Usage Information Leaflet

Teriparatide (r-Human Parathyroid Hormone) Injection 750 mcg/3 mL

OSTEOTIDE

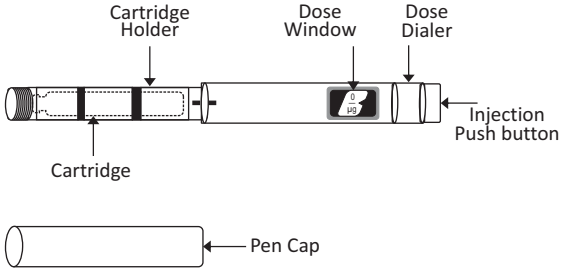
PRE-FILLED DISPOSABLE PEN DEVICE

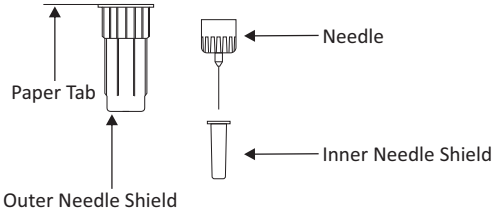
Before using the **OSTEOTIDE PRE-FILLED PEN DEVICE (Osteotide pen)** please read and follow the below instructions carefully.

Pen Features:

1. Prefilled disposable pen containing 28 days doses.
2. Dose setting indicator (marker arrow) for 20µg fixed daily dose.

Pen Parts:





*Pen Needles are provided free with pen device.
Pen needles are also available at your local pharmacy.

Storage:

1. Store the **Osteotide pen** in the refrigerator between 2-8°C (36-46°F) at all times.
2. You should inject **Osteotide** right after you take the pen out of the refrigerator.
3. Put the pen back into the refrigerator right after use.
4. Do not freeze. Do not use **Osteotide pen** if it has been frozen.
5. Do not store the **Osteotide pen** with the needle attached. Keeping the needle attached may cause a leakage and/or air bubbles formation in the cartridge.

Materials:

Make sure that you have the following items before every dose

- 1 x Osteotide pre-filled pen device
- 1 x Disposable Pen needle: 32G x ¼" (0.23 x 6mm)
- 2 x Alcohol swabs

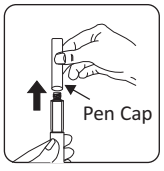
Note: *Pen needles and alcohol swabs are also available at your local/hospital pharmacy.*

I. Preparing the Osteotide pen:

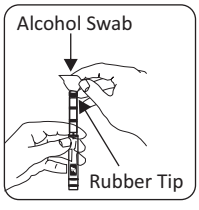
1.Always wash your hands before preparing the **Osteotide pen**.

2.Remove the **Osteotide pen** from the refrigerator.

3.Remove the Pen Cap by pulling it off (fig.1).



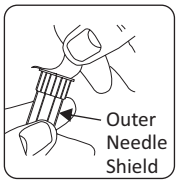
(fig.1)



(fig.2)

4.Look at the solution in the cartridge, it should not have any particles in it (fig.2).
If it is not clear, or if it has particles, then do not use it.

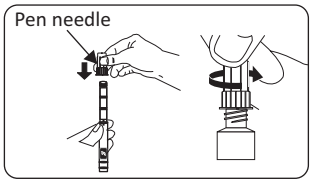
5.Use the first alcohol swab to wipe the rubber seal at the end of the pen.



(fig.3)

II. Attaching the Pen Needle:

1. Pull off the Paper Tab from the Outer Needle Shield (fig.3).

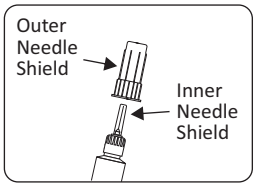


(fig.4)

2. Attach the Pen Needle to the tip of the pen by screwing it on (clockwise) (fig.4).
Do not over-tighten the needle.

3. Hold the pen with the needle pointing upwards and remove the Outer Needle Shield (fig.5).
Do not discard the Outer Needle Shield, it will be required during Step V.

