

Instructions For Use

MENOPUR (Men-oh-pyoor) (menotropins for injection) Pre-filled pen

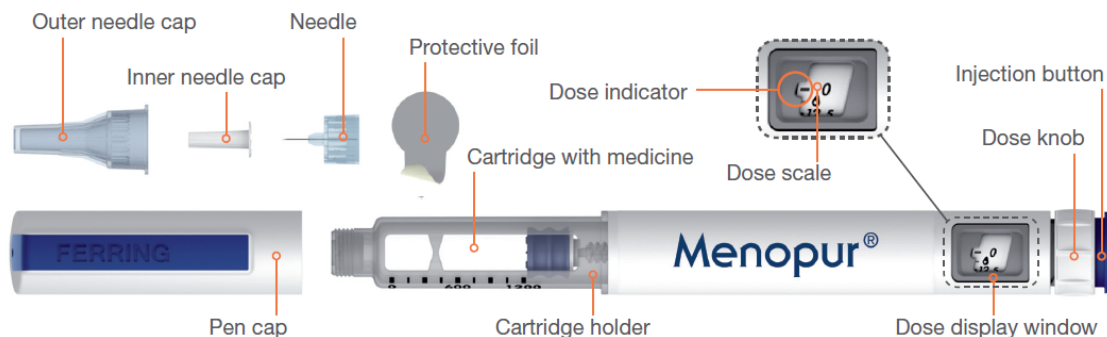
Your study doctor or nurse will show you how to prepare and inject MENOPUR the right way before you inject it for the first time.

Read these instructions completely before using your MENOPUR pre-filled pen and each time you get a new pen. There may be new information. Follow the instructions carefully even if you have used a similar injection pen before. Using the pen incorrectly could result in receiving an incorrect dose of medicine.

Call your study doctor or nurse if you have any questions about how to give your MENOPUR injection.

The MENOPUR pre-filled pen is a dial-a-dose pen that can be used to give more than 1 dose of MENOPUR. The pen is 1200 IU/1.92 mL fill volume:

MENOPUR pre-filled pen and its parts



Important information

- The MENOPUR pre-filled pen and the needles are for use by only one person and should not be shared with others.
- Use the pen only for the medical condition it is prescribed for and as directed by your healthcare provider.
- If you are blind or have poor eyesight, do not use this pen without help. Get help from a person with good eyesight who is trained to use the pen.
- Call your study doctor or nurse before giving your MENOPUR injection if you have questions.

Information about your MENOPUR pre-filled pen

The pen can be dialed to give doses from 6.25 units to 450 units of MENOPUR in marked increments of 6.25 units. See “**Examples of how to dial a dose using your Menopur pre-filled pen**” at the end of these instructions.

- The dosing scale of the pen is numbered from 0 to 450 units.
- Each number is separated by one line equal to one increment of 6.25 units.
- When turning the dial to your dose, you will hear a click sound and feel resistance on the dial for each increment to help you dial the correct dose.

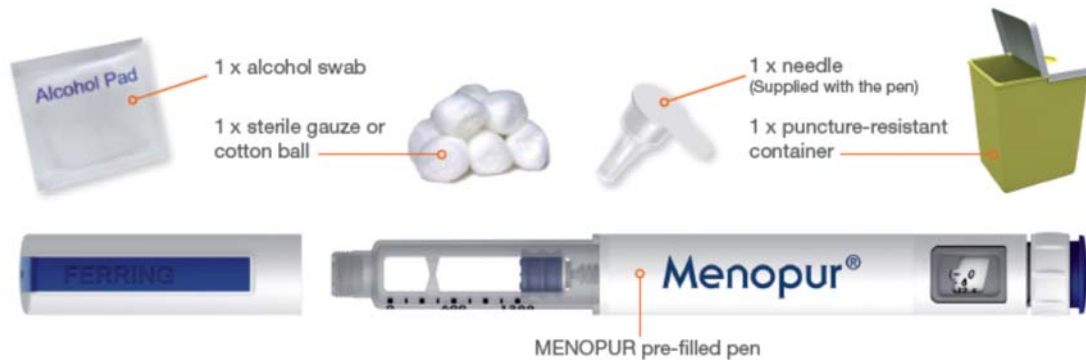
Cleaning

- If needed, the outside of your pen may be cleaned with a cloth moistened with water.
- Do not put the pen in water or any other liquid.

