

Package leaflet: Information for the user

FORSTEO 20 micrograms/80 microliters solution for injection in pre-filled pen Teriparatide

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What FORSTEO is and what it is used for
2. What you need to know before you use FORSTEO
3. How to use FORSTEO
4. Possible side effects
5. How to store FORSTEO
6. Content of the pack and other information

1. What is FORSTEO and what it is used for

FORSTEO contains the active substance teriparatide that is used to make the bones stronger, and to reduce the risk of fractures by stimulating bone formation.

FORSTEO is used to treat osteoporosis in adults. Osteoporosis is a disease that causes your bones to become thin and fragile. This disease is especially common in women after the menopause, but it can also occur in men. Osteoporosis is also common in patients receiving corticosteroids.

2. What you need to know before you use FORSTEO

Do not use FORSTEO

- if you are allergic to teriparatide or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from high calcium levels (pre-existing hypercalcaemia).
- if you suffer from serious kidney problems.
- if you have ever been diagnosed with bone cancer or other cancers that have spread (metastasised) to your bones.
- if you have certain bone diseases. If you have a bone disease, tell your doctor.
- if you have unexplained high levels of alkaline phosphatase in your blood, which means you might have Paget's disease of bone (disease with abnormal bone changes).. If you are not sure, ask your doctor.
- if you have had radiation therapy involving your bones.
- if you are pregnant or breast-feeding.

Warning and precautions

FORSTEO may cause an increase in the amount of calcium in your blood or urine.

Talk to your doctor or pharmacist before or while using FORSTEO:

- if you have continuing nausea, vomiting, constipation, low energy, or muscle weakness. These may be signs there is too much calcium in your blood.
- if you suffer from kidney stones or have a history of kidney stones.
- if you suffer from kidney problems (moderate renal impairment).

Some patients get dizzy or get a fast heartbeat after the first few doses. For the first doses, inject FORSTEO where you can sit or lie down right away if you get dizzy.

The recommended treatment time of 24 months should not be exceeded.

FORSTEO should not be used in growing adults.

Children and adolescents

FORSTEO should not be used in children and adolescents (less than 18 years).

Other medicines and FORSTEO

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, because occasionally they may interact (e.g. digoxin/digitalis, a medicine used to treat heart disease).

Pregnancy and breast-feeding

Do not use FORSTEO if you are pregnant or breast-feeding. If you are a woman of child-bearing potential, you should use effective methods of contraception during use of FORSTEO. If you become pregnant, FORSTEO should be discontinued. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Some patients may feel dizzy after injecting FORSTEO. If you feel dizzy you should not drive or use machines until you feel better.

Important information about some of the ingredients of FORSTEO:

This medicine contains less than 1 mmol sodium (23 mg) per dose. This means that it is essentially “sodium-free”.

3. How to use FORSTEO

Always use this medicine exactly as your doctor has told you to. Check with your doctor or pharmacist if you are not sure.

The recommended dose is 20 micrograms given once daily by injection under the skin (subcutaneous injection) in the thigh or abdomen. To help you remember to take your medicine, inject it at about the same time each day.

Inject FORSTEO each day for as long as your doctor prescribes it for you. The total duration of treatment with FORSTEO should not exceed 24 months. You should not receive more than one treatment course of 24 months over your lifetime.

FORSTEO can be injected at meal times.

Read the user manual booklet, which is included in the carton for instructions on how to use the FORSTEO pen.

Injection needles are not included with the pen. Becton, Dickinson and Company pen needles 29 to 31 gauge (diameter 0.25-0.33 mm) and 12.7, 8 or 5 mm length can be used.

You should take your FORSTEO injection shortly after you take the pen out of the refrigerator as described in the user manual. Put the pen back into the refrigerator immediately after you have used it.

Use a new injection needle for each injection and dispose of it after each use. Never store your pen with the needle attached. Never share your FORSTEO pen with others.

Your doctor may advise you to take FORSTEO with calcium and vitamin D. Your doctor will tell you how much you should take each day.

FORSTEO can be given with or without food.

If you use more FORSTEO than you should

If, by mistake, you have used more FORSTEO than you should, contact your doctor or pharmacist.

The effects of overdose that might be expected include nausea, vomiting, dizziness, and headache.

If you forget or cannot take FORSTEO at your usual time, take it as soon as possible on that day. Do not take a double dose to make up for a forgotten dose. Do not take more than one injection in the same day. Do not try to make up for a missed dose.

If you stop taking FORSTEO

If you are considering stopping FORSTEO treatment, please discuss this with your doctor. Your doctor will advise you and decide how long you should be treated with FORSTEO.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The most common side effects are pain in limb (frequency is very common, may affect more than 1 in 10 people) and feeling sick, headache and dizziness (frequency is common). If you become dizzy (light-headed) after your injection, you should sit or lie down until you feel better. If you do not feel better, you should call a doctor before you continue treatment. Cases of fainting have been reported in association with teriparatide use.

