REUSABLE TERIPARATIDE PEN INJECTOR

Terifrac Multi

USER'S MANUAL



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Nemera
we put patients first

Table of content

1. before the first use
2. construction of pen injector, pen needle and cartridge
3. installation of cartridge and pen needle
4. priming your **Terifrac Multi**
5. injecting a dose
6. removing a needle
7. replacing a cartridge
8. replacing a needle
9. storage and cleaning
10. information from the manufacturer

before the first use

Before the first use of Terifrac Multi pen injector carefully read ALL instructions included in this user's manual.
Terifrac Multi is a reusable, intuitive automatic teriparatide injector. It provides you with a precise, safe and effortless way to subcutaneously administer teriparatide doses recommended by the doctor, in the range from 2,5 to 20 micrograms (mcg), with incremental dose of 2,5 mcg.

Indication for use:

Terifrac Multi is intended to adult man and women to treat:

- osteoporosis and/or with a risk of the hip fracture in postmenopausal woman
- osteoporosis and/or with a risk of the hip fracture in men
- adult man and women after a bone fracture.

Terifrac Multi is recommended for use exclusively with teriparatide 3.0 ml cartridges according to ISO 11608-3.

Use Terifrac Multi only in doses recommended by your doctor.

Terifrac Multi is recommended for use with disposable needles: BD Micro-Fine 0.25mm x 5 mm, BD Micro-Fine 0.23mm x 4mm and BD Micro-Fine 0.25mm x 8mm according to ISO 11608-2.

Use a new needle for each injection to ensure sterility, prevent infections or leakage of teriparatide and reduce the risk of needle clogging.

Terifrac Multi is intended for use by one person only and should not be shared with others.

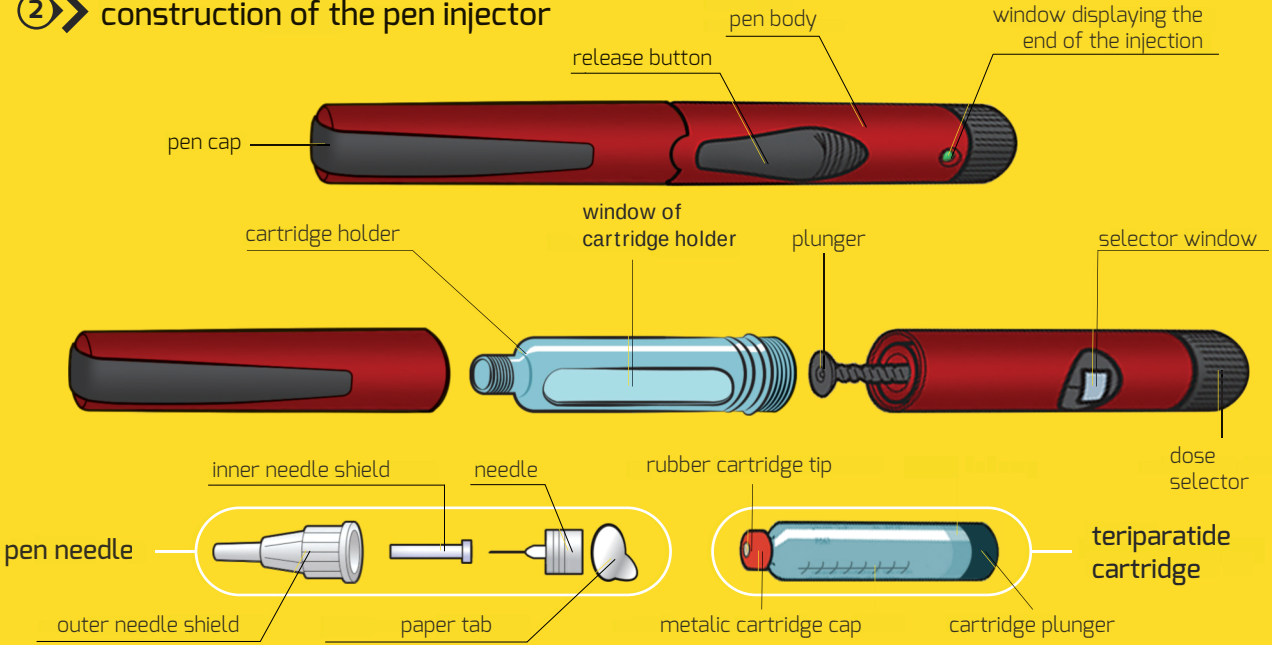
Terifrac Multi can be used in the home environment by people from different cultural backgrounds, people of different ethnicity, with all levels of education

before the first use

Contraindications for use:

