

## **Package leaflet: Information for the user**

### **Menotrophin Ferring 600 IU solution for injection in a pre-filled pen**

### **Menotrophin Ferring 1200 IU solution for injection in a pre-filled pen**

menotrophin

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

#### **1. What Menotrophin Ferring is and what it is used for**

Menotrophin Ferring comes as a solution for injection in a pre-filled pen. The injection is given under your skin ('sub-cutaneous' injection) – usually in the tummy.

Menotrophin Ferring contains 'menotrophin', which is a mixture of two natural hormones called:

- follicle stimulating hormone (FSH) and
- luteinizing hormone (LH).

These hormones help reproductive organs to work normally. The FSH and LH hormones in menotrophin are obtained from the urine of women who have passed the menopause.

#### **What Menotrophin Ferring is used for**

Menotrophin Ferring is used to treat women who cannot become pregnant. It is used for:

- women whose ovaries do not produce eggs. This includes women with 'polycystic ovarian disease' ('PCOD'). Menotrophin Ferring is used when women have already had a medicine called 'clomiphene citrate', but this medicine has not helped.
- women in 'assisted reproductive technology' programmes. This includes:
  - o 'In vitro fertilisation' (IVF) or 'embryo transfer' (ET)
  - o 'Gamete intra-fallopian transfer' (GIFT)
  - o 'Intracytoplasmic sperm injection' (ICSI).

#### **How Menotrophin Ferring works**

Menotrophin Ferring helps the ovaries to develop lots of egg sacs ('follicles') where an egg might develop. This is called 'multiple follicular development'.

## 2. What you need to know before you use Menotrophin Ferring

### Checks before you use Menotrophin Ferring

Before you use Menotrophin Ferring, you and your partner should be checked by a doctor for the causes of your fertility problems. In particular, you should be checked for the following so that another more

suitable treatment can be given:

- Under-active thyroid or adrenal glands
- High levels of a hormone called prolactin – called ‘hyperprolactinemia’
- Tumours of the ‘pituitary gland’ – this is at the base of the brain
- Tumours of the ‘hypothalamus’ (under the part of the brain called the ‘thalamus’).

If you have any of the conditions listed above, **please tell your doctor before starting treatment with Menotrophin Ferring.**

### Do not use Menotrophin Ferring if:

- you are allergic to menotrophin or any of the other ingredients of Menotrophin Ferring (listed in Section 6)
- you have cancer of the womb (‘uterus’), ovaries, breasts, or parts of the brain such as the pituitary gland or hypothalamus
- you have sacs of fluid on your ovaries (‘ovarian cysts’) or enlarged ovaries – unless your enlarged ovaries are caused by PCOD
- you have any physical problems with the womb or other sexual organs
- you have bleeding from the vagina for an unknown reason
- you have fibroids – these are tumours in your womb that are not cancer
- you are pregnant or breast-feeding

### Warnings and precautions

#### Ovarian Hyperstimulation Syndrome (OHSS)

A serious side effect of this medicine, especially in women with PCOD, is ‘ovarian hyperstimulation syndrome’ or ‘OHSS’ (see Section 4).

Tell your doctor straight away if you have signs of OHSS, even if:

- some days have passed after your last injection
- you stop using Menotrophin Ferring.

These can be signs of high levels of activity in the ovaries, which might become severe. If this happens, your doctor will stop your Menotrophin Ferring treatment and you will be treated in a hospital.

Keeping to your recommended dose, and careful monitoring of your treatment, will reduce your chances of getting these symptoms.

#### Scans and tests

While you are being treated with this medicine, your doctor will normally arrange for you to have **ultrasound scans** and sometimes **blood tests** to check your response to treatment.

#### Pregnancy risks

Being treated with hormones like Menotrophin Ferring can increase the risk of:

- pregnancy outside of the womb (ectopic pregnancy) if you have ever had fallopian tube disease
- miscarriage
- multiple pregnancy (for example twins or triplets)
- physical defects in the baby at birth (congenital malformations).

Some women who have been given infertility treatment with more than one medicine have developed tumours in the ovaries and in other reproductive organs. It is not yet known if treatment with hormones like Menotrophin Ferring causes these problems.

