

If you experience any side effects, including ones that are not listed in the patient information leaflet in the Terrosa pack, speak to your nurse, doctor or pharmacist.

You can also report side effects directly by going to: www.mhra.gov.uk/yellowcard.

By reporting side effects, you can help provide more information about the safety of Terrosa.

Adverse events should be reported to the HPRA Pharmacovigilance. Earlsfort Terrace, IRL - Dublin 2.
Tel: +35316764971, Fax: +353 1 6762517,
Website: www.hpra.ie, e-mail: medsafety@hpra.ie.

Adverse events should also be reported to Women's Health Division of Gedeon Richter (UK) Ltd on +44 (0) 207 604 8806 or drugsafety.uk@gedeonrichter.eu



A guide to your **TERROSA®** ▼ (teriparatide) **TREATMENT**

Material created by Gedeon Richter. Only intended for patients who have been prescribed Terrosa.

This material should not be used as a substitute for the patient information leaflet for Terrosa or professional medical advice. Please see the patient information leaflet in your Terrosa pack for full details.

Date of Preparation: March 2021
UKI-TERR-2000075

▼ This medicinal product is subject to additional monitoring

YOUR TERROSA PEN



For further information about your treatment, including instructional videos showing you how to inject and change your cartridge, please visit:

Website: www.myterrosa.co.uk
Password: Terrosa01



To go to the website, type the address into your internet browser or scan the QR code with your smartphone camera to be directed to the site.

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

Terrosa 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 medicines called corticosteroids.

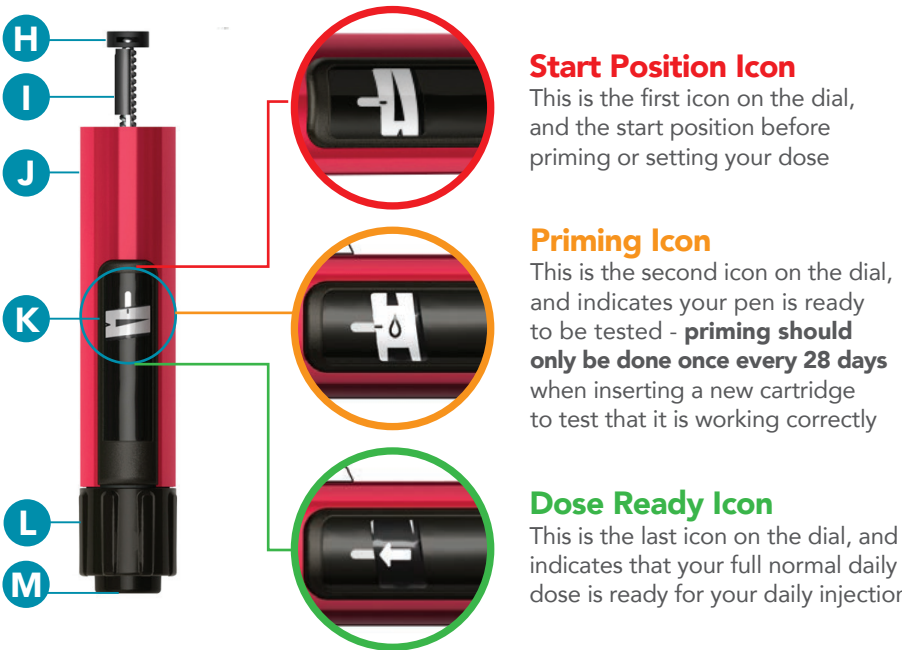
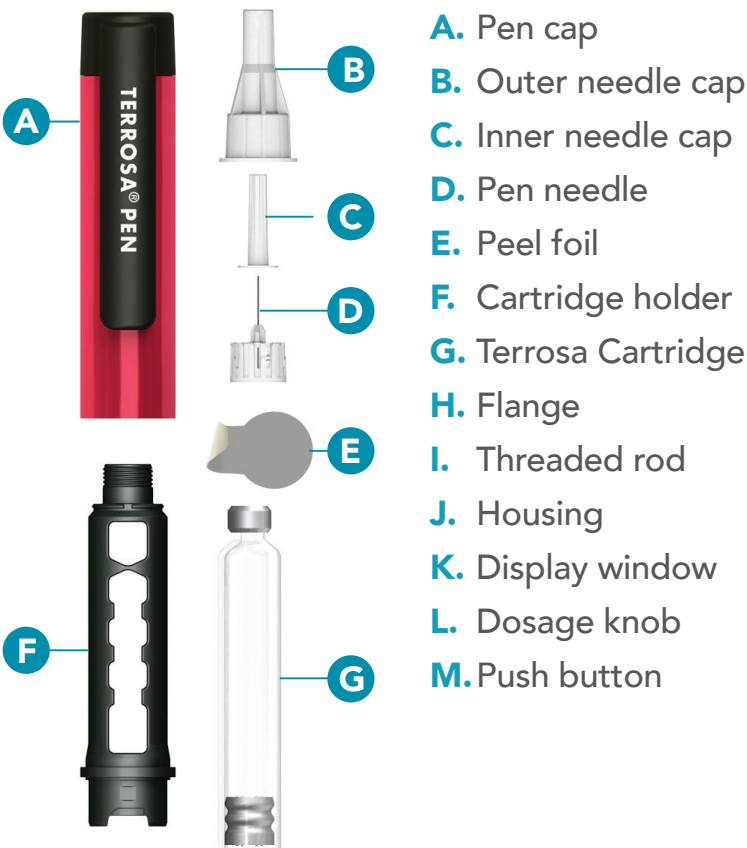
TECHNICAL BREAKDOWN

