

**PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS  
(PREPARATIONS) – 1986**

This medicine is dispensed with a physician's prescription only

## **Forteo**

Solution for injection in a pre-filled pen

**Active ingredient and its quantity:** teriparatide 250 mcg/ml

Each injected dose contains:

teriparatide 20 mcg

**Inactive ingredients and allergens in the preparation:** see section 6 "Additional information".

**Read the entire leaflet carefully before using this medicine.** This leaflet contains concise information about this medicine. If you have any further questions, contact your doctor or pharmacist.

Also read the User Manual of the **Forteo** pen.

This medicine has been prescribed for the treatment of your illness. Do not pass it on to others. It may harm them even if their illness seems to be the same as yours.

### **1. WHAT IS THIS MEDICINE INTENDED FOR?**

- For the treatment of postmenopausal women with osteoporosis at high risk for fracture (defined herein as having a history of osteoporotic fracture or multiple risk factors for fracture), or who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, **Forteo** reduces the risk of vertebral and nonvertebral fractures.
- To increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture or who have failed or are intolerant to other available osteoporosis therapy.
- For the treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone) at high risk for fracture or who have failed or are intolerant to other available osteoporosis therapy.

**Therapeutic group:** Calcium homeostasis, parathyroid hormones and analogues.

### **2. BEFORE USING THIS MEDICINE**

**Do not use this medicine if:**

- you are sensitive (allergic) to the active ingredient (teriparatide) or to any of the other ingredients of this medicine (see section 6). Symptoms of a serious allergic reaction of **Forteo** may include swelling of the face, lips, tongue or throat that may cause difficulty in breathing or swallowing. Call your doctor right away or get emergency medical help if you get any of these symptoms.

**Special warnings regarding the use of this medicine**

**Forteo may cause bone cancer:** During drug testing, **Forteo** caused some rats to develop a bone cancer called osteosarcoma.

Studies in people have not shown that **Forteo** increases your chance of getting osteosarcoma. There is little information about the chance of getting osteosarcoma in patients using **Forteo** beyond 2 years.

**Before using Forteo, tell your doctor about all of your medical conditions, including if:**

- you have a certain bone disease called Paget's disease or other bone disease.
- you have bone cancer or have had a history of bone cancer.
- you are a young adult whose bones are still growing.
- you have had radiation therapy.
- you are affected with a condition that runs in your family that can increase your chance of getting cancer in your bones.
- you have or have had too much calcium in your blood (hypercalcemia).
- you have or have had a skin condition with painful sores or wounds caused by too much calcium.
- you have or have had kidney stones.
- you take medicines that contain digoxin.
- you are pregnant or plan to become pregnant. It is not known if **Forteo** will harm your unborn baby.
- you are breastfeeding or plan to breastfeed. It is not known if **Forteo** passes into your breastmilk. You should not breastfeed while taking **Forteo**.

**Children and adolescents**

It is not known if this medicine is effective and safe in children.

This medicine is not intended for children or young adults whose bones are still growing.

**Tests and follow up**

During treatment with this medicine, your doctor may check the calcium levels in your urine.

**Drug interactions**

**If you are taking or have recently taken any other medicines, including non-prescription medications and nutritional supplements, inform your doctor or pharmacist.** You should tell your doctor or pharmacist especially if you are taking or planning to take:

- medicines that contain digoxin - reported cases show that hypercalcemia may cause digoxin toxicity. **Forteo** may temporarily increase calcium levels. Therefore, the signs and symptoms of digoxin toxicity should be considered when patients taking digoxin are also taking **Forteo**.

Know the medicines you take. Keep a list of them to show your doctor or pharmacist when you get a new medicine.

**Use of this medicine and food:**

You can inject at any time of the day, regardless of mealtimes or drinks.

**Pregnancy and breastfeeding:**

Pregnancy

If you are pregnant, think you are pregnant, or plan to become pregnant, consult your doctor before using this medicine. It is not known if **Forteo** will harm your unborn baby.

### Breastfeeding

If you are breastfeeding or plan to breastfeed, contact your doctor before using this medicine. It is not known if **Forteo** passes into your breastmilk. You should not breastfeed while taking **Forteo**.

### **Driving and using machines:**

Use of this medicine may cause dizziness (see section 4 “Side effects”). In case you experience this, avoid driving or operating machinery.