- Using Terifrac Multi without teriparatide cartridge may cause defective operation.
- Terifrac Multi is not recommended for self-administration of teriparatide by people who are blind, visually impaired or with severely limited motor skills without the assistance of a third party, trained in its use.
- Do not try to repair your Terifrac Multi, manipulate in it or pull it apart
- If no doubt, contact the manufacturer or distributor
- Damaged or outside the period of use specified by the manufacturer Terifrac Multi should be disposed according to the instruction of your doctor / healthcare provider / pharmacist / or local regulations.
- Do not use Terifrac Multi, if it is not working properly, or any of its parts look damaged.

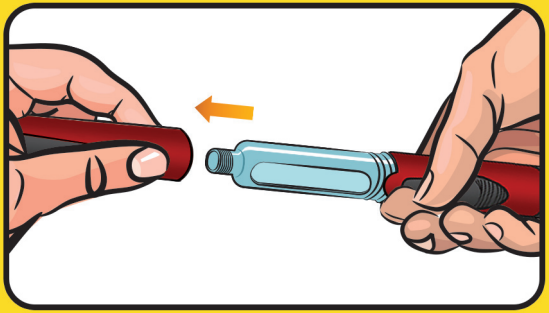
② construction of the pen injector



③ installation of cartridge and pen needle

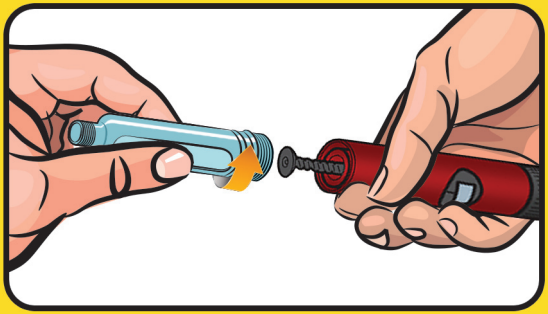
Wash your hands with soap thoroughly, and make sure that you have the following items:

- Terifrac Multi pen injector
- teripartide cartridge
- new disposable pen needle
- two alcohol swabs



Step 1
Pull off the cap

Step 2
Unscrew the cartridge holder from the pen body by turning it according to the direction shown on the drawing.

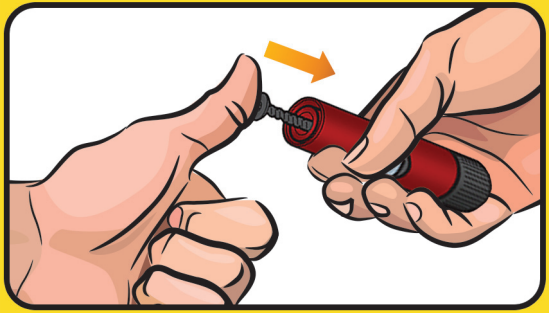


③ installation of cartridge and pen needle

Step 3

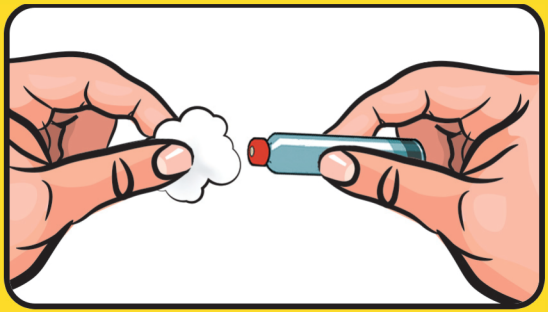
Press the plunger into the pen body.

If the plunger is stuck try to screw it into the pen body clockwise to the first resistance by holding the plunger. Then push the end of plunger into pen body as much is possible.



Step 4

Check the teriparatide cartridge.
Make sure that it is not cracked or broken, the teriparatide solution is clear and transparent and check the medicine expiration date. Wipe the teriparatide rubber cartridge tip with the alcohol swab.

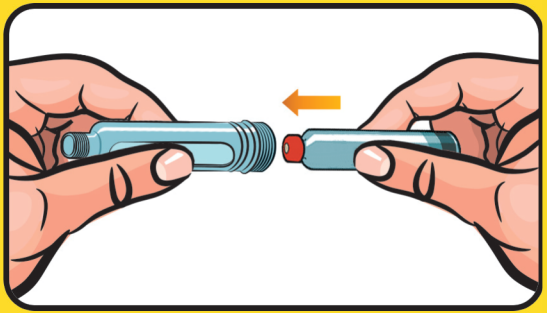


Do not use the teriparatide if cartidge is cracked or broken and after the medicine expiration date. Do not manipulate in pen injector mechanism. This may cause malfunction of pen injector.