YOUR TERROSA PEN

Getting familiar with the different parts of your pen is the first step to becoming comfortable with your injection.

See the diagram below for an explanation of each part of your pen.

Look out for these letters in your guide.



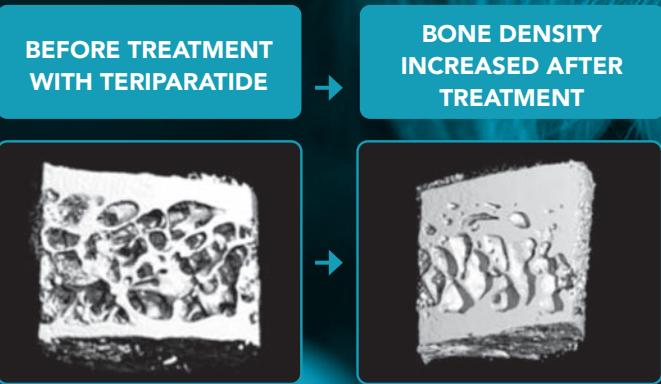
INTRODUCTION

TAKING YOUR TERROSA

You have been given this leaflet as you have been prescribed Terrosa for the treatment of your osteoporosis.

Terrosa is given as one simple injection each day from a cartridge-filled pen. One cartridge contains enough Terrosa to last for 28 days of injections.

The images below show a scan of an osteoporosis patient's bone, both before and after treatment with teriparatide (the active substance in Terrosa). Teriparatide increased bone density and helped to form new bone, which can be clearly seen in the images below. Improving bone structure in this way can help to reduce a patient's risk of fracture.



Adapted from Eriksen et al., 2014

In addition to the pen information and Terrosa patient information leaflet that you will receive with your Terrosa pen, this leaflet will provide additional support so that you can be comfortable taking your Terrosa every day.

TERROSA PEN PREPARATION

USING YOUR TERROSA PEN

The Terrosa Pen has been designed to make repeated injections simpler.

Your Terrosa Pen is re-usable. Your daily medicine is dispensed by a cartridge in your pen containing enough medicine for 28 days, **so you only need to change the cartridge once every 28 days.**

After you insert a new cartridge, **the cartridge must be tested** in the pen – this is called “priming” and you only need to do this once after inserting a new cartridge. Then, before your daily injection you must set your full dose, ready for injecting.

The Terrosa Pen display window (K) shows different icons depending on which stage you are at when using the pen. Pay attention to these icons as you read this booklet to help you follow the steps correctly.



If you have any technical issues with the pen, refer to the patient information leaflet for a list of common troubleshooting solutions.

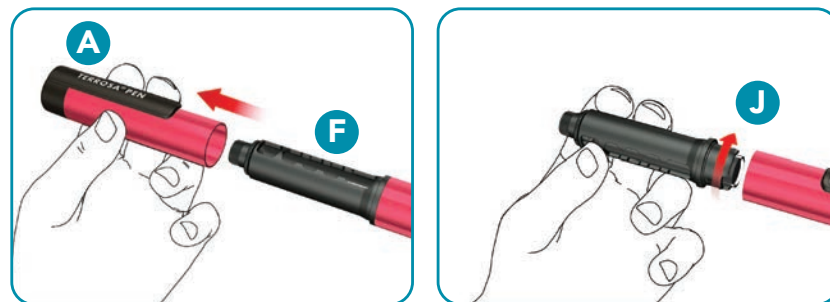
INSERTING A NEW CARTRIDGE

Follow the instructions every time you insert a new Terrosa cartridge into your Terrosa Pen. **Do not repeat these instructions before each daily injection**, otherwise you will not have enough Terrosa for 28 days, as each cartridge is designed for 28 days of use.