## **3. HOW TO USE THIS MEDICINE?**

Always use this medicine according to the doctor’s instructions. You must check with your doctor or pharmacist if you are not sure about the dosage and manner of treatment with this medicine.

The dosage and manner of treatment will be determined only by your doctor.

- Read the detailed Instructions for Use (User Manual) included with your **Forteo** pen.
- Use **Forteo** exactly as your doctor tells you to. Your doctor will tell you how much **Forteo** to use and when to use it.
- Before you try to inject **Forteo** yourself, your doctor will show you how to use the **Forteo** pen in order to inject your dose.
- The recommended dose is usually one injection of **Forteo** per day, in your thigh or abdomen (lower stomach area). Do not inject into a vein or a muscle. Consult your doctor about how to rotate injection sites.
- **Forteo** has enough medicine for 28 days. **Forteo** set to give a 20-microgram dose of medicine each day. Do not inject all the medicine in **Forteo** at any one time.
- Do not transfer the medicine from the **Forteo** pen to a syringe. This can result in taking the wrong dose of **Forteo**. If you do not have needles to use with your **Forteo** pen, talk with your doctor.
- **Forteo** should look clear and colorless. Do not use **Forteo** if it has particles in it, or if it is cloudy or colored.
- Inject **Forteo** right away after you take the pen out of the refrigerator.
- After each use, safely remove the needle, recap the pen, and put it back in the refrigerator right away.
- When you inject the first few doses of **Forteo**, make sure you are in a place where you can sit or lie down right away, in case you feel dizzy or have an abnormal heartbeat after the injection.
- Do not take more than one injection in the same day.
- Do not Share your **Forteo** pen with other people.
- You should not use **Forteo** for more than 2 years over your lifetime, unless your doctor finds that you need longer treatment (up to 3 years) because you have a high chance of breaking your bones.
- If your doctor recommends calcium and vitamin D supplements, you can take them at the same time you take **Forteo**.

**Do not exceed the recommended dose.**

**If you have accidentally taken a higher dose**, or if a child has swallowed the medicine, proceed immediately to a doctor or a hospital's Emergency Room and bring the package of the medicine with you. If you take too much **Forteo**, you may have nausea, vomiting, weakness, or dizziness.

Persist with the treatment as recommended by your doctor.

You should complete the treatment as recommended by your doctor. Even if there is an improvement in your health, do not discontinue treatment with this medicine without consulting your doctor.

**Do not take medicines in the dark! Check the label and dose each time you take your medicine. Wear glasses if you need them.**

**If you have any further questions regarding the use of this medicine, consult your doctor or pharmacist.**

#### **4. SIDE EFFECTS**

As with any medicine, the use of **Forteo** may cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not suffer from any of them.

**Forteo** can cause serious side effects including:

- **Bone cancer (osteosarcoma):** Tell your doctor right away if you have pain in your bones, pain in any areas of your body that does not go away, or any new or unusual lumps or swelling under your skin that is tender to touch.
- **Increased calcium in your blood.** Tell your doctor if you have nausea, vomiting, constipation, low energy, or muscle weakness. These may be signs there is too much calcium in your blood.
- **Worsening of your kidney stones.** If you have or have had kidney stones, your doctor may check the calcium levels in your urine while you use **Forteo** to see if there is worsening of this condition.
- **Decrease in blood pressure when you change positions.** Some people may feel dizzy, get a fast heartbeat, or feel light-headed right after the first few doses of **Forteo**. This usually happens within 4 hours of taking **Forteo** and goes away within a few hours. For the first few doses, give your injections of **Forteo** in a place where you can sit or lie down right away if you get these symptoms. If your symptoms get worse or do not go away, contact your doctor before you continue using **Forteo**.

**The most common side effects of Forteo include:**

- pain
- nausea
- joint aches

**Side effects observed in trials with postmenopausal women with osteoporosis and men with primary or hypogonadal osteoporosis:**

**Body as a whole:** Pain, headache, weakness, neck pain.

**Cardiovascular:** Hypertension, angina pectoris, temporary loss of consciousness (fainting).

**Digestive System:** Nausea, constipation, diarrhea, dyspepsia, vomiting, gastrointestinal disorders, tooth disorders.

**Musculoskeletal System:** Arthralgia, leg cramps.

**Nervous System:** Dizziness, depression, insomnia, vertigo.

**Respiratory System:** Rhinitis, cough increased, pharyngitis, dyspnea, pneumonia.

**Skin:** Rash, sweating.

**Side effects observed in trials with women and men with osteoporosis associated with corticosteroid therapy:**

- Nausea
- Gastritis
- Pneumonia
- Dyspnea
- Insomnia
- Anxiety
- Herpes zoster

**Side effects with an unknown frequency were observed after the drug was marketed** - it is not possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

- Cases of bone tumor and osteosarcoma have been reported rarely in the post-marketing period.
- Hypercalcemia: high level of calcium in the blood.