### **Blood clots**

Blood clots are more likely to form inside your blood vessels when you are pregnant. This is more likely if you have had treatment to help you become pregnant and:

- you are overweight
- you have a blood clotting disease ‘thrombophilia’
- you or someone in your family has had blood clots.

Tell your doctor if you think this applies to you.

### **Children**

Menotrophin Ferring is not used in children.

### **Other medicines and Menotrophin Ferring**

Tell your doctor if you are taking, have recently taken, or might take any other medicines.

Clomiphene citrate is another medicine used in the treatment of infertility. If Menotrophin Ferring is used at the same time as clomiphene citrate, the effect on the ovaries may be increased.

### **Pregnancy and breast-feeding**

Do not use Menotrophin Ferring if you are pregnant or breast-feeding.

### **Driving and using machines**

Menotrophin Ferring is unlikely to affect your ability to drive and use machines.

### **Important information about some of the ingredients of Menotrophin Ferring**

Menotrophin Ferring contains less than 1 mmol sodium (23 mg) per dose, so it is essentially ‘sodium-free’.

## **3. How to use Menotrophin Ferring**

Always use Menotrophin Ferring exactly as your doctor has told you. You should check with your doctor if you are not sure.

### **Women who are not producing eggs (not ovulating):**

Your treatment will start within the first 7 days of your menstrual cycle.

- Day 1 is the first day of your period.
- You will have injections every day for at least 7 days.

### How much Menotrophin Ferring?

The normal starting dose is between 75 and 150 IU every day.

- The dose may be adjusted depending on your response – up to 225 IU.
- You will have the chosen dose for at least 7 days before the doctor changes it.
- The dose will normally be increased by 37.5 IU at a time. It will not be increased by more than 75 IU each time.

Your doctor will monitor the effect of Menotrophin Ferring treatment. The treatment cycle will stop if you do not respond to the treatment after 4 weeks.

### If you have a good response to Menotrophin Ferring:

You will get a single injection of a hormone called ‘human chorionic gonadotrophin’ (hCG).

- The dose will be between 5,000 and 10,000 IU
- You will get the hCG injection one day after your last Menotrophin Ferring injection.

You should have sex on the day of the hCG injection **and** the day after. Alternatively, sperm may be injected directly into your womb, known as ‘artificial insemination’

- Your doctor will then monitor you closely for at least two weeks.

### If you do not respond to Menotrophin Ferring:

- Your doctor will monitor the effect of Menotrophin Ferring treatment

- Depending on your progress, your doctor may decide to stop treatment with Menotrophin Ferring and not give you the hCG injection

### **Women in assisted reproduction programmes:**

If you are in an assisted reproduction programme, you will also have a medicine which helps a hormone called ‘Gonadotropin Releasing Hormone’ (GnRH) to work. This other medicine is called a ‘GnRH agonist’. Menotrophin Ferring should be started around 2 weeks after the start of the GnRH agonist therapy.

You may also be having a medicine called a ‘GnRH antagonist’.

Menotrophin Ferring treatment should be started on day 2 or 3 of the menstrual cycle (day 1 is the first day of your period).

### How much Menotrophin Ferring?

Menotrophin Ferring should be given every day for at least 5 days.

- The initial dose of Menotrophin Ferring is normally 150–225 IU.
- This dose may be increased according to your response to the treatment – up to a maximum of 450 IU per day.
- The dose should not be increased by more than 150 IU each time.

Normally, treatment should not continue for more than 20 days.

If enough egg sacs (or follicles) are present, you will be given a single injection of hCG at a dose of up to 10,000 IU to cause the release of an egg (ovulation).

Your doctor will closely monitor your progress for at least 2 weeks after you have been given the hCG injection.

Your doctor will monitor the effect of Menotrophin Ferring treatment.

- Depending on your progress, your doctor may decide to stop treatment with Menotrophin Ferring and not give you the hCG injection.
- In this case, you will be told to use a barrier method of contraception (for example a condom). Otherwise you should not have sexual intercourse until your next period has started.

### **Using Menotrophin Ferring**

Follow the ‘Instructions for Use’, supplied in the package with the pre-filled pen, very carefully.