If you experience discomfort such as redness of the skin, pain, swelling, itching, bruising or minor bleeding around the area of the injection (frequency is common), this should clear up in a few days or weeks. Otherwise tell your doctor as soon as possible.

Some patients may have experienced allergic reactions soon after injection, consisting of breathlessness, swelling of the face, rash and chest pain (frequency is rare). In rare cases, serious and potentially life-threatening allergic reactions including anaphylaxis can occur.

Other side effects include:

Common: may affect up to 1 in 10 people

- increase in blood cholesterol levels
- depression
- neuralgic pain in the leg
- feeling faint
- irregular heart beats
- breathlessness
- increased sweating
- muscle cramps
- loss of energy
- tiredness
- chest pain
- low blood pressure
- heartburn (painful or burning sensation just below the breast bone)
- being sick(vomiting)

- a hernia of the tube that carries food to your stomach
- low haemoglobin or red blood cell count (anaemia)

Uncommon: may affect up to 1 in 100 people

- increased heart rate
- abnormal heart sound
- shortness of breath
- haemorrhoids (piles)
- accidental loss or leakage of urine
- increased need to pass water
- weight increase
- kidney stones
- pain in the muscles and pain in the joints. Some patients have experienced severe back cramps or pain which lead to hospitalisation.
- increase in blood calcium level
- increase in blood uric acid level
- increase in an enzyme called alkaline phosphatase.

Rare: may affect up to 1 in 1,000 people

- reduced kidney function, including renal failure
- swelling, mainly in the hands, feet and legs.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via **the national reporting system** listed in [Appendix V](#)*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store FORSTEO

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and pen after EXP. The expiry date refers to the last day of that month.

FORSTEO should be stored in a refrigerator (2°C to 8°C) at all times. You can use FORSTEO for up to 28 days after the first injection, as long as the pen is stored in a refrigerator (2°C to 8°C).

Do not freeze FORSTEO. Avoid placing the pens close to the ice compartment of the refrigerator to prevent freezing. Do not use FORSTEO if it is, or has been, frozen.

Each pen should be properly disposed of after 28 days, even if it is not completely empty.

FORSTEO contains a clear and colourless solution. Do not use FORSTEO if solid particles appear or if the solution is cloudy or coloured.

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 to protect the environment.

6. Contents of the pack and other information

What FORSTEO contains

- The active substance is teriparatide. Each millilitre of the solution for injection contains 250 micrograms of teriparatide.

- The other ingredients are glacial acetic acid, sodium acetate (anhydrous), mannitol, metacresol, and water for injections. In addition, hydrochloric acid and/or sodium hydroxide solution may have been added for pH adjustment.

What FORSTEO looks like and contents of the pack

FORSTEO is a colourless and clear solution. It is supplied in a cartridge contained in a pre-filled disposable pen. Each pen contains 2.4 mL of solution enough for 28 doses. The pens are available in cartons containing one or three pens. Not all pack sizes may be available.

Marketing Authorisation Holder

Eli Lilly Nederland B.V., Grootslag 1-5, NL-3991 RA Houten, The Netherlands

Manufacturer

Lilly France S.A.S, Rue du Colonel Lilly, F-67640 Fegersheim, France.