Storage

- Before use, store the pen in a refrigerator at 36 °F to 46 °F (2 °C to 8 °C). Do not freeze.
- After first use, the pen should be refrigerated. It may be stored for up to 28 days at 36 °F to 77 °F (2°C to 25°C). **Do not freeze the pen.**
- Always store the pen with the pen cap on and without a needle attached.
- Do not use the pen after the expiration date (EXP) printed on the pen label. The expiration date is the last day of the month of expiration.
- Do not store the pen in extreme temperatures or direct sunlight, such as in a car or freezer.
- Store the pen out of the reach of children and anyone who has not been trained to use the pen.

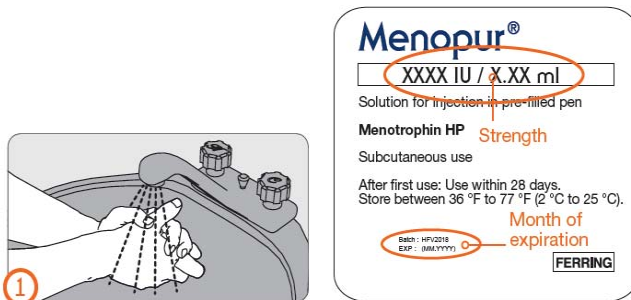
Supplies you will need to give your MENOPUR injection



Before use – (Step 1)

Step 1:

- Wash your hands.
- Check the expiration date on the pen label.



Attaching needle – (Step 2 to 6)

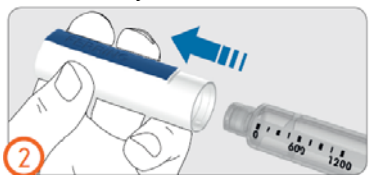
Important:

- Always use a new needle for each injection.
- Only use the single-use click-on needles supplied with the pen.

Step 2:

- Pull off the pen cap.
- Check that the pen is not damaged.
- Check that the medicine in the cartridge is clear and does not contain particles.

- Do not use the pen if it is damaged, contains particles or if the medicine in the cartridge is cloudy.



Step 3:

- Pull off the protective foil from the needle.



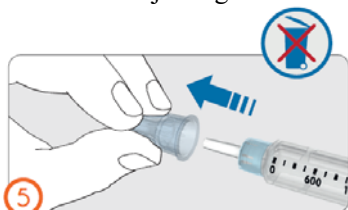
Step 4:

- Click the needle onto the pen.
- You will hear or feel a click when the needle is safely on.



Step 5:

- Pull off the outer needle cap.
- **Do not** throw the outer needle cap away. You will need it to throw away the needle after injecting the medicine.



Step 6:

- Pull off the inner needle cap and throw it away.

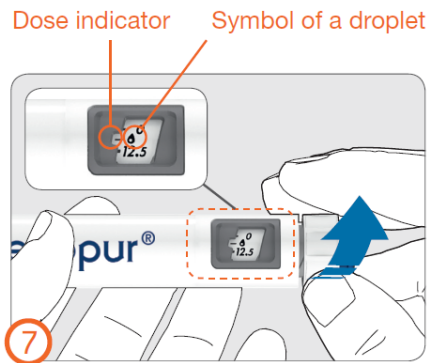


Priming – (Step 7 to 9)

- Before using the pen for the first time, you need to remove air bubbles from the cartridge (Priming) to receive the correct dose of medicine.
- Only prime your pen the first time you use it.
- Perform Step 7 to 9 even if you do not see air bubbles.
- If the pen has already been used proceed directly to Step 10.