A doctor or nurse will be there for your first injection of Menotrophin Ferring. Your doctor will decide if you can give yourself the following injections at home – after you have been fully trained.

You will be given Menotrophin Ferring as an injection under the skin (‘sub-cutaneous’ injection). This is usually in the tummy. Each pre-filled pen may be used for several injections.

### **If you take more Menotrophin Ferring than you should**

Tell your doctor.

### **If you forget to take Menotrophin Ferring**

Do not take a double dose to make up for a forgotten dose. Tell your doctor.

## **4. Possible side effects**

Like all medicines, Menotrophin Ferring can cause side effects, although not everybody gets them.

### **Serious side effects**

#### **Ovarian Hyperstimulation Syndrome (OHSS)**

**Tell your doctor straight away** if you experience any of the following, which may be signs of OHSS:

- you have pain or swelling of the tummy
- you feel or are sick
- you have diarrhoea
- you put on weight
- you have difficulty breathing
- you need to pass water less often.

**Tell your doctor straight away, even if a few days have passed since your last injection, or you stop using Menotrophin Ferring.** You may need urgent medical treatment. These side effects may mean that your ovaries have been stimulated too much, known as Ovarian Hyperstimulation Syndrome (OHSS). In cases of severe OHSS, build-up of fluid in the tummy, pelvis or chest cavity, difficulty in breathing, decreased urination, formation of blood clots in blood vessels (thromboembolism) and twisting of ovaries (ovarian torsion) have been reported as rare complications.

### **Allergic reactions**

Tell your doctor straight away if you have:

- rash
- itching
- swelling of the throat and difficulty breathing.

If you notice any of the above signs, tell your doctor straight away.

### **Other side effects**

**Common side effects** (may affect up to 1 in 10 people):

- Headache
- Feeling sick (nausea)
- Pain or swelling of the tummy
- Pelvic pain
- Pain, redness, swelling, itching or bruising where the injection was given.

**Uncommon side effects** (may affect up to 1 in 100 people):

- Being sick (vomiting)
- Pain in the tummy
- Diarrhoea
- Feeling tired (fatigue)
- Feeling dizzy
- Sacs of fluid within ovaries (ovarian cysts)
- Breast problems, such as pain, tenderness, discomfort, swelling or nipple pain
- Hot flushes.

**Very rare side effects** (may affect up to 1 in 1,000 people):

- Spots (acne).

**Other side effects** (it is not known yet how many people they may affect):

- Problems with eyesight
- Fever
- Feeling generally unwell
- Increase in weight
- Muscle and joint pains
- Twisting of the ovary (ovarian torsion) because of overstimulation
- Hives
- Blood clots because the ovaries have been overstimulated.

### **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 via HPRC Pharmacovigilance,

Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. How to store Menotrophin Ferring

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 pre-filled pen label and carton after 'EXP'. The expiry date refers to the last day of that month.

Before use:

Store in a refrigerator, between 2 °C and 8 °C.

Do not freeze.

After opening:

Use each pre-filled pen within 28 days of opening. Store below 25 °C.

Always store the pen with the pen cap on, in order to protect from light.

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 Menotrophin Ferring contains

The active substance is highly purified menotrophin (human menopausal gonadotrophin, HMG).

#### Menotrophin Ferring 600 IU solution for injection in a pre-filled pen:

One pre-filled multidose pen delivers menotrophin corresponding to follicle stimulating hormone activity FSH 600 IU and luteinizing hormone activity LH 600 IU.

#### Menotrophin Ferring 1200 IU mL solution for injection in a pre-filled pen:

One pre-filled multidose pen delivers menotrophin corresponding to follicle stimulating hormone activity FSH 1200 IU and luteinizing hormone activity LH 1200 IU.

The other ingredients are:

- Phenol
- Methionine
- Arginine hydrochloride
- Polysorbate 20
- Sodium hydroxide
- Hydrochloric acid
- Water for injections

### What Menotrophin Ferring looks like and contents of the pack

Menotrophin Ferring is a clear and colourless solution for injection in a pre-filled pen.

Menotrophin Ferring 600 IU mL solution for injection in a pre-filled pen is available in packs of 1 pre-filled pen and 12 injection needles.