Before inserting a cartridge in your Terrosa Pen, write down the **batch (Lot) number** of the cartridge and its **first injection date** in your treatment tracker, which can be found on page 12 of this booklet. The date of first injection should also be recorded on the outer carton of Terrosa.

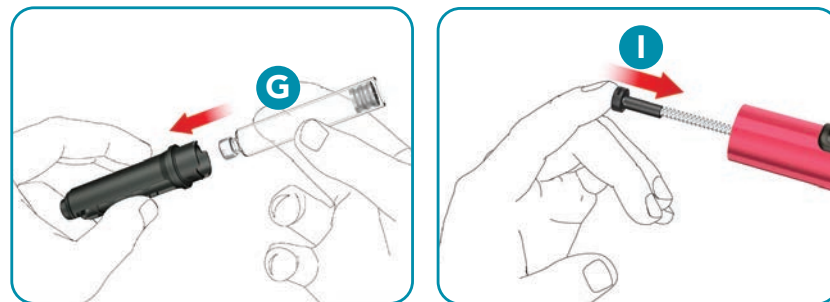
1. REMOVING THE LID

Remove the pen cap. (A) Remove the cartridge holder (F) by turning it (to unlock the bayonet coupling mechanism).

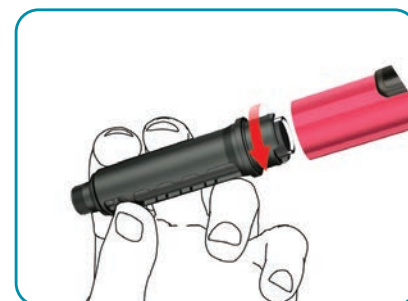


2. ADDING A NEW CARTRIDGE

A. If you're inserting a cartridge for the first time: Add the new Terrosa cartridge (G) into the holder, metal cap first. Screw the cartridge holder back in.



B. If you're replacing an empty cartridge: Push back the threaded rod (I) carefully with your finger, in a straight line and as far as it will go. The threaded rod cannot be pushed back to the pen housing (J) entirely.



3. ATTACH THE CARTRIDGE HOLDER

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

For more information about the Terrosa cartridge, read the patient information leaflet for the Terrosa cartridge provided separately.



To watch the instructional video on inserting a cartridge for the first time, scan the QR code on the left with your smartphone camera, or go to <https://www.myterrosa.co.uk/terrosa-support.php?video=1> or if you're replacing your cartridge, scan the QR code on the right or go to <https://www.myterrosa.co.uk/terrosa-support.php?video=4> using the password "Terrosa01".



PREPARING FOR YOUR TERROSA INJECTION

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

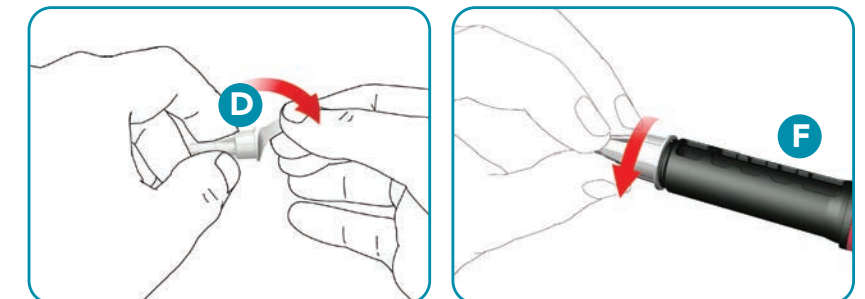
The cartridge should appear colourless. If the cartridge is cloudy, discoloured or contains particles, do not use the pen and contact your doctor, nurse or pharmacist.

ATTACHING 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.