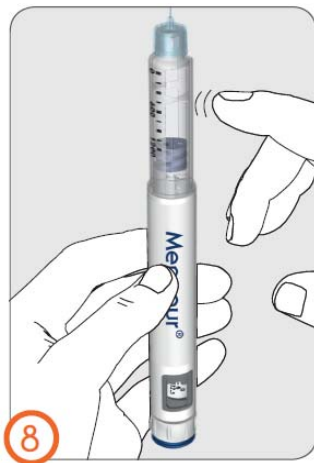
Step 7:

- Turn the dose knob clockwise until a symbol of a droplet lines up with the dose indicator.
- If you dial the incorrect priming dose, the priming dose can be corrected either up or down without loss of medicine by turning the dose knob in either direction until the symbol of a droplet lines up with the dose indicator.



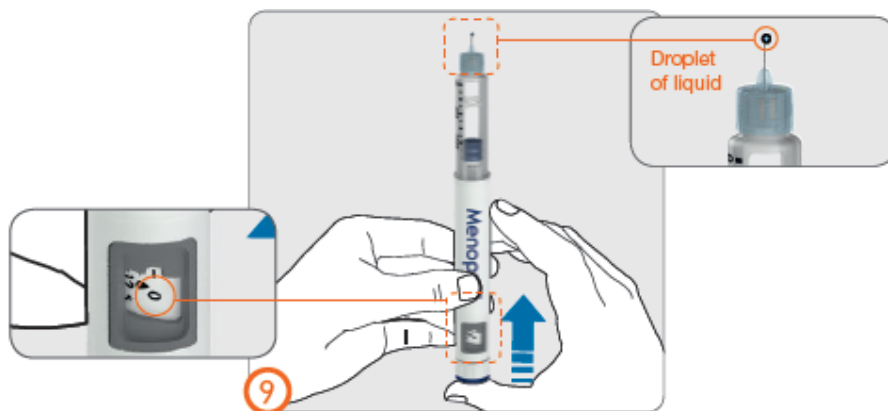
Step 8:

- Hold the pen with the needle pointing upwards. Tap with your finger on the cartridge holder to make any air bubbles in the cartridge rise to the top of the cartridge.



Step 9:

- With the needle still pointing upwards (away from the face), press the injection button all the way in until you see the number '0' lined up with the dose indicator.
- Check that a droplet of liquid appears at the tip of the needle.
- If no droplet(s) appear repeat Steps 7 to 9 (Priming) until a droplet appears.
- If no droplet appears after 5 tries, remove the needle (See Step 13), attach a new needle (See Steps 3 to 6), and repeat priming (See Steps 7 to 9).

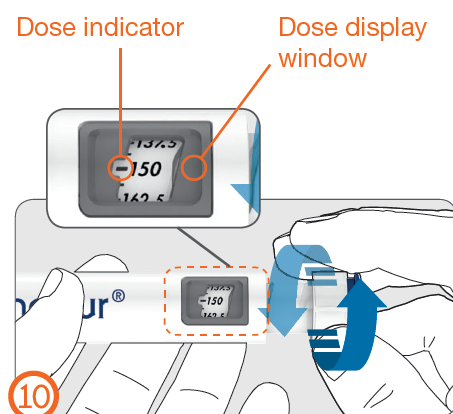


Dialing the dose – (Step 10)

Step 10:

- Turn the dose knob clockwise until the prescribed dose lines up with the dose indicator in the dose display window.
- The dose can be corrected either up or down without loss of medicine by turning the dose knob in either direction until the correct dose lines up with the dose indicator.
- Do not press the injection button when dialing the dose to avoid loss of medicine.

See below for “**Examples of how to dial a dose using your MENOPUR pre-filled pen**”



Split-dosing:

- You may need more than one pen to complete your prescribed dose.
- If you are not able to dial your complete dose, this means there is not enough medicine left in the pen. You will need to give a split-dose injection which means you will also need another pen for your injection.
- See “**Giving a split-dose of MENOPUR**” for examples of how to calculate and record your split dose.