**Side effects reported since market introduction that were temporally related to Forteo therapy include:**

- Allergic reactions: anaphylactic reactions, drug hypersensitivity, angioedema, urticaria.
- Laboratory results: an increase in the level of uric acid in the blood.
- Respiratory system: acute dyspnea, chest pain.
- Musculoskeletal system: muscle spasms of the leg or back.
- Other: injection site reactions including injection site pain, swelling and bruising; facial edema.

**If a side effect occurs, if any of the side effects gets worse, or if you suffer from a side effect that was not specified in this leaflet, you should consult your doctor.**

**Reporting of side effects**

Side effects may be reported to the Ministry of Health by clicking on the link “Reporting Side Effects due to Drug Treatment” that can be found on the Home Page of the Ministry of Health’s website ([www.health.gov.il](http://www.health.gov.il)), which refers to the online form for reporting side effects, or via the following link:

<https://sideeffects.health.gov.il>

## **5. HOW TO STORE THIS MEDICINE?**

- **Avoid poisoning!** This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting without an explicit instruction from your doctor.
- Do not use the medicine after the expiration date (exp. date) appearing on the package and the pen. The expiration date refers to the last day of that month.

### **Storage conditions:**

- Store in the refrigerator (2°C-8°C). Do not freeze. Do not use the medicine if it has been frozen.
- May be used within 28 days after the first injection. The **Forteo** pen should be discarded after 28 days even if it has medicine in it. See the User Manual.
- A pen in use should be stored in the refrigerator at a temperature between 2°C-8°C.
- Do not use **Forteo** if it has particles in it, or if it is cloudy or colored.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. ADDITIONAL INFORMATION**

### **In addition to the active ingredient, the medicine also contains:**

mannitol, metacresol, glacial acetic acid, sodium acetate (anhydrous), hydrochloric acid solution 10%, sodium hydroxide solution 10%, water for injection.

### **What the medicine looks like and the contents of the package:**

- **Forteo** is a clear, colorless solution in pre-filled injector pen.
- Each 2.4 ml syringe contains 600 mcg teriparatide and is sufficient for 28 days of treatment.
- The pen is intended for multiple administrations and must be disposed of upon completion of use.
- The package contains one pen.

**License holder name and address:** Eli Lilly Israel Ltd., 4 HaSheizaf St., P.O.Box 4246, Ra'anana 4366411.

**Manufacturer's name and address:** Lilly France S.A.S., Fegersheim, France.

Revised in August 2024.