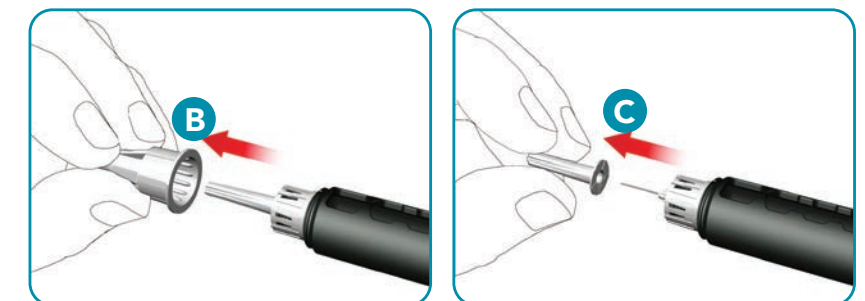
1. ATTACH THE PEN NEEDLE

Pull off the peel foil (E). Screw the pen needle (D) clockwise onto the cartridge holder. Make sure that the pen needle is attached correctly and sits firmly on the cartridge holder.



2. EXPOSING THE NEEDLE

Remove the outer needle cap (B) and save it. Remove and dispose the inner needle cap (C). While attaching the needle some drops of liquid may escape, this is normal.



To watch an instructional video of these steps, scan the QR code with your smartphone camera to open the link, or go to <https://www.myterrosa.co.uk/terrosa-support.php?video=2> using the password "Terrosa01".

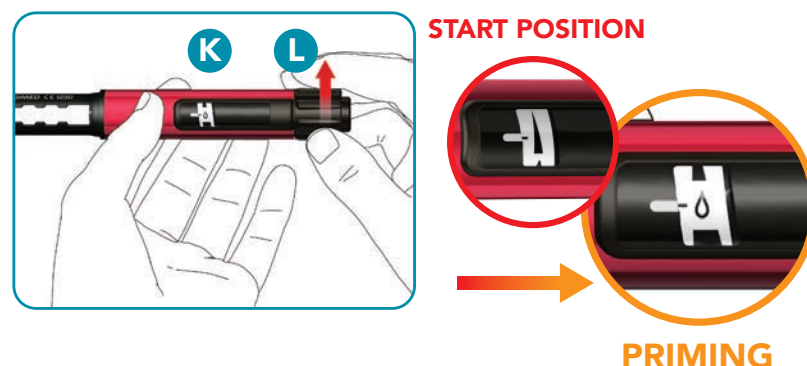
PRIMING YOUR CARTRIDGE

With each new cartridge you insert, you must only prime your cartridge once. This means expelling a small amount of liquid from your Terrosa pen through the needle, to prepare your cartridge for your daily injections and test that it is working correctly. **You do not need to repeat this step every day.**

You will need to insert a new cartridge every 28 days.
Each cartridge must only be primed once.

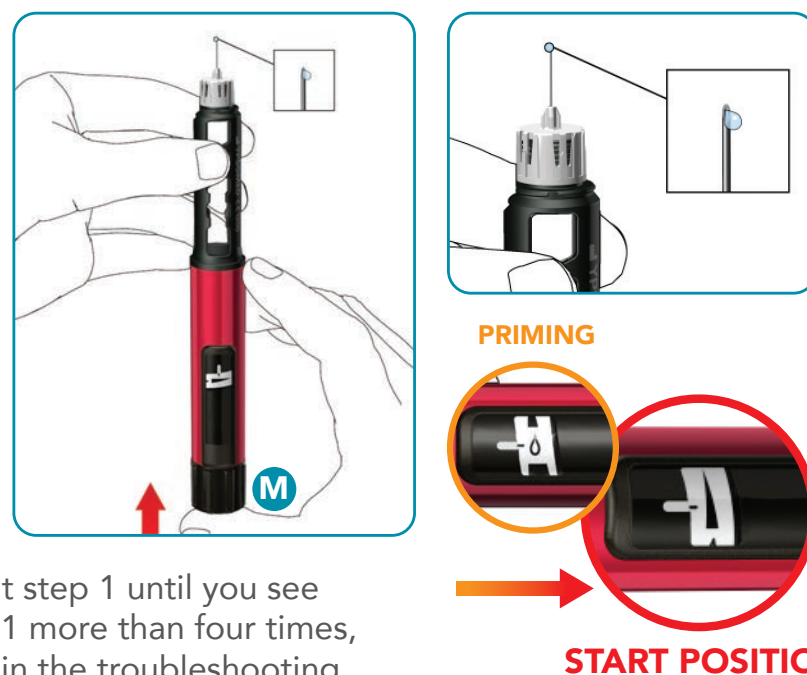
1. SETTING THE PEN TO PRIMING MODE

Turn the dosage knob (L) clockwise until you see the priming icon on the display window (K). Make sure that the two indicator stripes are aligned. Between the start position icon and the priming icon, you should hear **2 audible "clicks"**.