Menotrophin Ferring 1200 IU solution for injection in a pre-filled pen is available in packs of 1 pre-filled pen

and 21 injection needles.

**Marketing Authorisation Holder**

Ferring Ireland Limited  
United Drug House  
Magna Drive  
Magna Business Park  
Citywest Road  
Dublin 24

**Manufacturer**

Ferring GmbH  
Wittland 11, D-24109 Kiel, Germany

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Cyprus, Greece, Denmark, Finland, Iceland, Ireland, Norway, Portugal, Sweden: Menotrophin Ferring  
Italy: Meropur  
Malta: Menopur

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## Instructions for Use

### MENOPUR® Pre-filled pen

Menotrophin solution for injection



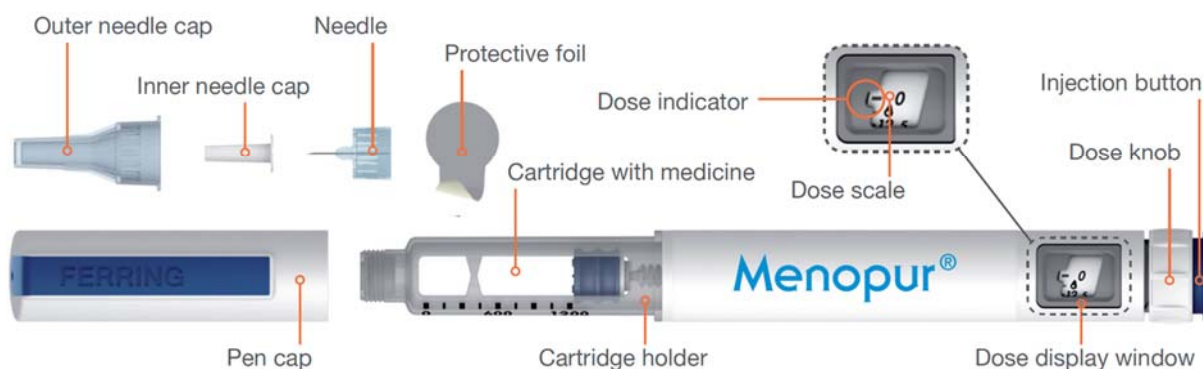
Your healthcare provider (doctor, nurse or pharmacist) should show you how to prepare and inject MENOPUR the right way before you inject it for the first time.

Read this booklet 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 healthcare provider if you have any questions about how to give your MENOPUR injection.

The MENOPUR pre-filled pen is a disposable, dial-a-dose pen that can be used to give more than 1 dose of MENOPUR. The numbers you see in the dose display window represent the number of international units (IU) of MENOPUR. The pen is available in 2 different presentations:

- 600 IU
- 1200 IU

#### MENOPUR pre-filled pen and its parts



#### Instructions for use – MENOPUR pre-filled pen

##### 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.

##### Information about your MENOPUR pre-filled pen



The pen can be dialled to give doses from 6.25 IU to 450 IU of MENOPUR in marked increments of 6.25 IU.

- The dose scale of the pen is numbered from 0 to 450 IU.
- Going from one line that is labelled with a dose to the very next line that does not have a label will increase or decrease the dose by 6.25 IU depending if you are turning the dose up or down. See “Examples of how to dial a dose” on Page 20 to 21<sup>1</sup>.
- 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.