3 installation of cartridge and pen needle

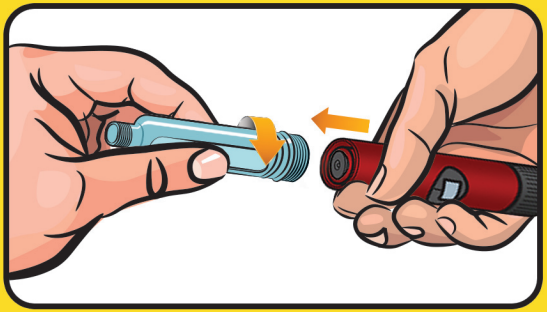
Step 5

Insert teriparatide cartridge into the cartridge holder, metallic tip to the front.



Step 6

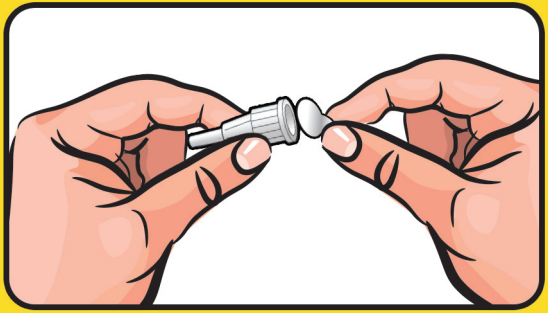
Attach the cartridge holder to the pen body by turning it according to direction shown on the drawing, until first resistance is met.



③ installation of cartridge and pen needle

Step 7

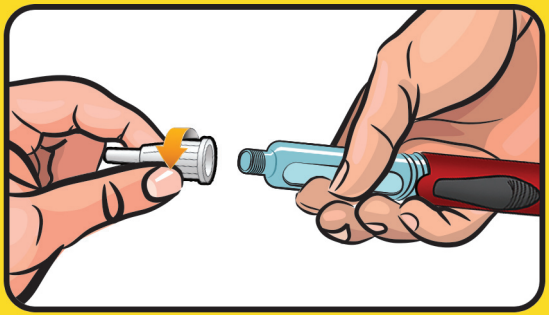
Take a new sterile needle. Check the needle expiration date and the paper tab on the outer needle shield remove the paper tab from the outer needle shield.



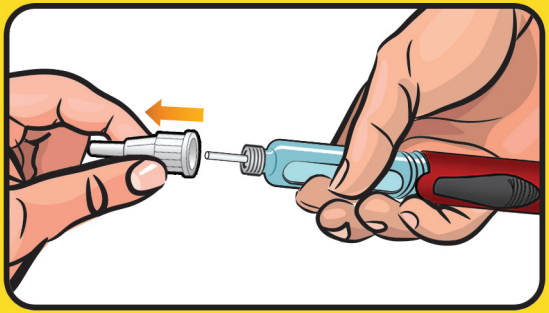
For each injection use a new needle.
Do not use needles if the paper cover if damaged.
Reuse of the same needle or needle with a damaged unit pack (paper cover) is not in line with epidemiological recommendations.

Step 8

Hold the pen injector by the cartridge holder. Attach the outer needle shield to the cartridge holder until first resistance is met, according to the direction shown on the drawing.

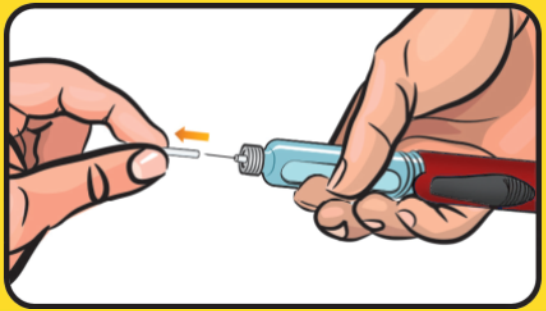


3 installation of cartridge and pen needle



Step 9

Remove the outer needle shield.
Retain it for removal of the needle after the completion of the injection process.