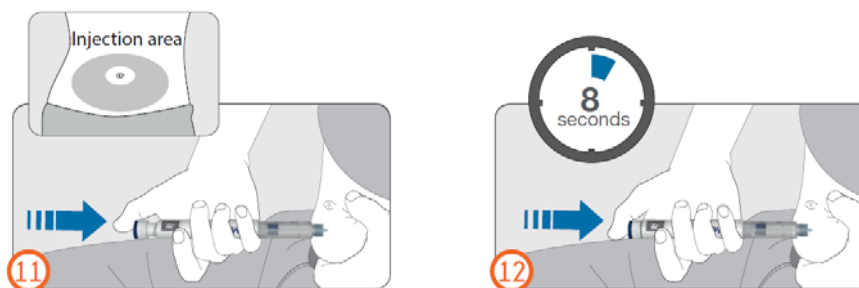
Injecting the dose – (Step 11 to 12)

Important:

- Read Steps 11 and 12 below before giving your injection.
- This medicine should be given by injection just under the skin (subcutaneously) in the stomach-area (abdomen).
- Use a new injection site for each injection to lower the risk of skin reactions such as redness and irritation.
- Do not inject into an area that is sore (tender), bruised, red, hard, scarred or where you have stretch marks.

Step 11 and 12:

- Wipe the skin of your injection site with an alcohol swab to clean it. Do not touch this area again before you give your injection.
- Hold the pen so the dose display window is visible during injection.
- Pinch your skin and insert the needle straight into your skin as shown by your healthcare provider. Do not touch the injection button yet.
- After the needle is inserted, place your thumb on the injection button.
- Press the injection button all the way in and hold.
- Keep pressing the injection button in and when you see the number '0' lined up with the dose indicator, wait for 8 seconds (slowly count to 8) before releasing the injection button. This will make sure you get your full dose.



- Slowly remove the needle from the injection site by pulling it straight out of the skin.
- If blood appears at the injection site, press a gauze pad or cotton ball lightly to the injection site.

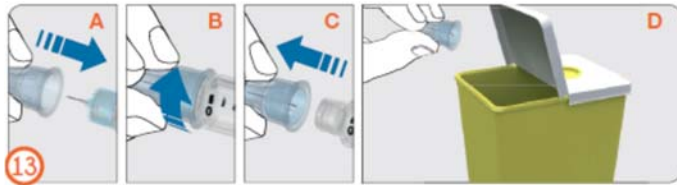
Note:

- Do not tilt the pen during injection and removal from skin.
- Tilting the pen can cause the needle to bend or break off.
- If a broken needle remains stuck in the body or remains under the skin, get medical help right away.

Disposal of Needle – (Step 13)

Step 13:

- Carefully replace the outer needle cap over the needle with a firm push (See figure 13A).
- Unscrew the needle in counter-clockwise direction to remove the needle from the pen (See figure 13B and 13C).
- Throw away the used needle carefully in the sharps disposal container provided (See figure 13D).



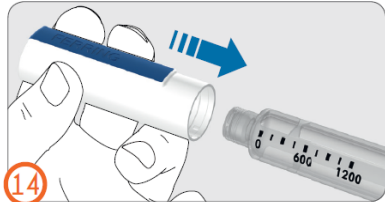
Note:

- Always remove the needle after every use. The needles are for single-use only.
- Do not store the pen with the needle attached.

Replace pen cap – (Step 14)

Step 14:

- Firmly replace the pen cap on the pen for protection between injections.



Note:

- The pen cap will not fit over a needle.
- Keep the pen cap on the pen when it is not in use.

What should I do with used pen needles and MENOPUR pens?

Needles:

Put your used needles in a sharps disposal container provided by the study doctor or nurse immediately after use.

When your sharps disposal container is full, you will need to follow your community guidelines for the right way to dispose of it. There may be state or local laws about how you should throw away used needles. For more information about sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at <http://www.fda.gov/safesharpsdisposal>.