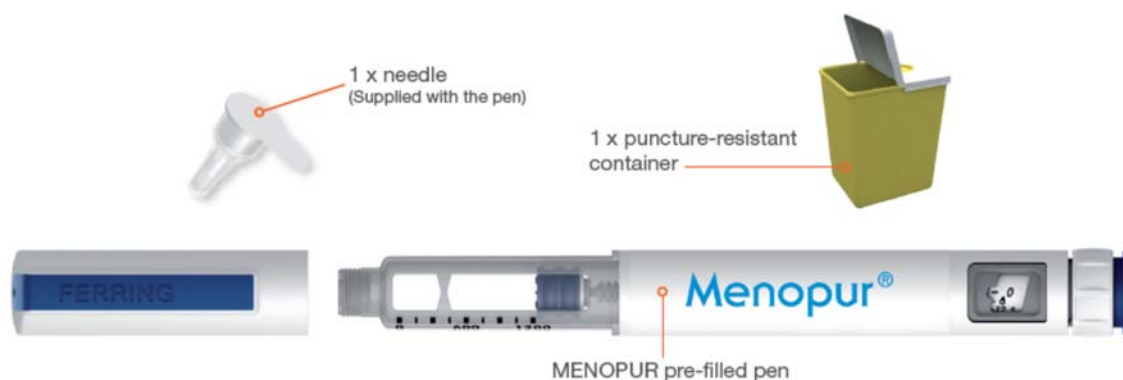
### Cleaning

- 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

- Do not freeze.
- Before use, store the pen in a refrigerator between 2 °C to 8 °C.
- After first use, use each pre-filled pen within 28 days and store below 25 °C.
- 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, direct sunlight or very cold conditions, such as in a car or freezer.
- Store the pen out of the sight and reach of children.

## **Supplies you will need to give your MENOPUR injection**



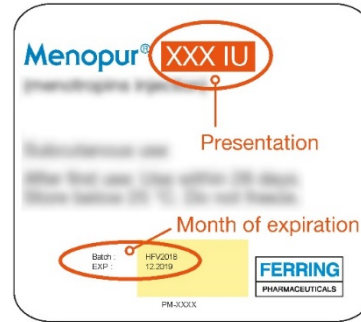
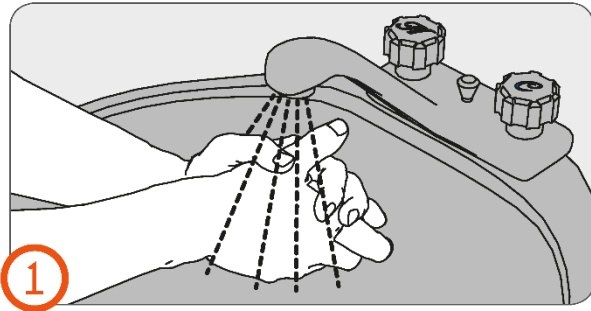
### **Before use – (Step 1)**

1.
  - Wash your hands.
  - Make sure you have the correct pen with correct presentation.

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<sup>1</sup> Reference to page numbers is to the printed Instructions For Use booklet

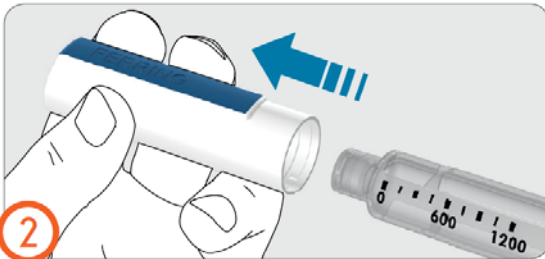
- Check the expiration on the pen label.



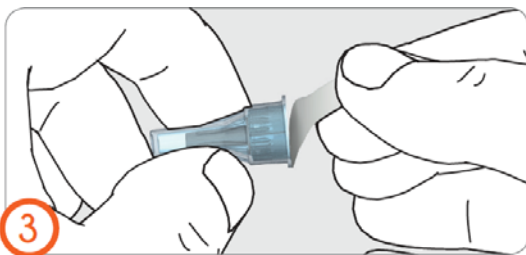
### Attaching needle – (Step 2 to 6)

#### Important:

- Always use a new needle for each injection.
  - Only use the single-use click-on needles supplied with the pen.
2.
    - Pull off the pen cap.
    - Check that the pen is not damaged.
    - Check that the medicine is clear and does not contain particles.
    - Do not use the pen if it is damaged, contains particles or has unclear medicine in the cartridge.

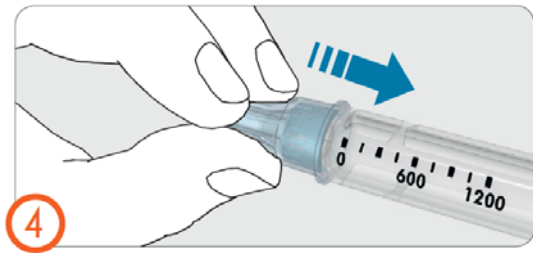


3.
  - Pull off the protective foil from the needle.



