

PACKAGE LEAFLET

Package leaflet: Information for the user

Terrosa 20 micrograms/80 microliters solution for injection Teriparatide

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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

1. What Terrosa is and what it is used for

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.

2. What you need to know before you use Terrosa

Do not use Terrosa:

- if you are allergic to teriparatide or any of the other ingredients of this medicine (listed in section 6).
- if you have high levels of calcium in your blood (hypercalcaemia).
- if you suffer from serious kidney problems.
- if you have ever had bone cancer or if other cancers 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

Terrosa may increase calcium in your blood or urine.

Talk to your doctor before or while using Terrosa:

- 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 had 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 of Terrosa. For the first doses, inject Terrosa in a place where you can sit or lie down right away if you get dizzy.

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

Before inserting a cartridge in Terrosa Pen write down the batch (Lot) number of the cartridge and its first injection date on a calendar. The date of first injection should also be recorded on the outer carton of Terrosa (see the provided space on the box: {First use:}) (see section 3.).

Terrosa should not be used in growing adults.

Children and adolescents

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

Other medicines and Terrosa

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. This is important, because some medicines (e.g. digoxin/digitalis, a medicine used to treat heart disease) may interact with teriparatide.

Pregnancy and breast-feeding

Do not use Terrosa 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 Terrosa. If you become pregnant while using Terrosa, Terrosa 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 Terrosa. If you feel dizzy you should not drive or use machines until you feel better.

Terrosa contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially “sodium-free”.

3. How to use Terrosa

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

The recommended dose is 20 micrograms (corresponding to 80 microliters) given once a day 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. Terrosa can be injected at meal times. Inject Terrosa each day for as long as your doctor prescribes it for you. The total duration of treatment with Terrosa should not exceed 24 months. You should not receive more than one treatment course of 24 months over your lifetime.

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

Terrosa can be given with or without food.

Terrosa cartridges are designed to be used only with the Terrosa Pen reusable, multidose delivery system and compatible pen needles. The pen and injection needles are not included with Terrosa. However, for treatment initiation a cartridge and pen pack should be used containing one carton of

Terrosa cartridge and one carton of Terrosa Pen.

Before the first use, insert the cartridge into the pen. For the correct use of this medicine it is very important to closely follow the detailed Instructions for Use of your pen which are provided with the pen.

Use a new injection needle for each injection to prevent contamination and safely dispose of the needle after use.

Never store your pen with the needle attached.

Never share your pen with others.

Do not use your Terrosa Pen to inject any other medicine (e.g. insulin).

The pen is customised for use with Terrosa only.

Do not refill the cartridge.

Do not transfer the medicine into a syringe.

You should inject Terrosa shortly after you take the pen with inserted cartridge out of the refrigerator. Put the pen with inserted cartridge back into the refrigerator immediately after you have used it. Do not remove the cartridge from the pen after each use. Store it in the cartridge sleeve during the whole 28-day treatment period.

Preparing the pen for use

- To ensure the correct administration of Terrosa always read the Instructions for Use of Terrosa Pen, which is included in the carton of the pen.
- Wash your hands before handling the cartridge or pen.
- Check the expiry date on the cartridge label before inserting the cartridge into the pen. Make sure that there are at least 28 days remaining before its expiry date. Insert the cartridge into the pen before the first use as detailed in the pen instructions. Write down the batch (Lot) number of each cartridge and its first injection date on a calendar. The date of first injection should also be recorded on the outer carton of Terrosa (see the provided space on the box: {First use:}).
- After inserting a new cartridge and before the first injection from this cartridge prime the pen according to the instructions which are provided. Do not prime again after the first dose.

Injecting Terrosa

- Before you inject Terrosa, clean your skin where you intend to inject (thigh or abdomen) as instructed by your doctor.
- Gently hold a fold of cleansed skin and insert the needle straight into the skin. Press the push button and hold it pressed in until the dose indication has returned to the start position.
- After your injection, leave the needle in the skin for six seconds to make sure that you receive the whole dose.
- As soon as you have finished the injection, attach the outer needle protective cap on the pen needle and screw the cap anti-clockwise to remove the pen needle. This will keep the remaining Terrosa sterile and prevent leaking from the pen. It will also stop air going back into the cartridge and the needle from clogging.
- Replace the cap on your pen. Leave the cartridge in the pen.

If you use more Terrosa than you should

If, by mistake, you have used more Terrosa than you should, contact your doctor or pharmacist. The expected effects of overdose include nausea, vomiting, dizziness, and headache.

If you forget to use Terrosa

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

If you stop using Terrosa

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

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 (which may affect more than 1 in 10 people). Other common side effects (affecting up to 1 in 10 people) include feeling sick, headache and dizziness. 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 occurred after teriparatide use.