**The drug registration number in the National Drug Registry in the Ministry of Health:**  
129-28-30777-00

## PEN USER MANUAL

# FORTEO

## Solution for injection in a pre-filled pen

**The active ingredient and its quantity:** teriparatide 250 mcg/ml

**Each injected dose contains:** teriparatide 20 mcg

### Instructions for use

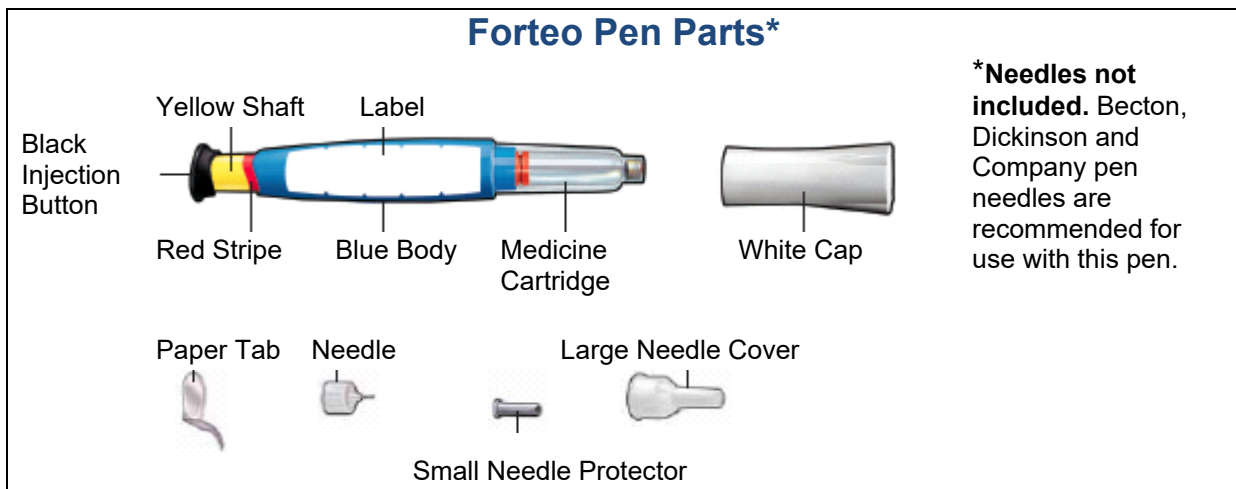
**Important:** First read the Patient Leaflet that comes inside your Forteo carton.

Before you use your new Forteo pen, please read the entire *Instructions for Use* completely. Follow the directions carefully when using the Forteo pen.

Do not share your pen or needles because infection or disease can be spread from one person to another.

**The Forteo pen contains 28 days of medicine. Throw away the Forteo pen 28 days after first use, even if it is not completely empty. Do not inject more than one dose of Forteo in the same day.**

**Do not transfer the medicine to a syringe.**




**Wash your hands before every injection. Prepare the injection site as your healthcare provider instructed.**

**1 Pull off white cap**

Check the **Forteo** pen label to make sure you have the right medicine and that it has not expired.


Do not use if the **Forteo** pen looks damaged, if the medicine in the cartridge is not clear and colorless, or if it has particles in it.

**2 Attach new needle**



Pull off paper tab. Push needle **straight** onto medicine cartridge. Screw on needle clockwise until firmly attached. Pull off large needle cover and **save it**.


**3 Set dose**



**Pull out black injection button until it stops.** **Check** to make sure red stripe shows. **Pull off small needle protector and throw away.**

If you cannot pull out the black injection button, see *Troubleshooting, Problem E*, on back page.

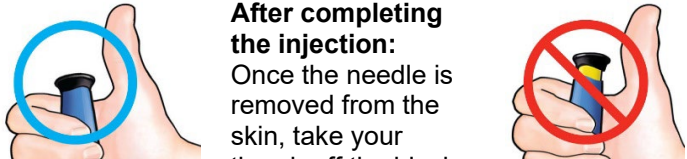
**4 Inject dose**



Gently hold a fold of skin on your thigh or abdomen and insert needle straight into skin. **Push in black injection button until it stops. Hold it in and count to 5 slowly. You must wait until the count of 5 to make sure you receive the correct dose.** Then pull the needle from skin.

**IMPORTANT**




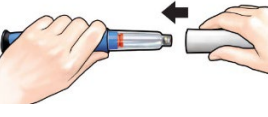
**5 Confirm dose**



**After completing the injection:** Once the needle is removed from the skin, take your thumb off the black injection button. **Check** to make sure the black injection button is all the way in. If the yellow shaft does not show, you have finished the injection steps the right way.

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 on the same day. Instead, **you MUST reset the Forneo pen** (see *Troubleshooting, Problem A*, on back page).



<b>6</b> <b>Remove needle</b>				
	<p>Put large needle cover on needle. Do not try to put the needle cover back on with your hands.</p>	<p>Unscrew the covered needle all the way by giving the large needle cover 3 to 5 counter-clockwise turns.</p>	<p>Pull off needle and throw away in a puncture-resistant container.</p>	<p>Push white cap back on. Right after use, place <b>Forteo</b> pen in the refrigerator (2°C-8°C).</p>

**For more information, or if you have any questions, turn to the back of this page.**

*Lilly*



**FORTEO**  
Solution for injection in a pre-filled pen

**Troubleshooting**

**Problem**

**Solution**

**A.** The yellow shaft is still showing after I push in the black injection button. How do I reset my Forteo pen?



To reset the Forteo pen, follow the following steps:

1. **If you have already injected, DO NOT inject yourself a second time on the same day.**
2. Remove the needle.
3. Attach a new needle, pull off the large needle cover and save it.
4. Pull out the black injection button until it stops. Check to make sure the red stripe shows.
5. Pull off the small needle protector and throw away.
6. 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.**
7. If you still see the yellow shaft showing, contact Eli Lilly Israel Ltd. (see *Contact Information* below) or your healthcare provider.
8. Put the large needle cover on needle. Unscrew the needle all the way by giving the needle cover 3 to 5 counter-clockwise turns. Pull off the covered needle and throw away as instructed by your healthcare provider. Push the white cap back on and put your Forteo pen in the refrigerator (2°C-8°C).