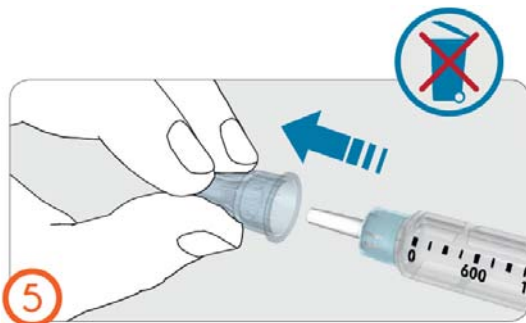
4.
  - Click the needle onto the pen.

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



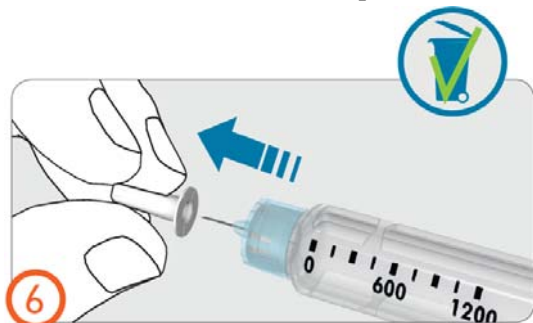
5.

- 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.



6.

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

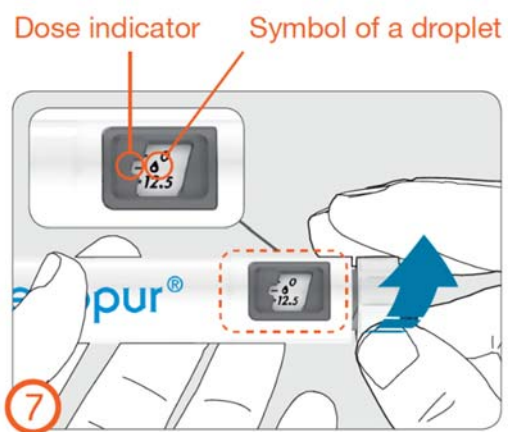


### Priming – (Step 7 to 9)

- 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 go directly to Step 10.

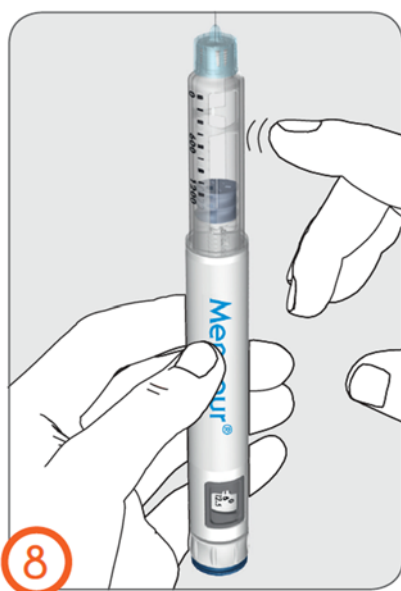
7.

- 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.



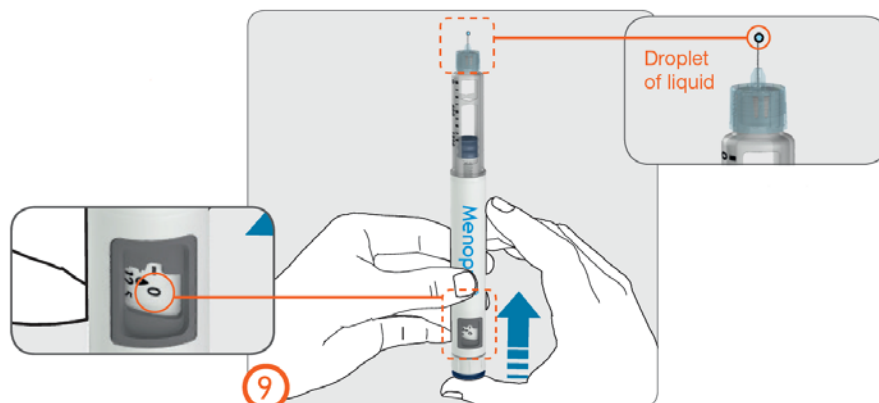
8.

