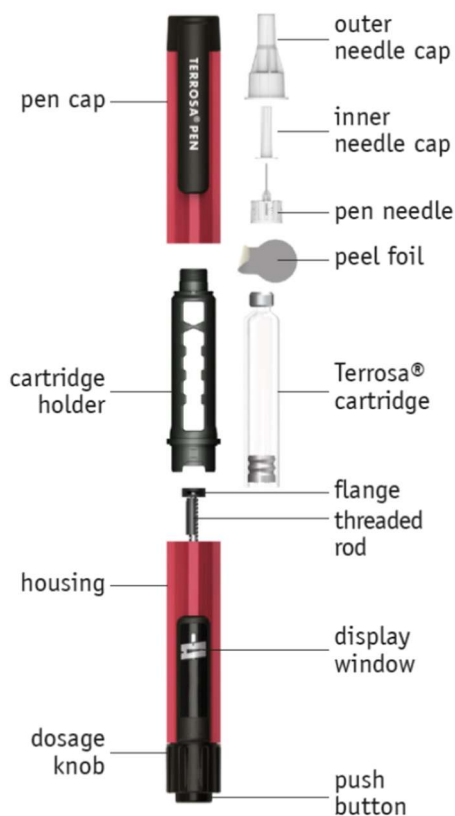


Instructions for use
Terrosa Pen

Re-usable pen injector to be used with Terrosa cartridges for subcutaneous injections

Always follow instructions provided below and on the back page when using the Terrosa Pen.

Terrosa Pen parts



push button; display window; threaded rod; flange; Terrosa cartridge; peel foil; pen needle; inner needle cap; outer needle cap; pen cap; cartridge holder, dosage knob, housing

Pen preparation - First use/changing cartridges

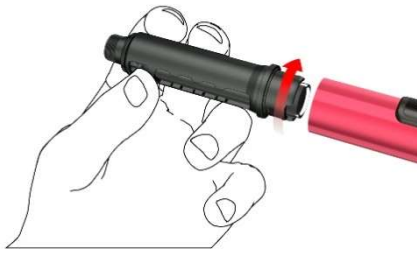
Write down the first injection date of each new cartridge. This helps you to know when the 28 daily doses per cartridge are used (see section 2 “Warnings and precautions” and section 3 “Preparing the pen for use” in the Package leaflet of Terrosa).

Follow the instructions every time you insert a new Terrosa cartridge into your Terrosa Pen. Do not repeat this before each daily injection, otherwise you will not have enough Terrosa for 28 days. Read the patient information leaflet for Terrosa cartridge provided separately.

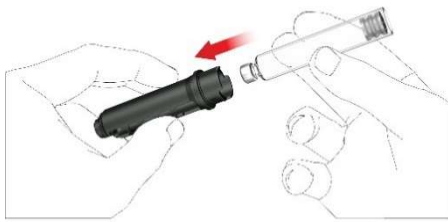
A: Remove the pen cap.



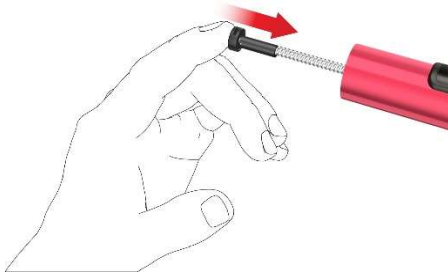
B: Remove the cartridge holder by turning it (bayonet coupling).



C: Remove the empty cartridge, in the case of changing cartridge. Insert a new Terrosa cartridge into the cartridge holder, with the metal crimped cap of the cartridge first.



D: Push back the threaded rod carefully with your finger, in a straight line and as far as it will go. This is not necessary when the rod is already in the starting position, such as at the very first use. The threaded rod cannot be pushed back to the pen housing entirely.

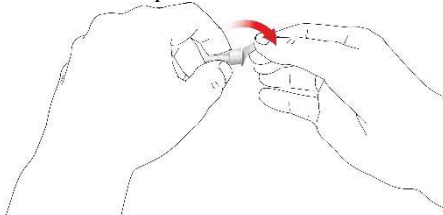


E: Attach the cartridge holder to the housing by turning it 90 degrees, until it stops.



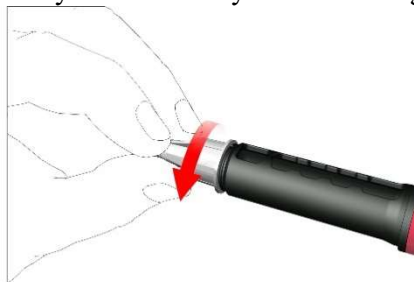
F: Attach a new pen needle as follows:

- Pull off the peel foil.



- Screw the pen needle clockwise onto the cartridge holder. Make sure that the pen needle is attached

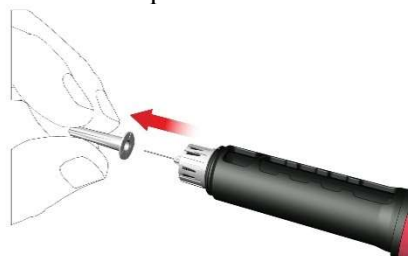
correctly and sits firmly on the cartridge holder.