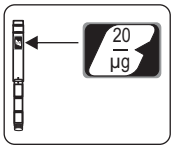
Note: *Use a new needle before every injection. Discard the needle after every injection.*



(fig.5)

Dialing the Dose:

1. Turn the dose dialer clockwise until you see "20 µg" in the dose window aligned with the marker arrow (fig 6).



(fig.6)

Priming the Osteotide pen:

- Dial the dose to "20 µg" as mentioned in Step III.
- Hold the pen with the needle pointing upwards.
- Tap the cartridge to dislodge any air bubbles.
- Expel one complete dose by pressing the injection button completely.

Note: *Prime your **Osteotide Pen** once only i.e. before the first injection. Each new **Osteotide pen** must be primed before its first use.*

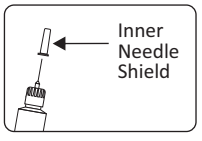
IV. Injecting the Dose:

1. When "20 µg" is aligned with the marker arrow it means that the dose is ready to inject. Do not rotate the dose dialer back once the dose is dialed. If it is dialed back, repeat Step III.
2. Disinfect the site of injection by rubbing the skin with the second alcohol swab.

Note:

- *The site of injection can be either the abdomen or thigh areas.*
- *It is recommended to alternate the position of the injection site between the left and right sides on a day-to-day basis. E.g. If on a day, one injects on the left thigh (or left side of the abdomen), then on the next day, inject on the right thigh (or right side of the abdomen).*

3. Pull off the Inner Needle Shield (fig.7).

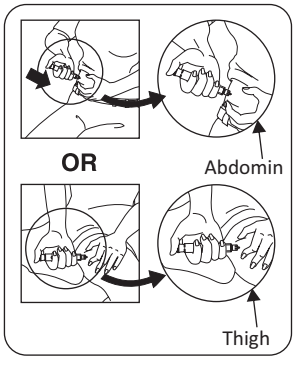


(fig.7)

4. Gently hold a fold of skin (fig. 8) at the selected site of injection and push the needle straight into the skin at a 90° angle (perpendicular to the skin).
5. Make sure you can still see "20 µg" in the dose window. Inject the dose by pressing down only the Injection Button with your thumb.

Note:

- *Do not apply pressure with the pen & needle onto the skin, only push the injection button with your thumb.*
- *Only inject into the skin, not the muscle. Be especially careful of this while injecting into the thigh areas.*
- *It is recommended to be prone (lying down) or in a sitting position during the time of injection. Try to stay in the same position for at least 5 minutes after the injection.*



(fig.8)

6. Continue to hold down the injection Button firmly and count slowly to 10 to ensure that the dose has been completely injected into the skin. Pull out the Needle and pen from your skin when you finish counting.
7. When the dose is completely injected, you will see "0 µg" in the dose window.

Note*:*

- *Inject Osteotide once daily only.*
- *20µg is a fixed once daily dose. It will not change.*
- *Maintain the same approximate daily injection time.*
- *Do not inject the entire contents of the **Osteotide pen** at once, it is multi-dose pen device.*
- *In case you miss a dose or by mistake you inject two doses in a single day, do not worry and continue your normal regimen from the next day onwards.*

V. After Injection:

1. Carefully reattach the Outer Needle Shield onto the needle.
2. Remove the needle by unscrewing it (anticlockwise). Place the used needle in a puncture-resistant disposable container and properly discard it as directed by your healthcare professional.
3. Replace the Pen Cap onto the pen.

VI. The next day dose:

1. Repeat steps I through V.

Other information:

- Each **Osteotide pen** contains 28 days dose plus an additional priming dose.
- Discard the **Osteotide pen** after 28 days, even if it is not completely empty.
- Do not use the **Osteotide pen** after the expiration date printed on the carton and pen label.
- Osteotide must not be used for a period of more than 24 months.
- Do not share your **Osteotide pen** with anyone.
- Do not transfer the contents of the **Osteotide pen** to a syringe or any other container.
- Keep the **Osteotide pen** out of reach of children.
- The **Osteotide pen** is not recommended for use by the blind or the vision impaired without the help of a trained person.
- The directions regarding needle handling are not intended to replace local, healthcare professional, or institutional policies.