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.**

**B.** How can I tell if my Forteo pen works?

The black injection button should be all the way in to show that the full dose of medicine has been injected from the Forteo pen

Use a new needle every time you inject to be sure your Forteo pen will work properly.

**C.** I see an air bubble in my Forteo pen.

A small air bubble will not affect your dose and it will not harm you. You can continue to take your dose as usual.

**D. I cannot get the needle off.**



1. Put the large needle cover on the needle.
2. Use the large needle cover to unscrew the needle.
3. Unscrew the needle all the way by giving the large needle cover 3 to 5 counter-clockwise turns.
4. If you still cannot get the needle off, ask someone to help you.

**E. What should I do if I have difficulty pulling out the black injection button?**



**Change to a new Forteo pen to take your dose as instructed by your healthcare provider.**

When the black injection button becomes hard to pull out, this means there is not enough medicine in your **Forteo** pen for another dose. You may still see some medicine left in the cartridge.

## Cleaning and Storage

### Cleaning Your Forteo Pen

- Wipe the outside of the **Forteo** pen with a damp cloth.
- Do not place the **Forteo** pen in water, or wash or clean it with any liquid.

### Storing Your Forteo Pen

- After each use, refrigerate (2°C-8°C) the **Forteo** pen right away. Read and follow the instructions in the *Patient Leaflet*.
- Do not store the **Forteo** pen with a needle attached. Doing this may cause air bubbles to form in the medicine cartridge.
- Store the **Forteo** pen with the white cap on.
- Do not freeze **Forteo**. If the medicine has been frozen, throw the pen away and use a new **Forteo** pen.
- If the **Forteo** pen has been left out of the refrigerator, do not throw the pen away. Place the pen back in the refrigerator (2°C-8°C) and call your healthcare provider or Eli Lilly Israel Ltd. (see *Contact Information* below).

## Other Important Notes

- The **Forteo** pen contains 28 days of medicine.
- Each device contains additional volume to allow troubleshooting of the pen 2 times.
- Do not transfer the medicine to a syringe. This may result in you accidentally taking the wrong dose.
- Read and follow the instructions in the User Manual so that you use your **Forteo** pen the right way.
- Check the **Forteo** pen label to make sure you have the right medicine and that it has not expired.
- Do not use the **Forteo** pen if it looks damaged. Look at the **Forteo** medicine in the cartridge. If the medicine is not clear and colorless, or if it has particles, do not use it. Call Eli Lilly Israel Ltd. (see *Contact Information* below) if you notice any of these.
- Use a new needle for each injection.
- During injection, you may hear one or more clicks – this is normal.
- The **Forteo** 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 pen.
- Keep your **Forteo** pen and needles out of the reach and sight of children.

<b>Disposal of Pen Needles and Pen</b>	
<b>Disposal of Pen Needles and the Forteo Pen</b> <ul style="list-style-type: none"><li>• Before throwing away the <b>Forteo</b> pen, be sure to remove the pen needle.</li><li>• Throw away your <b>Forteo</b> pen and used needles as instructed by your healthcare provider, local or state laws, or institutional policies.</li></ul>	
<b>Dispose of the Forteo pen 28 days after first use.</b>	1 <sup>st</sup> use date ____ / ____ / ____ Throw away after ____ / ____ / ____

<b>Contact Information</b>
<b>If you have questions or need help with your Forteo pen, contact Eli Lilly Israel Ltd. or your healthcare provider for assistance.</b>
<b>Manufactured by</b> Lilly France S.A.S, Fegersheim, France <b>License holder:</b> Eli Lilly Israel Ltd., 4 HaSheizaf St., P.O.Box 4246, Ra'anana 4366411
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**The drug registration number in the National Drug Registry in the Ministry of Health: 129-28-30777-00**