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

België/Belgique/Belgien

Eli Lilly Benelux S.A./N.V.
Tél/Tel: + 32 (0) 2 548 84 84

България

ТП "Ели Лили Недерланд" Б.В. - България
Тел: + 359 2 491 41 40

Česká republika

Eli Lilly ČR, s.r.o.
Tel: + 420 234 664 111

Danmark

Eli Lilly Danmark A/S
Tlf: + 45 45 26 60 00

Deutschland

Lilly Deutschland GmbH
Tel: + 49 (0) 6172 273 2222

Eesti

Eli Lilly Holdings Limited Eesti filiaal
Tel: + 372 6817 280

Ελλάδα

ΦΑΡΜΑΣΕΡΒ-ΛΙΑΛΥ Α.Ε.Β.Ε.
Τηλ: + 30 210 629 4600

España

Elanco Valquímica, S.A.
Tel: + 34-91 623 1732

France

Lilly France SAS
Tél: + 33 (0) 1 55 49 34 34

Hrvatska

Eli Lilly Hrvatska d.o.o.
Tel: +385 1 2350 999

Ireland

Eli Lilly and Company (Ireland) Limited
Tel: + 353 (0) 1 661 4377

Ísland

Icepharma hf.
Sími: + 354 540 8000

Italia

Eli Lilly Italia S.p.A.
Tel: + 39 055 42571

Lietuva

Eli Lilly Holdings Limited atstovybė
Tel: + 370 (5) 2649600

Luxembourg/Luxemburg

Eli Lilly Benelux S.A./N.V.
Tél/Tel: + 32 (0) 2 548 84 84

Magyarország

Lilly Hungária Kft.
Tel: + 36 1 328 5100

Malta

Charles de Giorgio Ltd.
Tel: + 356 25600 500

Nederland

Eli Lilly Nederland B.V.
Tel: + 31(0) 30 6025800

Norge

Eli Lilly Norge A.S
Tlf: + 47 22 88 18 00

Österreich

Eli Lilly Ges. m.b.H.
Tel: + 43 (0) 1 711 780

Polska

Eli Lilly Polska Sp. z o.o.
Tel: + 48 (0) 22 440 33 00

Portugal

Lilly Portugal Produtos Farmacêuticos, Lda
Tel: + 351 21 412 66 00

România

Eli Lilly România S.R.L.
Tel: + 40 21 4023000

Slovenija

Eli Lilly farmacevtska družba, d.o.o.
Tel: + 386 (0) 1 580 00 10

Slovenská republika

Eli Lilly Slovakia, s.r.o.
Tel: + 421 220 663 111

Suomi/Finland

Oy Eli Lilly Finland Ab
Puh/Tel: + 358 (0) 9 8545 250

Κύπρος

Phadisco Ltd

Τηλ: + 357 22 715000

Latvija

Eli Lilly Holdings Limited, pārstāvniecība Latvijā

Tel: + 371 67364000

Sverige

Eli Lilly Sweden AB

Tel: + 46 (0) 8 7378800

United Kingdom

Eli Lilly and Company Limited

Tel: +44 (0) 1256 315000

This leaflet was last revised in

Detailed information on this medicine is available on the European Medicines Agency web site:

<http://www.ema.europa.eu>

This leaflet is available in all EU/EEA languages on the European Medicines Agency web site.

PEN USER MANUAL

Forsteo

FORSTEO 20 micrograms (μg)/ 80 microlitres solution for injection, in pre-filled pen

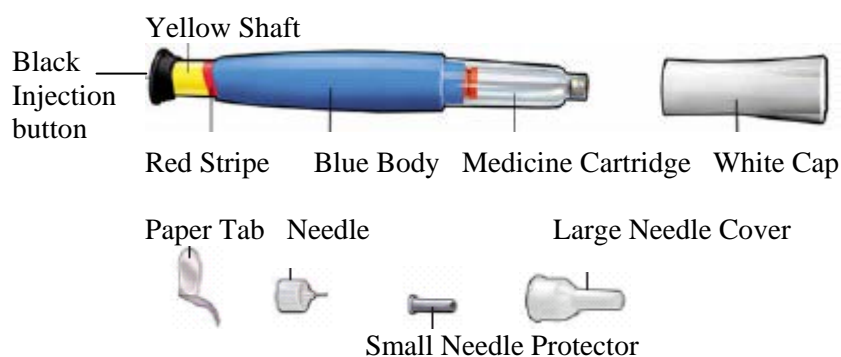
Instructions for use

Before you use your new pen, please read the section *Instructions for use* completely. Follow the directions carefully when using the pen. Also read the package leaflet provided.

Do not share your pen or your needles as this may risk transmission of infectious agents.

Your pen contains 28 days of medicine.

Forsteo parts*



* Needles not included. Becton, Dickinson and Company pen needles 29 to 31 gauge (diameter 0.25-0.33 mm) and 12.7, 8 or 5 mm length can be used. Ask your doctor or pharmacist which needle gauge and length are best for you.

Always wash your hands before every injection. Prepare the injection site as directed by your doctor or pharmacist.

1



Pull off white cap

2

Attach new needle



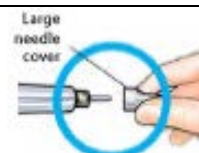
Pull off paper tab.



Push needle **straight** onto medicine cartridge.



Screw on needle until firmly attached.



Pull off large needle cover and **save it**.

3 Set dose



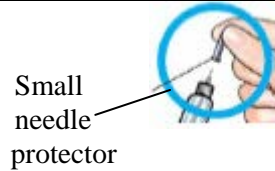
Pull out black injection button **until it stops**.

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



Red stripe

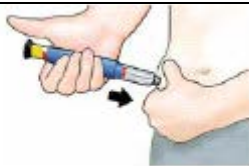
Check to make sure red stripe shows.



Small needle protector

Pull off small needle protector and throw away.

4 Inject dose



Gently hold a fold of skin from thigh or abdomen and insert needle straight into skin.