If you have discomfort around the area of the injection such as redness of the skin, pain, swelling, itching, bruising or minor bleeding (which can occur in up to 1 in 10 people), this should clear up in a few days or weeks. Otherwise tell your doctor.

Rarely, patients may suffer allergic reactions consisting of breathlessness, swelling of the face, rash and chest pain. These reactions usually occur soon after injection. 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
- nerve pain in the leg
- feeling faint
- spinning sensation
- irregular heartbeats
- breathlessness
- increased sweating
- muscle cramps
- loss of energy
- tiredness
- chest pain
- low blood pressure
- heartburn (painful or burning sensation just below the breast bone)
- vomiting
- a hernia of the tube that carries food to your stomach (hiatus hernia)
- 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
- piles (haemorrhoids)
- leakage of urine
- increased need to pass water
- weight increase
- kidney stones
- pain in the muscles and pain in the joints. Some patients have had severe back cramps or pain which led to admission into hospital.
- 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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom: Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2,

Tel: +353 1 6764971

Fax: +353 1 6762517, Website: www.hpra.ie,

e-mail: medsafety@hpra.ie

5. How to store Terrosa

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 the cartridge after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C – 8 °C). Do not freeze.

Keep the cartridge in the outer carton in order to protect from light.

You can use Terrosa for up to 28 days after the first injection, as long as the cartridge/pen with the cartridge inserted is stored in a refrigerator (2 °C to 8 °C).

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

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

Terrosa contains a clear and colourless solution. Do not use Terrosa 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 protect the environment.

6. Contents of the pack and other information

What Terrosa contains

- The active substance is teriparatide. Each dose of 80 microliters contains 20 micrograms of teriparatide. One cartridge of 2.4 mL contains 600 micrograms of teriparatide (corresponding to 250 micrograms per mL).
- The other ingredients are: glacial acetic acid, mannitol, metacresol, sodium acetate trihydrate, hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment), water for injections.

What Terrosa looks like and contents of the pack

Terrosa is a colourless and clear solution. It is supplied in a cartridge. Each cartridge contains 2.4 mL of solution, enough for 28 doses.

Terrosa 20 micrograms/80 microliters solution for injection: 1 or 3 cartridge(s) packed in a plastic tray sealed with lid foil and packed in a carton.

Terrosa cartridge and pen pack: 1 Terrosa cartridge packed in a plastic tray sealed with lid foil and packed in a carton and 1 Terrosa Pen packed into a separate carton.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Gedeon Richter Plc.

Gyömrői út 19-21.

1103 Budapest

Hungary

This leaflet was last revised in March 2019.

Other sources of information

Detailed and updated information on this product is available by scanning the QR code included below or the outer carton with a smartphone. The same information is also available on the following URL:

www.terrosapatient.com



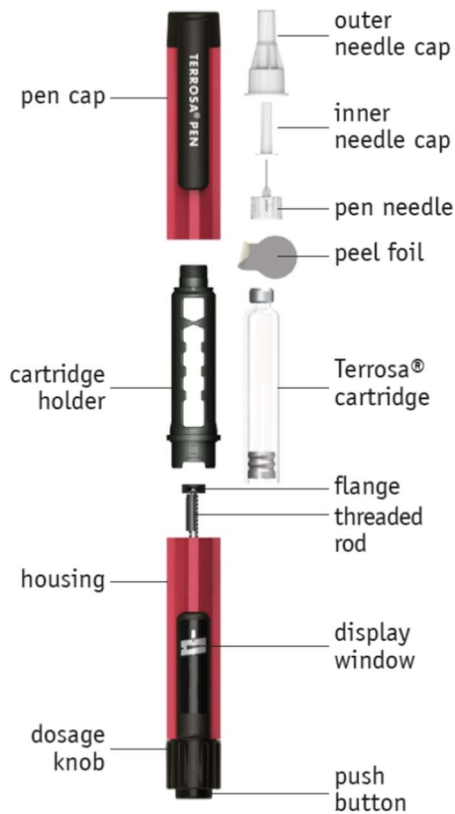
Detailed information on this medicine is available on the European Medicines Agency web site:

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

Instructions for use Terrosa Pen

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

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.

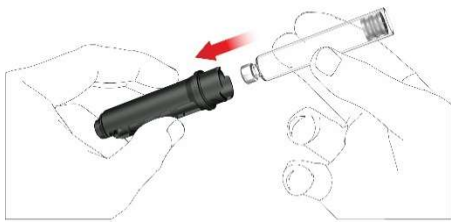
A: Remove the pen cap.



