PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4 / S4

MENOPUR ® 75 IU, Powder for solution for injection

MENOPUR ® SOLVENT, Solution for injection

MENOPUR ® 600 IU, Powder and solvent for solution for injection

MENOPUR ® 1200 IU, Powder and solvent for solution for injection

Menotrophin

MENOPUR ® 75 IU:

Powder contains sugar (lactose monohydrate, 20 mg/vial)

MENOPUR ® 600 IU & 1200 IU:

Powder contains sugar (lactose monohydrate, 21 mg/vial)

Solvent contains metacresol (0,33 % *m/v*) as preservative.

Read all of this leaflet carefully before you are given MENOPUR ®

- Keep this leaflet. You might need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- MENOPUR ® has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What MENOPUR ® is and what it is used for

2. What you need to know before you use MENOPUR ®

3. How to use MENOPUR ®

4. Possible side effects

5. How to store MENOPUR ®

6. Contents of the pack and other information

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1. What MENOPUR ® is and what it is used for

MENOPUR ® is a highly purified, sterile freeze dried powder for injection. It contains the active ingredient menotrophin with follicle stimulating hormone activity (FSH) and luteinising hormone activity (LH)

MENOPUR ® is used for infertility treatment.

In females:

- Women who cannot become pregnant because their ovaries do not produce eggs (including polycystic ovarian disease).
- Women in assisted reproductive technology programs (ART) (including in vitro fertilisation/embryo transfer [IVF/ET], gamete intra-fallopian transfer [GIFT] and intracytoplasmic sperm injection [ICSI]. MENOPUR ® helps the ovaries to develop many egg sacs (follicles) where an egg might develop (multiple follicular development).

In males:

- To treat low sperm count (oligospermia).

2. What you need to know before you use MENOPUR ®

MENOPUR ® should not be administered to you:

- if you are hypersensitive (allergic) to menotrophin or any of the other ingredients of MENOPUR ® (listed in section 6)
- if you have tumours of the uterus (womb), ovaries, breasts, testicles, prostate, pituitary gland or hypothalamus
- if you have cysts on your ovaries or enlarged ovaries (unless caused by polycystic ovarian disease).
- if you have any physical defects of the uterus (womb) or other sexual organs
- if you suffer from bleeding from the vagina where the cause is not known
- if you have fibroids of the uterus (womb)
- if you are pregnant or breastfeeding

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- if you have experienced an early menopause.

Warnings and precautions

Tell your doctor or health care provider before being given the injection:

- if you experience pain in the abdomen
- if you experience swelling in the abdomen
- if you experience nausea
- if you are vomiting
- if diarrhoea occurs
- if you gain weight
- if you experience difficulty in breathing
- if a decrease in urination occurs.

Tell your doctor straight away; even if the symptoms develop some days after the last injection has been given. These can be signs of high levels of activity in the ovaries which might become severe.

If these symptoms become severe, the infertility treatment should be stopped and you should receive treatment in hospital.

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

If you stop using MENOPUR ® you might still experience these symptoms. Please contact your doctor immediately if any of these symptoms occur (see section 3, 'If you stop using MENOPUR ®').

While you are being treated with MENOPUR ®, your doctor will normally arrange for you to have ultrasound scans and sometimes blood tests to monitor your response to treatment.

Being treated with hormones like MENOPUR ® can increase the risk of:

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- ectopic pregnancy (pregnancy outside of the womb) if you have a history of fallopian tube disease
- miscarriage
- multiple pregnancy (twins, triplets, etc.)
- congenital malformations (physical defects present in baby at birth).

Some women who have been given infertility treatment have developed tumours in the ovaries and other reproductive organs. It is not yet known if treatment with hormones like MENOPUR ® causes these problems.

Infertility treatment can increase the chances of blood clots in the veins especially if you are overweight or if you or someone in your family (blood relative) has had blood clots. Tell your doctor if you think this applies to you.

Special populations

Elderly

MENOPUR ® is not recommended for elderly patients.

Children

MENOPUR ® is not recommended for children.

Other medicines and MENOPUR ®

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Pregnancy, breastfeeding and fertility

You should not use MENOPUR ® if you are pregnant or breastfeeding your baby.

MENOPUR ® is indicated for use in infertility (see section 1).

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult

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your doctor, pharmacist or other health care provider for advice before taking MENOPUR ®.

Driving and using machines

MENOPUR ® may make you feel dizzy which may influence your ability to drive and use machinery.

It is not always possible to predict to what extent MENOPUR ® may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which MENOPUR ® affects them.

MENOPUR ® contains sodium

MENOPUR ® contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to use MENOPUR ®

Do not share medicines prescribed for you with any other person.