Push in black injection button until it stops. Hold it in and **count to 5 s-l-o-w-l-y**. Then pull the needle from skin.

IMPORTANT

5 Confirm dose



After completing the injection:

Once the needle is removed from the skin, **check** to make sure the black injection button is all the way in. If the yellow shaft does not show, you have completed the injection steps correctly.



You should **NOT** see any of the yellow shaft. If you do and have already injected, do not inject yourself a second time on the same day. Instead, **you MUST reset FORSTEO** (see *Troubleshooting Problem A*).

6

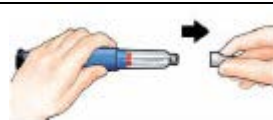
Remove needle



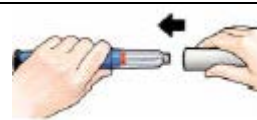
Put large needle cover on needle.



Unscrew the needle all the way by giving the large needle cover 3 to 5 complete turns.



Pull off needle and throw away as directed by your doctor or pharmacist.



Push white cap back on. Place FORSTEO in the refrigerator immediately after use.

The directions regarding needle handling are not intended to replace local, healthcare professional or institutional policies.



Forsteo

FORSTEO, 20 microgram (μg) 80 microlitres solution for injection, in pre-filled pen

Troubleshooting

Problem

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



Solution

To reset the FORSTEO, follow the steps below.



- 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 count to 5 s-l-o-w-l-y. 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, please contact your doctor or pharmacist
- 8) Put the large needle cover on needle.
Unscrew the needle all the way by giving the needle cover 3 to 5 complete turns. Pull off needle cover and throw away as directed by your doctor or pharmacist. Push the white cap back on, and place FORSTEO in the refrigerator.


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 counting to 5 s-l-o-w-l-y.**

B. How can I tell if my FORSTEO works?



The FORSTEO is designed to inject the full dose every time it is used according to the directions in the

		<p>section <i>Instructions for Use</i>. The black injection button will be all the way in to show that the full dose has been injected from the FORSTEO.</p> <p>Remember to use a new needle every time you inject to be sure your FORSTEO will work properly.</p>
<p>C. I see an air bubble in my FORSTEO.</p>		<p>A small air bubble will not affect your dose nor will it harm you. You can continue to take your dose as usual.</p>
<p>D. I cannot get the needle off.</p>		<ol style="list-style-type: none"> 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 complete turns. 4) If you still cannot get the needle off, ask someone to help you.

<p>E. What should I do if I cannot pull out the black injection button?</p>		<p>Change to a new FORSTEO to take your dose as directed by your doctor or pharmacist.</p> <p>This indicates that you have now used all the medicine that can be injected accurately even though you may still see some medicine left in the cartridge.</p>
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Cleaning and Storage	
<p>Cleaning Your FORSTEO</p> <ul style="list-style-type: none"> • Wipe the outside of the FORSTEO with a damp cloth. • Do not place the FORSTEO in water, or wash or clean it with any liquid. <p>Storing Your FORSTEO</p> <ul style="list-style-type: none"> • Refrigerate the FORSTEO immediately after every use. Read and follow the instructions in the <i>Information for the Patient leaflet</i> on how to store your pen. • Do not store the FORSTEO with a needle attached as this may cause air bubbles to form in the cartridge. • Store the FORSTEO with the white cap on. • Never store the FORSTEO in the freezer. • If the medicine has been frozen, throw the device away and use a new FORSTEO. • If the FORSTEO has been left out of the refrigerator, do not throw the pen away. Place the pen back in the refrigerator and contact your doctor or pharmacist.. 	

Disposal of Pen Needles and Device
<p>Disposal of Pen Needles and FORSTEO Device</p> <ul style="list-style-type: none"> • Before disposing of the FORSTEO device, be sure to remove the pen needle. • Dispose of your FORSTEO and used needles as directed by your doctor or pharmacist. • Dispose of the device 28 days after first use.

Other Important Notes
<ul style="list-style-type: none"> • The FORSTEO contains 28 days of medicine. • Do not transfer the medicine into a syringe.

- Write down your first injection date on a calendar.
- Read and follow the instructions in the *Information for the Patient leaflet* for using the product.
- Check the FORSTEO label to make sure you have the correct medicine. and that it has not expired.
- Contact your doctor or pharmacist if you notice any of the following:
 - The FORSTEO appears damaged
 - The solution is NOT clear, colourless and free of particles
- Use a new needle for each injection.
- During injection, you may hear one or more clicks – this is a normal device operation.
- The FORSTEO is not recommended for use by the blind or visually impaired persons without the assistance of a person trained in the proper use of the device.
- Keep the FORSTEO out of the sight and reach of children.

Manufactured by Lilly France, F-67640 Fegersheim, France
for Eli Lilly and Company.
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