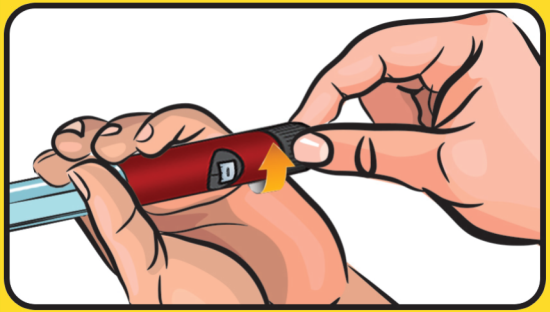
Step 10

Remove the inner needle shield as recommended by the manufacturer.

To minimise the risk of unintended needle penetration and transmission of infectious diseases, never replace the inner needle shield once removed. If by accident you puncture your skin, clean the wounded spot with a skin disinfectant.

4 priming

Prime your Terifrac Multi before each injection. Hold Terifrac Multi with needle pointing up.Tap lightly with your finger on the cartridge holder to move any air bubbles in the cartridge to the top of the cartridge.



Step 11

The number in the dose selector window corresponds to the drug volume in micrograms (mcg). Choose 5 mcg of teriparatide as a test dose.

How to select the test dose?

1. Turn the dose selector according to the direction shown on the drawing.
2. Turn the dose selector until figure 5 appears in the dose selector window.



Step 12

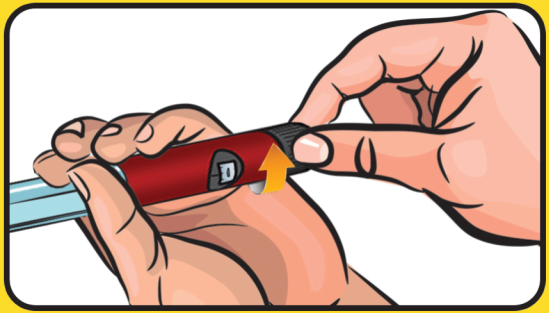
Hold the pen with the needle pointing upwards. Using your thumb, slide the release button in the needle direction. Hold the release button until a green dot appears in the window displaying the end of injection. If a drop of teriparatide appears on the tip of the needle the pen injector is ready for use.

If a drop of teriparatide does not appear at the end of the needle, repeat steps 11 and 12. If a drop of teriparatide does not appear after several attempts, remove the needle with step 17. Repeat steps 7 through 12, afterwards.

5 injecting a dose

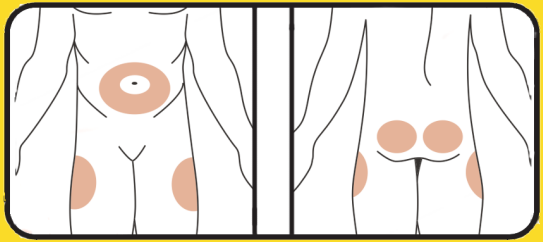
Step 13

Select a dose of teriparatide you want to inject. To do that, turn the dose selector according to the direction shown on the drawing, until the desired figure corresponding to the number of teriparatide mcg appears in the dose selector window. Make sure that dose selector window shows the correct number of doses. If the dialled dose is to high you can correct it by turning the dose selector backwards.



Step 14

Select the injection site (abdomen, thighs, buttocks) and wipe your skin with an alcohol swab. Rotate your injection sites daily.

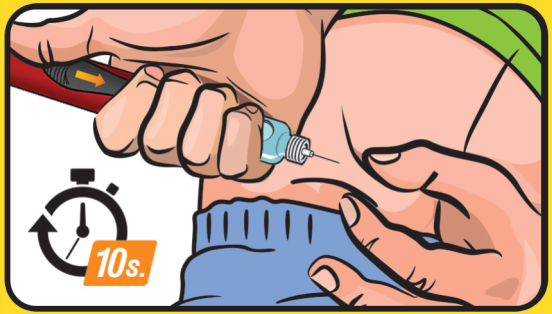


If by accident you inject yourself a dose higher than prescribed, immediately contact your doctor.

5 injecting a dose

Step 15

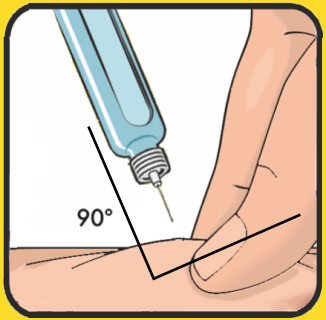
Gently hold a fold of the skin and insert the tip of the needle into subcutaneous tissue in a 90 degrees angle. Using your thumb slide the release button in the needle direction, hold the release button until a green dot appears in the window displaying the end of injection. Count to 10 slowly, while not removing the needle from the skin.