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

MENOPUR ® should only be used under the supervision of a medical practitioner suitably qualified in the treatment of infertility

There are many different dosage schemes and your doctor will decide which one is appropriate for you.

In females:

To induce follicular maturation:

In menstruating patients, treatment will be started within the first 7 days of the menstrual cycle. A daily dose of 75 to 150 IU of MENOPUR ® will be given for at least 7 days. The dose may then be adjusted by your doctor, according to your body's response, up to a maximum daily dose of 225 IU of MENOPUR ®.

To induce multiple follicular development:

Stimulation of follicular growth is produced by MENOPUR ® in daily doses of 150 to 225 IU. Treatment will

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be maintained for at least 5 days. A maximum daily dose of 450 IU may be given and treatment beyond 20 days is not recommended.

In males:

Treatment of oligospermia:

MENOPUR ® will be given in a dose of 75 IU every other day. A maintenance of 75 to 150 IU every week is recommended. Treatment will normally continue for at least 90 to 120 days.

Your doctor will tell you how long your treatment with MENOPUR ® will last. If you have the impression that the effect of MENOPUR ® is too strong or too weak, tell your doctor or pharmacist.

Method of administration

MENOPUR ® will be administered as an injection under the skin or in the muscle:

- MENOPUR ® 75 IU is intended for injection under the skin [subcutaneous (S.C.)] or into the muscle [intramuscular (I.M.)], after reconstitution with the solvent provided
- MENOPUR ® 600 IU and 1200 IU are intended for S.C injection as the syringe provided is for S.C. administration only.

If your clinic has asked you to inject MENOPUR ® yourself, you should follow the instructions provided below (see section 6).

The first injection of MENOPUR ® should be given under the supervision of a doctor.

MENOPUR ® is provided as a powder in small bottles (vials) and must be dissolved before it is injected.

The liquid (solvent) which you should use to dissolve MENOPUR ® is provided with the powder.

- MENOPUR ® 75 IU:

- Once MENOPUR ® 75 IU dry powder has been mixed with the solvent it should be used straight away.

- MENOPUR ® 600 IU and 1200 IU:

- The reconstituted solution is intended for multiple uses over a period of 28 days and can be stored below

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30°C.

If you use more MENOPUR ® than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use MENOPUR ®

Do not give a double dose to make up for forgotten individual doses.

Please tell your doctor, nurse or pharmacist.

If you stop using MENOPUR ®

If you stop using MENOPUR ® you might experience some symptoms (see section 2, 'Warnings and precautions'). Please contact your doctor immediately if any of these symptoms occur

4. Possible side effects

MENOPUR ® can have side effects.

Not all side effects reported for MENOPUR ® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using MENOPUR ®, please consult your health care provider for advice.

If any of the following happens, stop using MENOPUR ® and tell your doctor immediately or go to the casualty department at your nearest hospital:

- rash or itching,
- swelling of the throat,
- difficulty in breathing.

These are all very serious side effects. If you have them, you may have had a serious reaction to MENOPUR ®. You may need urgent medical attention or hospitalisation.

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Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following symptoms, even if they develop some days after the last injection has been given.

Treatment with MENOPUR ® may cause high levels of activity in the ovaries leading to a disease called Ovarian Hyperstimulation Syndrome (OHSS), especially in women with polycystic ovaries.

Symptoms include:

- pain and swelling in the abdomen
- nausea
- vomiting
- diarrhoea
- weight gain.

In cases of severe OHSS:

- fluid in abdomen, pelvis and/or chest cavity
- difficulty in breathing
- decreased urination
- formation of blood clots in blood vessels (thromboembolism)
- twisted ovaries (ovarian torsion).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Common side effects:

- overstimulation of the ovaries resulting in high levels of activity (ovarian hyperstimulation syndrome)
- pain in the abdomen
- swelling in the abdomen
- pelvic pain
- injection site pain and reactions (such as redness, bruising, swelling and/or itching)

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- headache
- nausea.

Uncommon side effects:

- vomiting
- discomfort in abdomen
- diarrhoea
- fatigue
- dizziness
- sacs of fluid within ovaries (ovarian cysts)
- breast complaints (include breast pain, breast tenderness, breast discomfort, nipple pain and breast swelling)
- hot flushes

Rare side effects:

- acne
- rash.

Unknown side effects: (the frequency of these side effects reported during post-marketing experience is not known)

- twisted ovaries (ovarian torsion)
- fever
- blood clots in your legs (venous thrombosis, pulmonary embolism)
- eyesight disturbances
- feeling sick
- increase in weight
- pains in muscle and joint e.g. back pain, neck pain and pain in arms and legs

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- itching
- hives.