2. PRIMING THE CARTRIDGE

Hold the pen with the needle pointing upwards. Press the push button (M) fully in. Hold it pressed in until the display window has turned back to the start position icon. Some drops of medicine must be expelled from the needle tip.

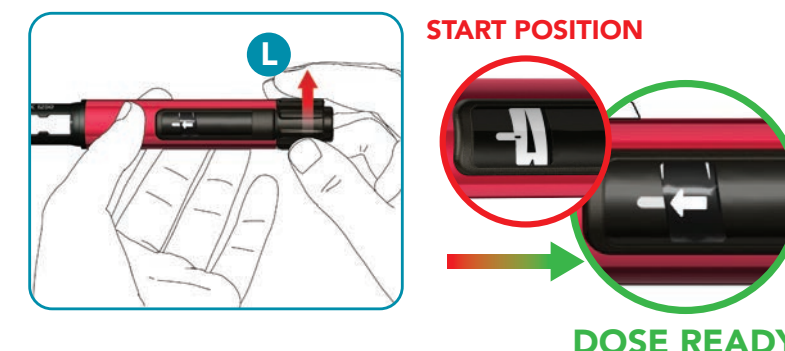


Note: If no drops emerge, repeat step 1 until you see some drops. Do not repeat step 1 more than four times, but follow the instructions given in the troubleshooting section of the patient information leaflet.

INJECTING YOUR DAILY DOSE

1. SETTING THE DOSE

To set the fixed daily dose of 80 microlitres, turn the dose knob clockwise until it stops and cannot be rotated any further. Make sure the display window shows the dose ready icon and the two indicator stripes are aligned.

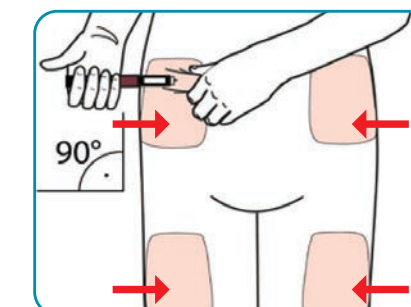


Between the start position icon and the dose ready icon, you should hear **8 audible "clicks"**. Do not try to force the dose knob any further.

Note: If the cartridge contains less than the fixed daily dose of 80 microlitres, the dose knob cannot be turned clockwise up to the dose ready icon. In this case, remove the pen needle, change the cartridge and proceed with priming before injecting your dose.

2. INSERTING THE NEEDLE

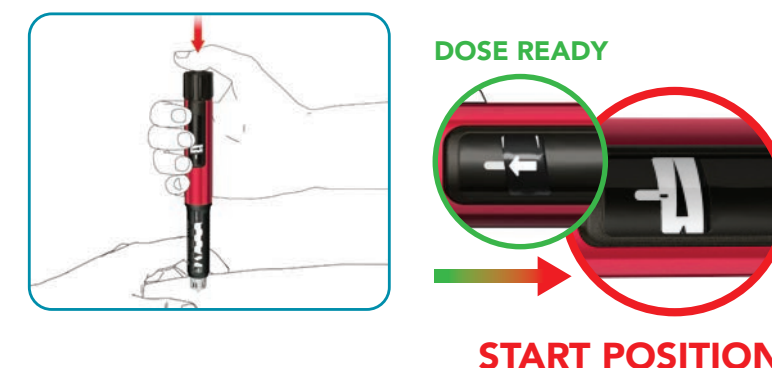
Select an appropriate injection site as indicated on the diagram and clean your skin. Gently hold a fold of skin between the thumb and index finger. Insert the needle straight and gently into the skin.



Note: Do not tilt the pen after inserting the needle, as the needle may break and get stuck in the skin. Immediately consult a doctor if a broken needle gets stuck in the skin.

3. INJECTING YOURSELF

Press the push button until the display window has returned to the start position icon, and then hold for another 6 seconds. Pull the pen out slowly and check the display window is at the start position icon to make sure the full dose has been injected.



To watch an instructional video of these steps, scan the QR code with your smartphone camera to open the link, or go to <https://www.myterrosa.co.uk/terrosa-support.php?video=2> using the password "Terrosa01".