- 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.



9.

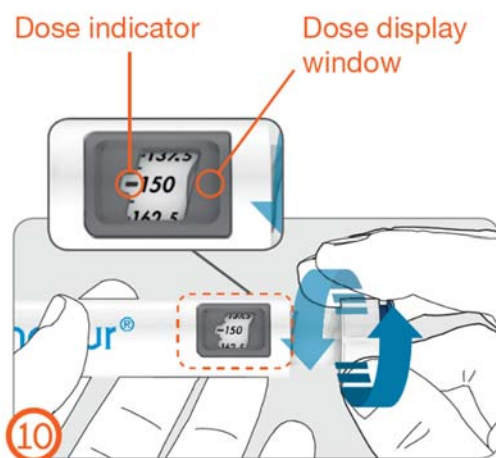
- With the needle still pointing upwards (away from the face) press the injection button all the way in until you see the number '0' lined up with the dose indicator.



- 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).
- If you still do not see a droplet after using a new needle, try a new pen.

### Dialing the dose – (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 dialling the dose to avoid loss of medicine.
- See “Examples of how to dial a dose” on Page 20 to 21<sup>1</sup>.



### 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 or throw away your current pen and use a new pen for your injection.

See “Giving a split-dose of MENOPUR“ on Page 22 to 23<sup>1</sup> for examples of how to calculate and record your split dose.

### Injecting the dose – (Step 11 to 12)

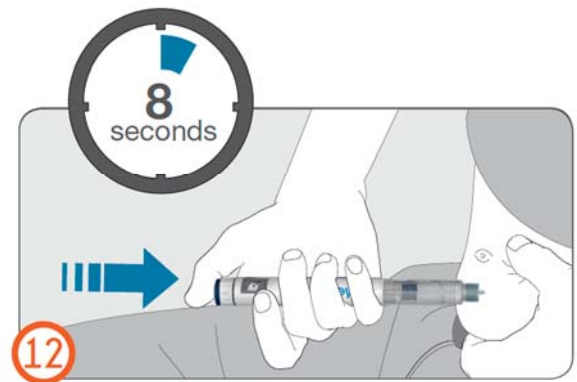
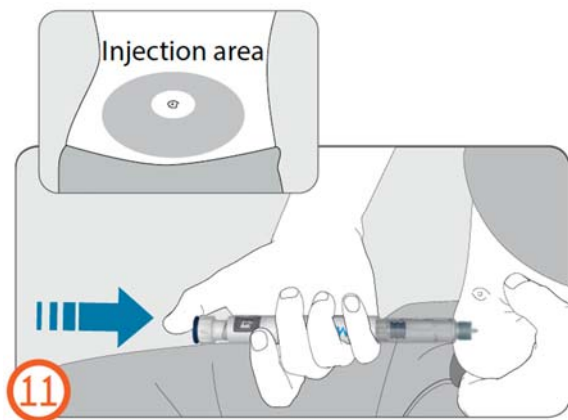
#### *Important:*

- Read Step 11 and 12 on Page 14 to 15<sup>1</sup> 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.

### 11.

- 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 (See Figure 11).
- 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) (See Figure 12).  
This will make sure you get your full dose.



## 12.

- After pressing in the injection button for 8 seconds, release the injection button. Then 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:*

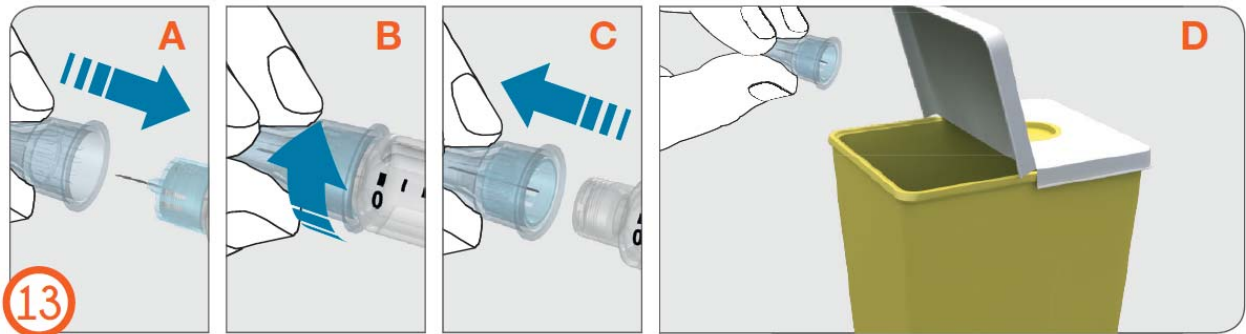
- Do not tilt the pen during injection and removal from skin.
- Tilting the pen can cause the needle to bend or break off.
- If a broken needle remains stuck in the body or remains under the skin, get medical help right away.