- Remove the outer needle cap and save it.



- Remove and dispose the inner needle cap.



While attaching the needle some drops may escape, this is normal.

G: Priming

The pen must be primed and tested after inserting a new cartridge and prior the first injection from each cartridge.

- Turn the dose knob clockwise until you see a droplet sign on the dose display. Make sure that the two indicator stripes are aligned. During dose dialling the pen provides an audible clicking sound and a noticeable resistance.



- Hold the pen with the **needle pointing upwards**.
 - Press the push button fully in. Hold it pressed in until the dose indication has turned back to the start position. Some drops of medicine must be expelled from the needle tip.
- If no drops emerge, repeat step G until you see some drops. Do not repeat step G more than four times, but follow the instructions given under Troubleshooting section on the back page.



Administration using the Terrosa Pen

Wash your hands carefully with soap to minimise the risk of infection.

Make sure you have ready:

- your Terrosa Pen with inserted cartridge
- a compatible pen needle
- a puncture-resistant sharps disposal container for used needles.

Do not use the pen if the **cartridge is cloudy, discoloured or contains particles**.

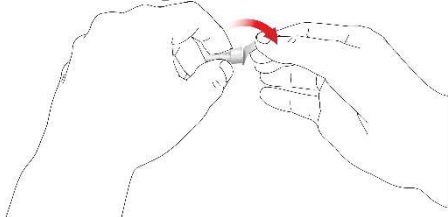
Read the patient information leaflet for Terrosa cartridge provided separately.

1. Attach the pen needle

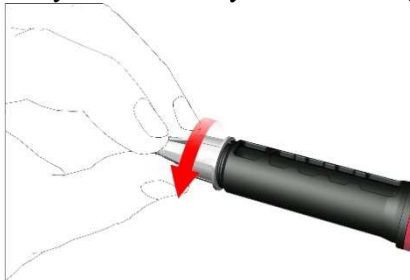
Use a new needle for every injection. Do not use the pen needle if the packaging is damaged or not opened by yourself.

Note: There is no need to change the needle when using directly after the pen preparation. In this case continue with step “2. Setting the dose and injection”.

- Pull off the peel foil.



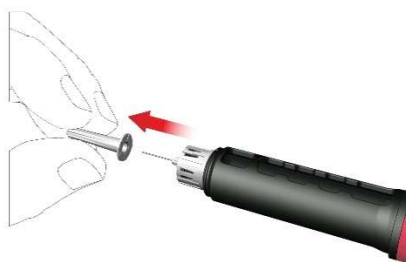
- Screw the pen needle clockwise onto the cartridge holder. Make sure that the pen needle is attached correctly and sits firmly on the cartridge holder.



- Remove the outer needle cap and save it.



- Remove and dispose the inner needle cap.



While attaching the needle some drops may escape, this is normal.

2. Setting the dose and injection

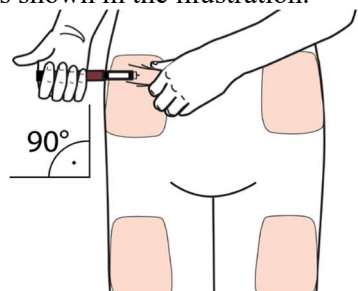
Warning: Ensure the use of the correct medicine. Check the label of the cartridge before its insertion into the cartridge holder.

- To set the fixed daily dose of 80 microliters, turn the dose knob clockwise until it stops and cannot be rotated any further. Make sure the display shows an arrow sign and it is aligned with the indicator stripe. During dose dialling the pen provides an audible clicking sound and a noticeable resistance. Do not try to force the dose knob any further.



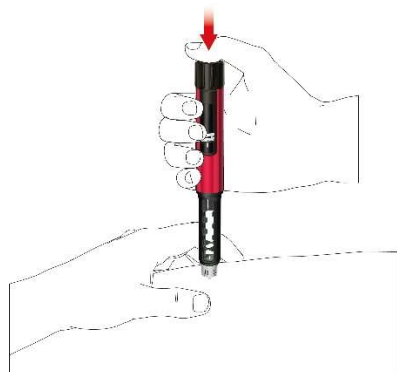
Note: If the cartridge contains less than 80 microliters, the dose knob cannot be turned clockwise up to the arrow sign. In this case, remove the pen needle, change the cartridge and proceed with priming according to the pen preparation steps.

- Select an appropriate injection site and prepare your skin as recommended by your doctor. Gently hold a skin fold between the thumb and index finger. Insert the needle straight and gently into the skin, as shown in the illustration.



Warning: Prevent the pen needle from bending or breaking. Do not tilt the pen after the needle has been inserted into the skin. Tilting the pen may result in bending or breaking of the needle. Broken needles can get stuck in the skin. Immediately consult the doctor if a broken needle gets stuck in the skin.

- Press the push button until the dose indication has returned to the start position. Keep the needle in the skin fold for a further 6 seconds.