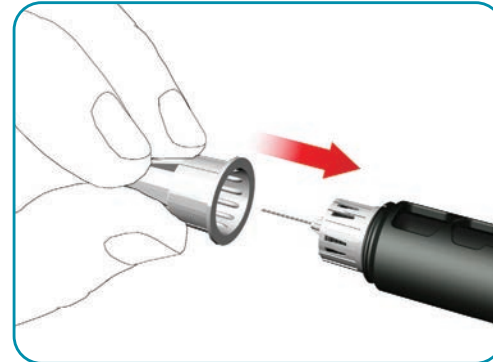
To watch an instructional video of these steps, scan the QR code with your smartphone camera to open the link, or go to <https://www.myterrosa.co.uk/terrosa-support.php?video=3> using the password "Terrosa01".

ADMINISTRATION

DISPOSAL AND STORAGE OF YOUR TERROSA PEN

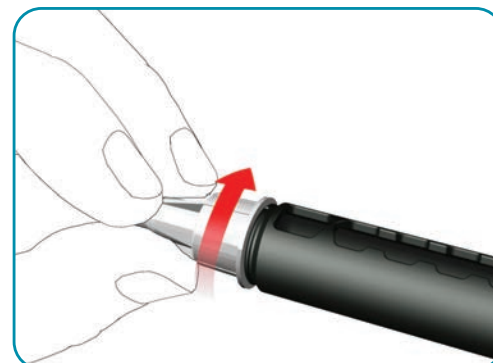
1. REMOVING THE PEN NEEDLE

Carefully attach the outer needle cap on the pen needle.



2. REPLACING THE NEEDLE CAP

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



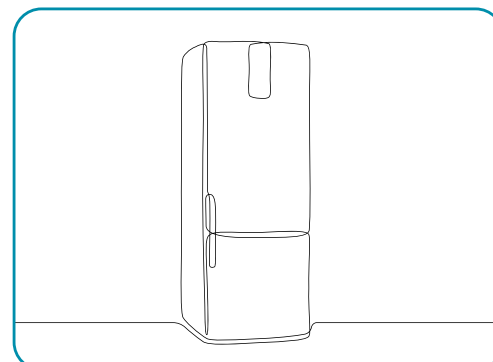
3. RE-ATTACH THE PEN CAP

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



4. STORING THE PEN

Put the Terrosa Pen, with the cartridge inserted, back into the refrigerator on a middle shelf, between 2 and 8 °C immediately after use.



ADMINISTRATION

CARING FOR YOUR TERROSA PEN

- Your Terrosa Pen can be re-used for up to two years. It is therefore important to 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 the 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.



For important information about storing and caring for your Terrosa Pen, scan the QR code with your smartphone camera to open the link, or go to <https://www.myterrosa.co.uk/terrosa-support.php?video=5> using the password "Terrosa01".



USING YOUR TERROSA COOL BAG

Your cool bag should be used whenever you travel and need to take your Terrosa treatment with you.

When starting treatment, you may request a cool bag from your homecare provider or healthcare professional which can be used to safely carry your Terrosa Pen and cartridges around whilst keeping them at a suitable temperature.

The cool bag will come with 6 "Cool Safe-Ice packs", a pouch and a user manual. The colour of the cool bag may vary.

Using the cool bag is simple. Follow these steps to ensure you use the cool bag correctly.

STEP 1:

Always use the "Cool Safe-Ice packs", which have been provided with your cool bag in accordance with the ice pack instructions. These keep your Terrosa at the correct temperature, whereas other types of ice packs may freeze your medication, damaging it.



STEP 2:

When freezing ice packs, freeze them flat and side by side (not on top of one another or bent) and freeze in a 3* rated freezer for 12 hours. If your ice pack leaks, dispose of it safely and wash your hands thoroughly afterwards.



STEP 3:

Once frozen, remove the inner black bag from your cool bag, and slot all 6 of your ice packs into the individual pockets on the sides of the inner black bag.



STEP 4:

Now that your cool packs are loaded into the inner black pouch, this can be placed into the cool bag. After placing the pouch into the cool bag, pinch the pouch walls and cool bag walls together to close the velcro fastening tightly on all four side of the bag. Ensure the ice packs are lying flush against the outside walls of the cool bag.



STEP 5:

Place your Terrosa Pen and cartridges, inside the free-hanging interior medicine bag. Don't place your medicine, or anything else, in the space beside the interior medicine bag as direct contact with the ice packs must be prevented at all times.



