pen.
- Wash your hands and prepare your skin using the under-the-skin (subcutaneous) injection method recommended by your health care professional.
- Use a new needle 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

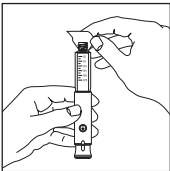
- Store your FORTEO pens in the refrigerator at all times, but not in a freezer. Do not let your FORTEO pen freeze. See the “Medication Guide” for complete storage information.
- Your FORTEO pen contains a cartridge, marked with lines and numbers to give you an idea of how much FORTEO is left in the 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 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

- Wash your hands before preparing your pen for use.
- Remove the FORTEO pen from the refrigerator.
- Remove the pen cap by pulling it off.



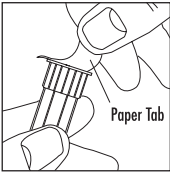
- A number of medicines come in pen delivery devices. Check the label on your pen before each use to make sure you are using your FORTEO pen.
- Look at the FORTEO medicine in the cartridge. It should be clear and colorless, and it should not have particles in it. If it is not clear and colorless, or 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.
- Use an alcohol swab to wipe the rubber seal on the end of the pen.



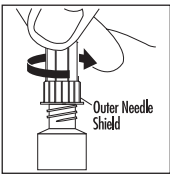
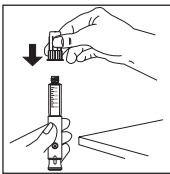
II. Attaching the Needle

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

- 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.
- Pull off the paper tab from the outer needle shield and throw the paper tab away.

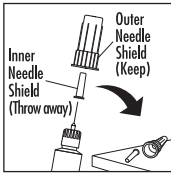


- Attach the capped needle to the end of the pen by pushing it on and turning it clockwise (to the right). Do **not** over-tighten the needle since it must be removed after the injection.



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- 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.



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

III. Priming the Pen

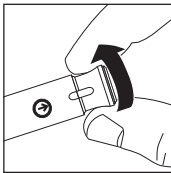
- Always use a new needle for every injection.**
- The pen must be primed before every injection.**

- 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.

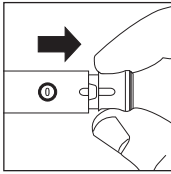
- Note:** A small air bubble may stay in the cartridge when you finish the priming step. If you have properly primed the pen, this small air bubble will not harm you or affect your FORTEO dose.

- The very small amount of the prime dose does not affect the total supply of 28 days of therapy that the pen will deliver.

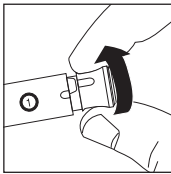
- Turn the dose knob clockwise (to the right) until you see the arrow (→) in the dose window and the raised notches on the pen and dose knob are in line.



- 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.



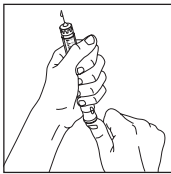
- Turn the dose knob clockwise (to the right) until you see the number “1” in the dose window. The “1” means **“ready to prime.”**



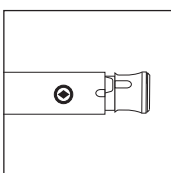
- If you cannot dial to the number “1”, see the “Questions and Answers” section at the end of this manual.



- 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.

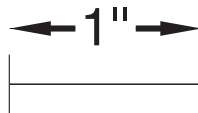
- Using your thumb, if possible, push in the blue injection button all the way and keep pressing. Continue to hold the blue injection button **firmly** and count **s-l-o-w-l-y** to 5. You should see either a few drops or a tiny stream of FORTEO come out of the tip of the needle. If nothing comes out 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).



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



LILLY FRANCE - Fegersheim PRINTED PACKAGING DEVELOPMENT	ITEM CODE PA 9291 FSAMP recto	PREVIOUS ITEM CODE PA 9290 FSAMP		1/2 NOIR U 2/2 ROUGE PMS 485	FINISHED PRODUCT CODE MS8971 / ND1040		Approved by NAME DATE	Signature	 Checked by
	SIZE (mm) 315 x 315	SICK CODE 2982	FILE N° 03R124		<input checked="" type="checkbox"/> Trade 001AM <input type="checkbox"/> Hospital	<input checked="" type="checkbox"/> Sample 001AMF1	Approved by NAME DATE	Signature	
	RESPONSIBLE NC	PROOF N° 6 DATE : 13.11.2003							



Control No.:	
Exp. Date:	
Read User Manual before injecting NDC 0002-8971-01 MS8971	
<div><div>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</div><div></div></div>	
Manufactured by Lilly France S.A.S., F-67640 Fegersheim, France for Eli Lilly and Company, Indianapolis, IN 46285, USA	
	
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