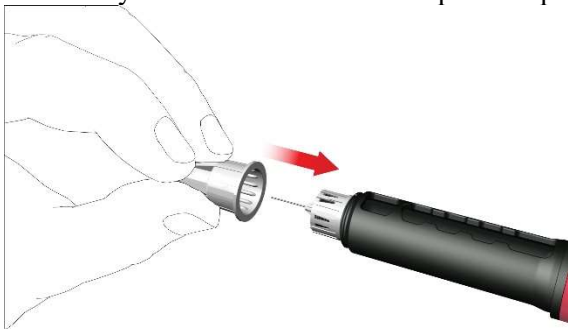


- Pull out the pen slowly. Check if the display is at the start position to make sure that the full dose has been injected.

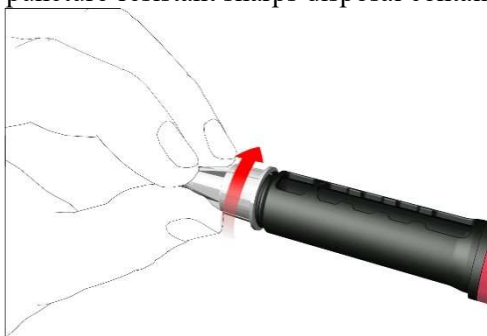


3. Removing the pen needle

- Carefully attach the outer needle cap on the pen needle.



- Screw the needle cap anti-clockwise to remove the pen needle. Dispose of it correctly, for example, in a puncture-resistant sharps disposal container.



4. Re-attach pen cap

- Do not remove the cartridge from the Terrosa Pen before it is empty.
- Re-attach the pen cap after each use.



- Put the Terrosa Pen, with the cartridge inserted, back into the refrigerator between 2 and 8 °C

immediately after use.

Note for healthcare professionals

Local, healthcare professional or institutional policies may replace the instructions regarding needle handling and disposal.

Additional information

The reusable fixed dose pen is designed for easy administration of Terrosa to treat osteoporosis. Each Terrosa cartridge contains 28 doses of fixed 80 microlitres Terrosa.

Use your Terrosa Pen only as prescribed by your doctor, in this Instructions for use and the Terrosa package leaflet.

The Terrosa Pen can be used by self-injecting patients above the age of 18 years, healthcare professionals or third parties such as, for instance, adult relatives.

The Terrosa Pen must not be used by blind or visually impaired patients without help from a trained able-bodied person. Consult your doctor in the case of hearing or handling problems.

The pen needles must be used only once and the Terrosa cartridge must be used by one person only.

Storage and care of Terrosa Pen

- Handle your pen with care. Do not drop your pen and avoid knocking it against hard surfaces. Protect it from water, dust and moisture.
- A damp cloth is sufficient to clean the Terrosa Pen. Do not use alcohol, other solvents or cleaning agents. Never immerse the Terrosa Pen in water, as this could damage the pen.
- Do not use your Terrosa Pen if it is damaged or if you have any doubts about its correct functioning.
- Transport and store the Terrosa Pen with inserted cartridge at temperatures specified in the Terrosa package leaflet, provided separately.
- Store your Terrosa Pen, cartridges and pen needles out of reach of children.
- Do not store the Terrosa Pen with a needle attached as this may cause air bubbles to form in the cartridge.

Disposal of Terrosa Pen and used accessories

The Terrosa Pen has a service life of two years. Before disposing of the Terrosa Pen always remove the pen needle and the cartridge. Needles and used cartridges must be disposed of separately and safely. The Terrosa Pen can be disposed of according to the instructions of the local authorities.

Warnings

Follow the instructions presented in this Instructions for use. If the instructions are not followed, there are risks of incorrect medication, inaccurate dosage, disease transmission or infection. Seek immediate medical advice if you have any health concern.

Troubleshooting

Follow the instructions given in the table if you have any questions regarding the use of Terrosa Pen:

Question	Answer
1. Small air bubbles are visible in the cartridge.	A small air bubble will not affect the dose, or harm.
2. Needle cannot be attached.	Use another needle instead.
3. Needle is broken/curved/kinked.	Use another needle instead.
4. During dose dialling the pen does not provide an audible signal.	Do not use this pen.
5. No medicine comes out of the needle during pen preparation step "G: Priming".	Change the needle and repeat the priming as described in pen preparation sections "F" and "G". If still no medicine is expelled, do not use this pen.
6. The dose knob cannot be turned clockwise up	The amount of Terrosa left in the cartridge is

to the arrow sign.	less than 80 microlitres. Change the cartridge and the pen needle and perform priming according to the pen preparation.
7. Display does not return to start position after injection.	Do not repeat the injection on the same day. Use a new needle for your injection on the following day. Set the dose and complete the injection as described in section “2. Setting the dose and injection”. If the display still does not return to start position after injection, do not use this pen.
8. Spillage from pen is observed.	Do not use this pen.
9. The dose knob inadvertently turned clockwise after completing the injection. How do I reset the dose knob to the start position?	Do not press the push button. Reset the pen by simply turning back the dose knob anti-clockwise to the start position.