In men, the following side effects were observed since MENOPUR ® has been marketed and frequency of these side effects is unknown:

- enlargement of the male breast tissue known as gynaecomastia
- acne
- weight gain
- administration site reactions and hypersensitivity may occur.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/documents/adverse-drug-reactions-and-quality-problem-reporting-form. By reporting side effects, you can help provide more information on the safety of MENOPUR ®.

5. How to store MENOPUR ®

MENOPUR ® 75 IU and MENOPUR ® SOLVENT:

- Store all medicines out of reach of children.
- Do not store above 30 ºC.
- Do not freeze.
- Store in the original container.
- Protect from light.
- For immediate and single use following reconstitution.
- Discard any unused portion.

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- Do not use this medicine after the expiry date stated on the container.
- Return all unused medicine to your pharmacist.

MENOPUR ® 600 IU and 1200 IU:

- Store all medicines out of reach of children.
- Prior to reconstitution: Store in a refrigerator (2 °C to 8 ºC). Do not freeze.
- Store in the original container, within the outer carton until required for use.
- After reconstitution: The solution can be stored for a maximum of 28 days below 30 ºC. Do not freeze.
- The reconstituted solution should not be administered if it contains particles or is not clear.
- Do not use MENOPUR ® after the expiry date which is stated on the carton.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MENOPUR ® contains

MENOPUR ® 75 IU:

- The active substance is menotrophin.

MENOPUR ® 75 IU is a highly purified, sterile freeze dried powder for injection. It contains the active ingredient menotrophin with follicle stimulating hormone activity (FSH) 75 IU and luteinising hormone activity (LH) 75 IU.

- The other ingredients are:

Powder: lactose monohydrate, polysorbate 20, sodium hydroxide, and hydrochloric acid.

MENOPUR ® SOLVENT: water for injection, sodium chloride and diluted hydrochloric acid.

MENOPUR ® 600 IU:

- The active substance is menotrophin.

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Each vial with powder contains highly purified menotrophin (human menopausal gonadotrophin, hMG) corresponding to follicle stimulating hormone activity (FSH) 600 IU and luteinising hormone activity (LH) 600 IU.

- The other ingredients are:

Powder: lactose monohydrate, polysorbate 20, sodium phosphate dibasic heptahydrate and phosphoric acid (concentrated).

Solvent: metacresol (0,33 % *m/v*) as preservative and water for injection.

MENOPUR ® 1200 IU:

- The active substance is menotrophin.

Each vial with powder contains highly purified menotrophin (human menopausal gonadotrophin, hMG) corresponding to follicle stimulating hormone activity (FSH) 1200 IU and luteinising hormone activity (LH) 1200 IU.

- The other ingredients are:

Powder: lactose monohydrate, polysorbate 20, sodium phosphate dibasic heptahydrate and phosphoric acid (concentrated).

Solvent: metacresol (0,33 % *m/v*) as preservative and water for injection.

Instructions for use

MENOPUR ® 75 IU:

Attach a reconstitution needle to the syringe. Withdraw the entire content from the ampoule with solvent and inject the total contents into the vial containing the powder. The powder should dissolve quickly to a clear solution. If not, roll the vial gently between the hands until the solution is clear. Shaking should be avoided.

In order to avoid the injection of large volumes up to 3 vials of the powder may be dissolved in 1 mL of the solvent provided

If needed, the solution can be drawn up into the syringe again to transfer it to the next vial with powder until the prescribed dose has been reached.

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When the prescribed dose has been reached, draw up the mixed solution from the vial into the syringe, change to a hypodermic needle and administer immediately (refer to step 9 below).

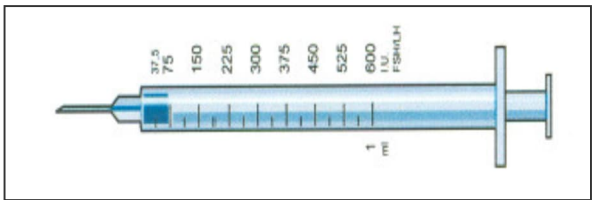
MENOPUR ® 600 IU and 1200 IU:

MENOPUR ® 600 IU must be dissolved with one pre-filled syringe with solvent before use.

MENOPUR ® 1200 IU must be dissolved with two pre-filled syringes with solvent before use.

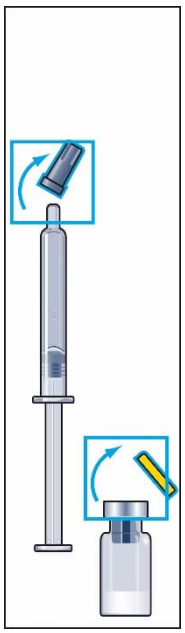
After dissolving the powder with the solvent, this vial contains medication for several days of treatment; you need to make sure you only draw up the amount of medication that was prescribed by your doctor.