If the green dot does not appear...

it means that there is no teriparatide in the cartridge. Note the number of units remaining, as it corresponds to the number of mcg of teriparatide which you must inject to complete the injection. Attach the outer needle shield and remove the needle. Replace the old cartridge with a new one, accordingly to Section 7 - replacing a cartridge. Prepare the pen injector to use accordingly to the actions described in steps 7 to 10. Perform the priming dose injection. Next, complete the interrupted dose delivery by turning the dose selector according to the direction shown on the drawing until the figure, which you have seen in the selector window, appears. Perform accordingly the actions described in steps 14 to 15.

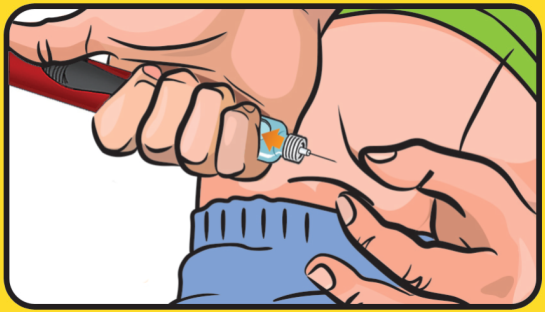




⑤ injecting a dose

Step 16

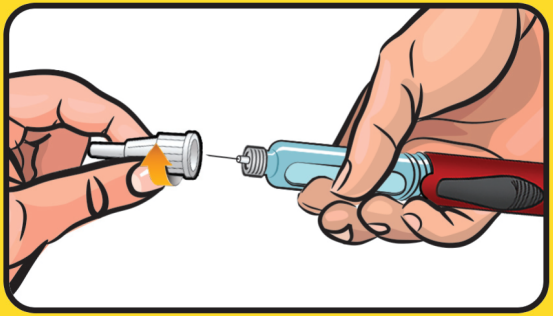
Remove the needle from the skin at the same angle it was inserted into subcutaneous tissue.



⑥ removing a needle

Step 17

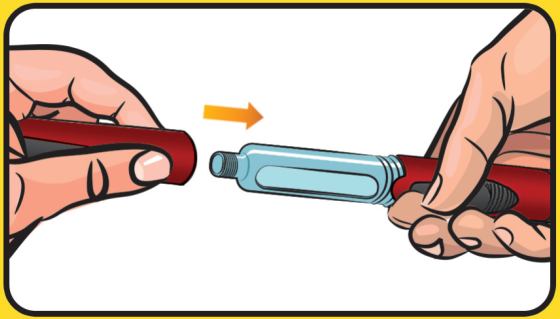
After the injection put the outer needle shield on the needle. Holding the cartridge holder rotate the outer needle shield according to the direction shown on the drawing. Remove the used needle.



Used needles and empty teriparatide cartridges are classified among potentially dangerous waste which can cause microbiological contamination. Keep them out of the reach of children. Dispose needle and cartridge in accordance with information from the manufacturer or local laws.

Step 18

Put the cap on the pen injector.
The teriparatide injection has been completed.

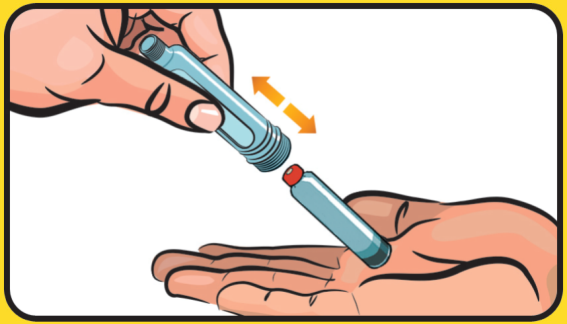


⑦ replacing an empty cartridge

Remove the cartridge holder from the pen body by turning it according to the direction shown on the drawing.

Shake the empty cartridge and remove it in accordance with information provided by the manufacturer of teriparatide.

Set the dose selector to "0" position by turning it according to the direction shown on the drawing.
Follow steps 3 through 6.



8 storage and cleaning

- Always keep your Terifrac Multi and needles out of the reach of other people, especially children.
- Terifrac Multi should always be stored and carried with the pen cap on, without a needle.
- Terifrac Multi with the teriparatide cartridge should be refrigerated at +2°C to +8°C.
- Terifrac Multi without the teriparatide cartridge, can be stored at -40°C to +70°C.
- Humidity range for storage is from 25% up to 98%
- Keep the pen injector far from extreme temperatures, humidity, dust and direct sun exposure.
- Terifrac Multi should be stored in its case.
- Clean your Terifrac Multi daily using a damp cloth. Do not immerse the injector into water. Pen injector should not be sterilized. Do not use alcohol or any aggressive disinfectants. They could destroy your pen.
- Terifrac Multi should be protected against major physical forces.