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

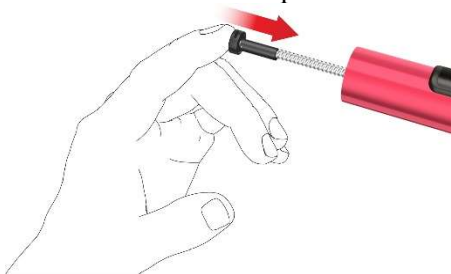


C: Remove the empty cartridge, in the case of changing cartridge. Insert a new Terrosa cartridge into the cartridge holder, with the metal crimped cap of the cartridge first.



Write down the first injection date of each new cartridge. This helps you to know when the 28 daily doses per cartridge are used.

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.

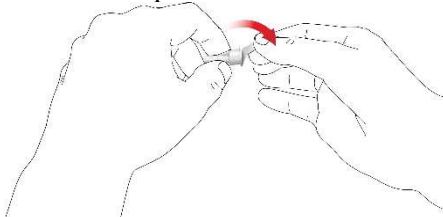


E: Attach the cartridge holder to the housing by turning it 90 degrees, until it stops.

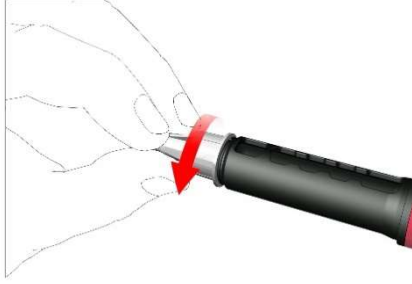


F: Attach a new pen needle as follows:

- Pull off the peel foil.



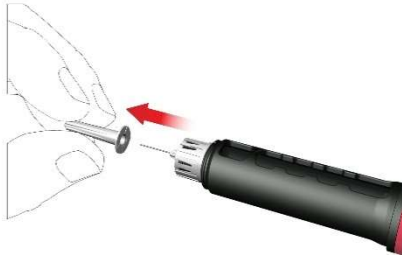
- Screw the pen needle clockwise onto the cartridge holder. Make sure that the pen needle is attached correctly and sits firmly on the cartridge holder.



- Remove the outer needle cap and save it.



- Remove and dispose the inner needle cap.

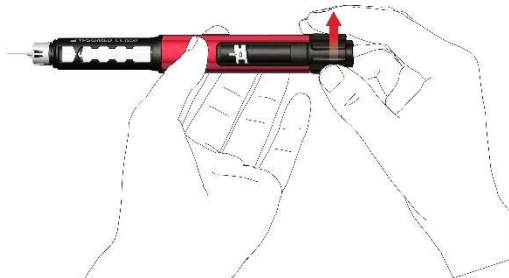


While attaching the needle some drops may escape, this is normal.

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.

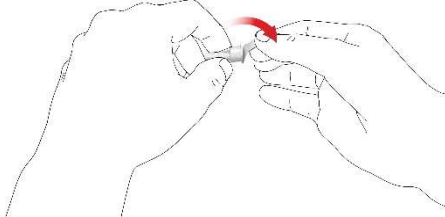
Read the patient information leaflet for Terrosa cartridge provided separately.

1. Attach the pen needle

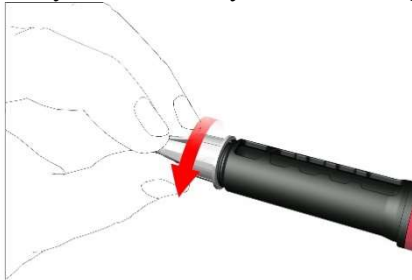
Use a new needle for every injection. Do not use the pen needle if the packaging is damaged or not opened by yourself.

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.



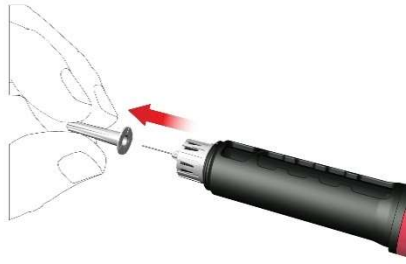
- Screw the pen needle clockwise onto the cartridge holder. Make sure that the pen needle is attached correctly and sits firmly on the cartridge holder.



- Remove the outer needle cap and save it.



- Remove and dispose the inner needle cap.

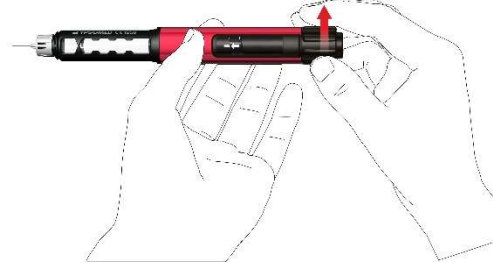


While attaching the needle some drops may escape, this is normal.