## **Disposal of needle – (Step 13)**

### 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 figures 13B and 13C).
- Throw away the used needle carefully (see figure 13D).

- See the section, “Disposal” on Page 18<sup>1</sup>.



*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)**

**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.



**Disposal**

*Needles:*

Put your used needles in a puncture resistant container, such as a sharps disposal container right away after use.

If you do not have a sharps disposal container, you may use a household container that is:

- made of a heavy-duty plastic,
- can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out,
- upright and stable during use,
- leak-resistant, and
- properly labelled to warn of hazardous waste inside the container.

You should dispose of your sharps disposal container when it is almost full. Ask your doctor, nurse or pharmacist for the right way to dispose. Do not throw away your used sharps disposal container in your household trash unless your community guidelines permit this.

*MENOPUR pre-filled pens:*

- Ask your pharmacist how to throw away medicines you no longer use.



**On the following pages, you will find more information on the subjects below<sup>1</sup>:**






- Examples of how to dial a dose.....page 20 to 21
- Giving a split-dose of MENOPUR.....page 22
- Split-dose diary.....page 23
- Frequently Asked Questions (FAQ).....page 24
- Warnings.....page 25
- Contact.....page 25

**Examples of how to dial a dose**

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

The chart to the right shows examples of prescribed doses, how to dial the examples of prescribed doses, and what the dose display window looks like for the prescribed doses.

Examples of prescribed dose (in IU) (units)	Priming dose	75
Dose to dial on pen	Priming symbol (Dial one click starting from 0 until you see the priming symbol of a droplet)	75 (Dial to 75)
Dose display window for example of prescribed dose		

118.75	225	262.5	343.75	450
118.75 (Dial to 112.5 plus 1 click)	225 (Dial to 225)	262.5 (Dial to 262.5)	343.75 (Dial to 337.5 plus 1 click)	450 (Dial to 450)
				

**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 throw



away the pen you are using and 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 Page 23<sup>1</sup>.

- 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” on Page 20 to 21<sup>1</sup> if needed.
- Call your healthcare provider 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

<b>A</b> Prescribed Dose	<b>B</b> Dose left in pen (Dose shown at dose indicator in dose display window)	<b>C = A minus B</b> Dose to inject on new pen (Dose shown at dose indicator in dose display window)
112.5	75 (75)	37.5 (37.5)
125	50 (50)	75 (75)
300	181.25 (175 plus 1 line)	118.75 (112.5 plus 1 line)

### **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 in the dose display window.
  - 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.

5. What if I do not have enough needles?

- If you need additional needles, contact your healthcare provider. Use only needles that come with your MENOPUR pre-filled pen or that your healthcare provider prescribes.

### **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, contact your healthcare provider or local representative of the marketing authorisation holder.

### **Contact**

If you have any questions or problems related to the pen, contact your healthcare provider or local representative of the marketing authorisation holder.

Marketed by:

Marketing Authorisation Holder:

Ferring Ireland Limited, United Drug House, Magna Drive,  
Magna Business Park, Citywest Road, Dublin 24.

Adverse events should be reported. You can report these directly via HPRA Pharmacovigilance,  
Website: [www.hpra.ie](http://www.hpra.ie).

Adverse events should also be reported to Ferring Ireland Ltd.

Tel: +353 86 0483100

E-mail: [EnquiriesIrelandMailbox@ferring.com](mailto:EnquiriesIrelandMailbox@ferring.com)

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