STEP 6:

Zip up your cool bag to close it. Don't store your cool bag in an overheated car for too long, nor in direct sunlight as your medicine won't stay as cool for as long. See the box below for further information about how long the cool bag will keep your Terrosa at the correct temperature for.



Your Terrosa Pen and cartridge can be kept inside the cool bag for up to 11 hours.* They can be put in the inner pouch as they are or in their respective boxes (but should not be in the starter box).

Don't use Terrosa if it has been stored for longer than one day at room temperature (up to 25 °C) or if it has been stored for more than one hour at a high temperature (over 25 °C), if not in a fridge or cool bag. If this occurs, please use a new cartridge.

***Tests have shown that the cool bag can keep a Terrosa pen and cartridge at a temperature of 2-8 °C for up to 11 hours.**

TREATMENT TRACKER

YOUR TERROSA TREATMENT TRACKER

Your Terrosa treatment tracker can help you keep a record of your cartridge changes and daily injections.

Each page of the tracker contains 28 days to last you for one Terrosa cartridge, and there are enough pages to last your entire treatment course.

Every time you insert a new cartridge, write the batch number and the date you first inject from the cartridge.

You can then fill in the dates of each day to help keep track of your injections, ticking off each day after you take your injection. You should also record the time of each injection to ensure you’re taking your injections at the same time each day.

Please note, with every new page, you’ll need a new cartridge!


Your tracker should look something like this:

Cartridge batch number:

E95008AN

First injection	Injection 2	Injection 3	Injection 4	Injection 5	Injection 6	Injection 7
24 Nov	25 Nov	26 Nov	27 Nov	28 Nov	29 Nov	30 Nov
8.30am ✓	8.35am ✓	8.30am ✓	8.35am ✓	8.30am ✓	8.35am ✓	8.30am ✓

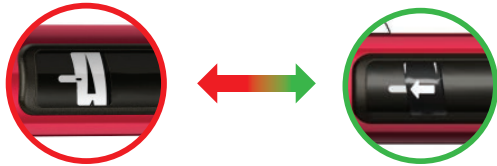
QUICK START INJECTION REMINDER



PRIMING:

You will need to prime after inserting each new cartridge, once every 28 days.

To recap the steps on priming, go back to the page titled “Priming your cartridge”.



SETTING THE DOSE:

During each daily dose, make sure you’re dialling between the **Start Position** and **Dose Ready** icons to administer your full dose of Terrosa.

TREATMENT TRACKER

Cartridge batch number:



Tick this box once you’ve **primed** your new cartridge ☐
(Remember that you only need to prime **once** after inserting each new cartridge)

First injection	Injection 2	Injection 3	Injection 4	Injection 5	Injection 6	Injection 7

Injection 8	Injection 9	Injection 10	Injection 11	Injection 12	Injection 13	Injection 14

Injection 15	Injection 16	Injection 17	Injection 18	Injection 19	Injection 20	Injection 21

Injection 22	Injection 23	Injection 24	Injection 25	Injection 26	Injection 27	Injection 28

You have now reached the end of your cartridge so will need to insert a new one before your injection tomorrow. If you’re nearly out of cartridges, contact your homecare provider.

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Injection 15	Injection 16	Injection 17	Injection 18	Injection 19	Injection 20	Injection 21
Injection 22	Injection 23	Injection 24	Injection 25	Injection 26	Injection 27	Injection 28

You have now reached the end of your cartridge so will need to insert a new one before your injection tomorrow. If you're nearly out of cartridges, contact your homecare provider.

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TOP TIPS AND NOTES

Top tips

- Remember to wash your hands carefully with soap before every injection
- Take your injection at the same time everyday
- Always use a new needle for every injection
- Take a note of what time you take your Terrosa every day
- Store the cartridge in the refrigerator between 2 and 8°C
- Do not store your pen with the needle attached
- Your Terrosa cartridge lasts for 28 days
- You can check with your homecare provider or healthcare professional when you should re-order the cartridge to avoid interruption to your treatment
- Take note of the day that your next cartridge will be delivered, and of the batch number when it arrives

For further information about your treatment, including instructional videos showing you how to inject and change your cartridge, please visit:

Website: www.myterrosa.co.uk
Password: Terrosa01



To go to the website, type the address into your internet browser or scan the QR code with your smartphone camera to be directed to the site.

Notes: