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.
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:
1. What FORSTEO is and what it is used for
2. Before you use FORSTEO
3. How to use FORSTEO
4. Possible side effects
5. How to store FORSTEO
6. Further information

1. WHAT FORSTEO IS AND WHAT IT IS USED FOR
FORSTEO is used to make the bones stronger, and to reduce the risk of fractures (bone-formation agent).
This product is used to treat osteoporosis. 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. BEFORE YOU USE FORSTEO
Do not use FORSTEO
• if you are allergic (hypersensitive) to teriparatide or any of the other ingredients of FORSTEO
• 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. If you are not sure, ask your doctor
• if you have had radiation therapy involving your bones
• if you are pregnant or breast-feeding
FORSTEO should not be used in children (less than 18 years) or in growing adults.

**Take special care with FORSTEO**
FORSTEO may cause an increase in the amount of calcium in your blood. Tell your doctor if you have continuing nausea, vomiting, constipation, low energy, or muscle weakness. These may be signs there is too much calcium in your blood.

FORSTEO may cause an increase in the amount of calcium in your urine. You should tell your doctor if you suffer from kidney stones or have a history of kidney stones. You should tell your doctor 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.

**Taking other medicines**
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, because occasionally they may interact (e.g. digoxin/digitalis, a medicine used to treat heart disease).

**Using FORSTEO with food and drink**
Forsteo can be given with or without food.

**Pregnancy and breast-feeding**
Do not use FORSTEO if you are pregnant or breast-feeding. Women of child-bearing potential should use effective methods of contraception during use of FORSTEO. If pregnancy occurs, 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 medicinal product 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 FORSTEO exactly as your doctor has told you to. You should check with your doctor or pharmacist if you are not sure.
Never share your FORSTEO pen with others.

The recommended dose of FORSTEO is 20 micrograms given once daily by injection under the skin (subcutaneous injection) in the thigh or abdomen. To help you remember to take FORSTEO, 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. You can use Becton Dickinson and Company’s insulin pen injection needles.

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.

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.

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

4. POSSIBLE SIDE EFFECTS
Like all medicines, FORSTEO can cause side effects, although not everybody gets them.

The most common side effects (affects more than 1 user in 10) are:

- pain in limb
Common side effects (1 to 10 users in 100) are:
- feeling sick
- headache
- dizziness
- 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)
- low haemoglobin or red blood cell count (anaemia)

Uncommon side effects (affects 1 to 10 users in 1000) are:
- increased heart rate
- shortness of breath
- haemorrhoids (piles)
- accidental loss or leakage of urine
- increased need to pass water
- weight increase
- kidney stones

Other uncommon side effects reported include pain in the muscles and pain in the joints. Some people may experience discomfort such as redness of the skin, pain, swelling, itching, bruising or minor bleeding around the area of the injection. This should clear up in a few days or weeks. Otherwise tell your doctor as soon as possible.

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.

Some patients treated with FORSTEO have had an increase in their blood calcium level.

Rare side effects (affects 1 to 10 users in 10,000): Some patients have experienced allergic reactions soon after injection, consisting of breathlessness, swelling of the face, rash and chest pain.

Cases of reduced kidney function, including renal failure have been reported in association with teriparatide use.
Other rare side effects include swelling, mainly in the hands, feet and legs. Some patients have experienced severe back cramps or pain, which led to hospitalisation.

FORSTEO may also cause an increase in an enzyme called alkaline phosphatase.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE FORSTEO
Keep out of the reach and sight of children.

Do not use FORSTEO after the expiry date which is stated on the carton and pen.

FORSTEO should be stored in a refrigerator (2°C and 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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER 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 3.0 mg/ml (preservative), and water for injections. In addition, hydrochloric acid and/or sodium hydroxide solution may have been added to adjust the acidity.

What FORSTEO looks like and contents of the pack
FORSTEO is a colourless and clear solution for injection under the skin (subcutaneous use). 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 and Manufacturer**
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 medicinal product, please contact the local representative of the Marketing Authorisation Holder.

<table>
<thead>
<tr>
<th>Country</th>
<th>Address</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belgïe/Belgique/Belgien</td>
<td>Eli Lilly Benelux S.A.</td>
<td>+32-(0)2 548 84 84</td>
</tr>
<tr>
<td>Luxembourg/Luxemburg</td>
<td>Eli Lilly Benelux S.A.</td>
<td>+32-(0)2 548 84 84</td>
</tr>
<tr>
<td>България</td>
<td>ТП &quot;Ели Лили Нederland&quot; Б.В. - България</td>
<td>тел. + 359 2 491 41 40</td>
</tr>
<tr>
<td>Magyarország</td>
<td>Lilly Hungária Kft.</td>
<td>+36 1 328 5100</td>
</tr>
<tr>
<td>Česká republika</td>
<td>ELI LILLY ČR, s.r.o.</td>
<td>+420 234 664 111</td>
</tr>
<tr>
<td>Malta</td>
<td>Charles de Giorgio Ltd.</td>
<td>+356 25600 500</td>
</tr>
<tr>
<td>Danmark</td>
<td>Eli Lilly Danmark A/S</td>
<td>+45 45 26 60 00</td>
</tr>
<tr>
<td>Nederland</td>
<td>Eli Lilly Nederland B.V.</td>
<td>+31-(0) 30 60 25 800</td>
</tr>
<tr>
<td>Deutschland</td>
<td>Lilly Deutschland GmbH</td>
<td>+49-(0) 6172 273 2222</td>
</tr>
<tr>
<td>Norge</td>
<td>Eli Lilly Norge A.S.</td>
<td>+47 22 88 18 00</td>
</tr>
<tr>
<td>Eesti</td>
<td>Eli Lilly Holdings Limited Eesti filiaal</td>
<td>+3726817280</td>
</tr>
<tr>
<td>Österreich</td>
<td>Eli Lilly Ges.m.b.H.</td>
<td>+43-(0) 1 711 780</td>
</tr>
<tr>
<td>Ellάδα</td>
<td>ΦΑΡΜΑΣΕΡΒ-ΛΙΛΛΥ Α.Ε.Β.Ε.</td>
<td>+ 30 210 629 4600</td>
</tr>
<tr>
<td>Polska</td>
<td>Eli Lilly Polska Sp. z o.o.</td>
<td>+48 (0) 22 440 33 00</td>
</tr>
<tr>
<td>España</td>
<td>Elanco Valquímica S.A.</td>
<td>+34-91 623-1732</td>
</tr>
<tr>
<td>Portugal</td>
<td>Lilly Portugal - Produtos Farmacêuticos, Lda</td>
<td>+351-21-4126600</td>
</tr>
<tr>
<td>România</td>
<td>Eli Lilly România S.R.L.</td>
<td>+40 21 4023000</td>
</tr>
<tr>
<td>Ireland</td>
<td>Eli Lilly and Company (Ireland) Limited.</td>
<td>+353-(0) 1 661 4377</td>
</tr>
<tr>
<td>Slovenija</td>
<td>Eli Lilly farmacevtska družba, d.o.o</td>
<td>+386 (0)1 580 00 10</td>
</tr>
</tbody>
</table>
This leaflet was last approved in July 2011

Detailed information on this medicine is available on the European Medicines Agency web site:
http://www.ema.europa.eu