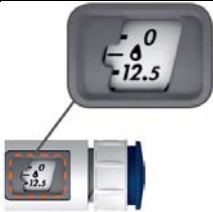

Do not throw away your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used disposal container.

MENOPUR pre-filled pens:

- Keep your used pen and its package to bring back to your study site at your next visit.

Examples of how to dial a dose using your MENOPUR pre-filled pen

The chart to the right shows examples of the priming and 225 units doses, how to dial these, and how the dose display window will look. Please remember that these are examples only. Please follow the instructions of your study doctor or nurse for dialling the correct doses.

Examples of prescribed dose (in units)	Dose to dial on pen		Dose display window for example of prescribed dose
Priming dose	Priming symbol (Dial one click starting from 0 until you see the priming symbol of a droplet)		
225	225 (Dial to 225)		

Giving a split-dose of MENOPUR

If you are not able to dial the full prescribed dose in your pen, this means that there is not enough medicine left in the pen to give the full dose. You will need to give part of your prescribed dose using your current pen and the remainder of the dose using a new pen (split-dose injection) or you may use a new pen to give your full prescribed dose in 1 injection. If you decide to give a split-dose injection, follow these instructions and write down how much medicine to give using the **split-dose diary** on table below. Be sure to keep any used pens and their packages to bring back to your study site at your next visit.

- Column A shows an example of a prescribed dose.
- Write down your prescribed dose in column A.
- Column B shows an example of the dose that is left in the pen (this is equal to what you are able to dial).
- Write down the dose that is left in your pen in column B. Give the injection using the rest of the medicine that is left in your pen.
- Prepare and prime a new pen (Step 1 to 9).
- Calculate and write down the remaining dose to inject in column C by subtracting the number in column B from the number in column A. Use a calculator to check your math if needed.
- See “**Examples of how to dial a dose using your MENOPUR pre-filled pen**” section above if needed.
- Call your study doctor or nurse if you have questions about how to calculate your split-dose.
- Inject the remaining dose of medicine (the number in column C) using your new pen to complete your prescribed dose.

Split-dose diary

A Prescribed dose	B Dose left in pen (Dose shown at dose indicator in dose display window)	A minus B = C Dose to inject on new pen (Dose shown at dose indicator in dose display window)
150	75 (75)	75 (75)
225	150 (150)	75 (75)
300	75 (75)	225 (225)

Frequently Asked Questions (FAQ)

1. Is the priming step necessary before each injection?
 - No. Priming must be performed only before giving the first injection with a new pen.
2. How do I know that the injection is complete?
 - You have pushed the injection button all the way in.
 - The number '0' has lined up with the dose indicator.
 - You have slowly counted to 8 while holding the injection button in and with the needle still in your skin.
3. Why do I have to count to 8 while holding the injection button?
 - Holding the injection button for 8 seconds allows for the full dose to be injected and absorbed under your skin.
4. What if the dose knob cannot be turned to the required dose?
 - The cartridge in the pen may not have enough medicine left to deliver the prescribed dose.
 - The pen does not allow you to dial a larger dose than the dose that is left in the cartridge.
 - You can inject the medicine left in the pen and complete the prescribed dose with a new pen (split-dose) or use a new pen to give the full prescribed dose.

Warnings

- Do not use a pen if it has been dropped or hit against hard surfaces.
- If the injection button is not easy to push in, do not use force. Change the needle. If the injection button still is not easy to push in after changing the needle, use a new pen.
- Do not try to repair a damaged pen. If a pen is damaged, report the pen failure to your study doctor immediately so he/she can dispense a replacement pen for you. Bring the damaged pen to the clinical trial site on your next visit.

Additional information

Needles

Needles are supplied with your pen. If you need additional needles contact your study doctor or nurse. Use only needles that have been provided by your study doctor or nurse.

Contact

If you have any questions or problems related to the pen, contact your study doctor or nurse.