2. Setting the dose and injection

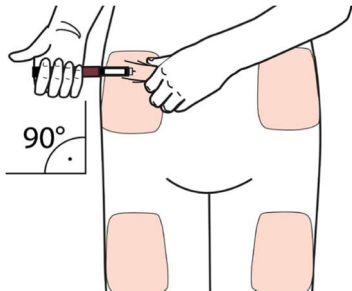
Warning: Ensure the use of the correct drug liquid. Check the label of the cartridge before its insertion into the cartridge holder.

- 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 the two indicator stripes are aligned. During dose dialling the pen provides an audible clicking sound and a noticeable resistance. Do not try to force the dose knob any further.



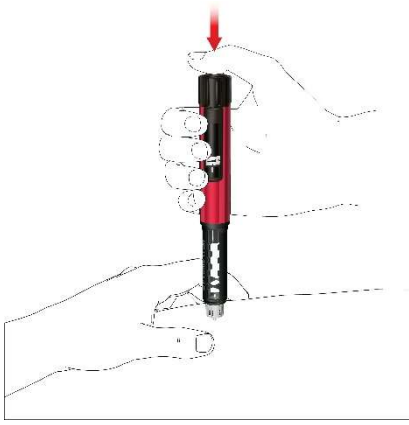
Note: If the cartridge contains less than 80 microliters, the dose knob cannot be turned clockwise up to the arrow sign. In this case, remove the pen needle, change the cartridge and proceed with priming according to the pen preparation steps.

- 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.

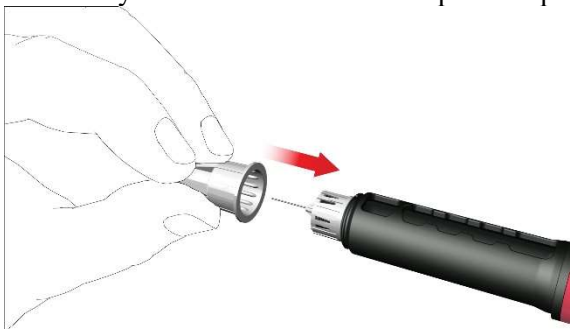


- Pull out the pen slowly. Check if the display is at the start position to make sure that the full dose has been injected.

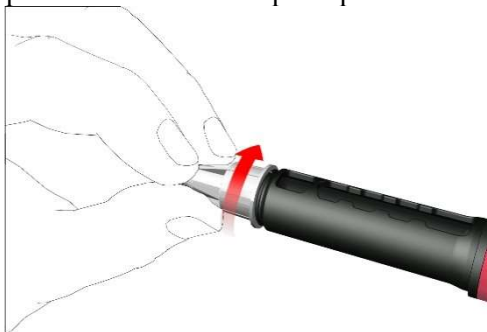


3. Removing the pen needle

- 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.

If you have any questions concerning the use of the Terrosa Pen, contact our **customer service** at any time.

telephone number: 00 44 (0) 207 604 8800

e-mail: medinfo.uk@gedeonrichter.eu

Compatible pen needles

- Ypsomed mylifeClickfine 29 to 31 gauge (diameter 0.25 – 0.33 mm) and 12, 10, 8 or 6 mm length
 - BD Micro-Fine Ultraneedles 29 to 31 gauge (diameter 0.25 – 0.33 mm) and 12.7, 8 or 5 mm length
- Pen needles from other manufacturers can be used according to their stated compatibility details.
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.

Warranty

The warranty covers manufacturing and material defects of your Terrosa Pen for two years of use, from purchase. It is limited to replacement of the pen. The warranty does not cover damages caused by:

- using cartridges other than Terrosa cartridges
- improper or careless use, handling or cleaning
- use contrary to the instructions for use
- the pen being used with a medical device, accessories or consumables other than those recommended by Gedeon Richter Plc.
- dropping, impact, application of force, contact with fluids
- other cases of exposure and wear, not in accordance with the instructions for use.

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. Contact customer service if the second needle cannot be attached.
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; contact customer service.
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; contact customer service.
6. The dose knob cannot be turned clockwise up to the arrow sign.	The amount of Terrosa left in the cartridge is 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; contact customer service.
8. Spillage from pen is observed.	Do not use this pen; contact customer service.
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.

Distributor:
Gedeon Richter Plc.
Gyömrői út 19-21.
1103 Budapest, Hungary

Legal manufacturer:
Ypsomed AG
Brunnmattstrasse 6
3401 Burgdorf, Switzerland



This instruction for use was last revised:
February 2019.