Do not immerse Terifrac Multi into water.



Problem:	Possible cause:	HOW TO ELIMINATE:
A higher dose was dialled then required.	User error.	You can correct the dose by turning the dose selector in the opposite direction.

Problem:	Possible cause:	HOW TO ELIMINATE:
Cannot attach the cartridge holder onto the pen body.	Incorrectly insert teriparatide cartridge.	Check if the cartridge was properly insert into the cartridge holder (metallic cap first)
	Pushed out plunger.	Push the plunger back into the pen body.

Problem:
Despite a number of priming procedures a drop of teriparatide has not appeared on the end of the needle.

Possible cause:	HOW TO ELIMINATE:
Incorrectly installed teriparatide cartridge.	Check if the cartridge was properly installed. There should be no space between the plunger and the cartridge.
Clogged pen needle.	Replace the needle with a new one.

Problem:
After the injection the green dot did not appear in the the window displaying the end of injection

Possible cause:	HOW TO ELIMINATE:
There was not enough teriparatide in the cartridge to inject the full set dose.	Note the number of units remaining, as it corresponds to the number of mcg of teriparatide which you must inject to complete the injection. Attach the outer needle shield and remove the needle. Replace the old cartridge with a new one, accordingly to Section 7. Prepare the pen injector to use accordingly to the actions described in steps 7 to 10. Perform the priming dose injection. Complete the interrupted dose delivery by turning the dose selector until the figure, which you have seen in the selector window, appears. Follow steps 14 through 15.

10 information from the manufacturer

- Package contents: Terifrac Multi reusable teriparatide pen injector, pen case, user's manual.
- Terifrac Multi meets the requirements of ISO 11608-1 standard with respect to generalrequirements dosing accuracy and robustness.
- Terifrac Multi in intended for use with disposable needles: BD Micro-Fine 0.25mm x 5mm, BD Micro-Fine 0.23mm x 4mm and BD Micro-Fine 0.25mm x 8mm.
- Terifrac Multi should be replaced:
  - after 2 years in use;
  - when decided by your doctor or
  - in any case where there are doubts as to Terifrac Multi functionality.
- Terifrac Multi is made of materials safe for the health of patients.

Particular attention should be paid to the information preceded by this sign which will ensure safe and comfortable use of the device.

In the events of serious incidents, this should be reported to the manufacturer and to the competent authority.

Manufacturer:
Nemera Szczecin Sp. z o.o.
ul. Tytanowa 3
70-856 Szczecin
plszc_info@nemera.net
www.nemera.net

Distributor/Importer:

TCM8-EN-V10
Date of isse: 10/2024

Legend of pictograms used in Instruction for Use, labels and package



Manufacturer - Indicates the medical device manufacturer



(red color) Caution - Indicates that caution is necessary when operating the device or control close to where the symbol isplaced or that the current situation needs operators awareness or operator action in order to avoid undesirable consequences



Consult instruction for use - Indicates the need for the user to consult the instructions



Patient information website - Indicates a website where a patient can obtain additional information on the medical product

Legend of pictograms used in Instruction for Use, labels and package



Indicates the date that medical device was manufactured



Temperature limit - Indicates the temperature limits to which the medical device can be safely exposed



Humidity limitation - Indicates the range of humidity to which themedical device can be safely exposed

MD

Indicates the item is a medical device

LOT

Batch code - Indicates the manufacturer's batch code so that the batch or lot can be identified

REF

Catalogue number - Indicates the manufacturer's catalogue number so that the medical device can be identified



Keep dry - Indicates a medical device that needs to be protected from moisture



Distributor - Indicates the entity distributing the medical device into the locale

notes

disposal of pen injector

Remember to dispose Your pen injector 2 years after first use. Below note the date of first and last use of Terifrac Multi

1st use on: ☐☐ – ☐☐ – ☐☐☐☐

Throw away after: ☐☐ – ☐☐ – ☐☐☐☐

REUSABLE TERIPARATIDE PEN INJECTOR

Terifrac Multi

USER'S MANUAL



Read the instructions carefully before using **Terifrac Multi.** Failure to follow of these instructions may have serious consequences to your health. Using the device in a different way from the process described in this manual is not recommended.