Your doctor has prescribed you a dose of MENOPUR ® in IU (units). To obtain the correct dose you should use one of the administration syringes graduated in FSH/LH units provided.



***Step 1*:**

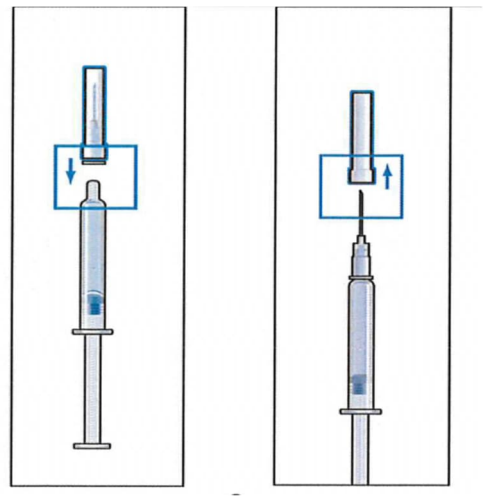
Remove the protective cap from the vial of powder and the rubber syringe cap from the pre-filled syringe with solvent.



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***Step 2*:**

Firmly attach the thick needle (reconstitution needle) to the pre-filled syringe with solvent and remove the protective cap from the needle.

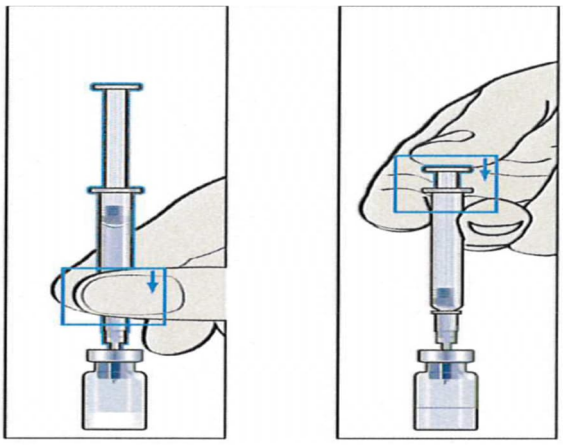


***Step 3*:**

MENOPUR ® 600 IU:

Insert the needle vertically through the centre of the rubber top of the powder vial and slowly inject all of the solvent to avoid creating bubbles.

Make sure to use one (1) pre-filled syringe of the solvent for MENOPUR ® 600 IU



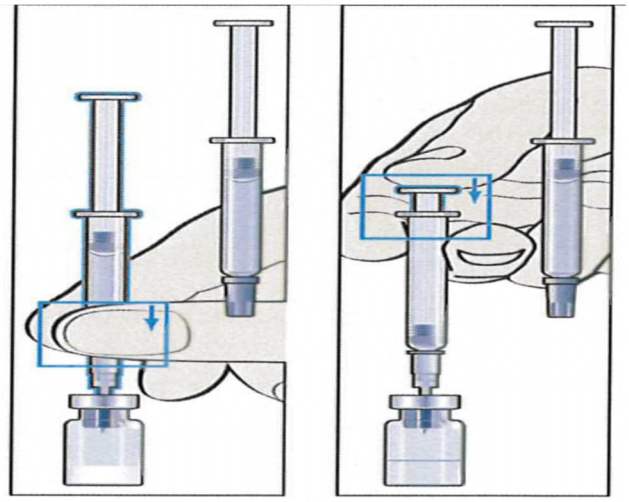
MENOPUR ® 1200 IU:

Insert the needle vertically through the centre of the rubber top of the powder vial and slowly inject all of the

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solvent to avoid creating bubbles.

Make sure to use two (2) pre-filled syringes of the solvent for MENOPUR ® 1200 IU.

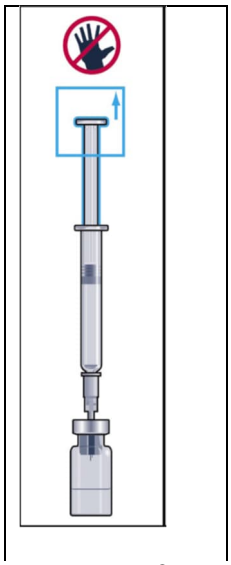


***Step 4*:**

MENOPUR ® 600 IU:

When adding the solvent a slight over-pressure is created in the vial. Therefore, let go of the syringe plunger to let it rise up by itself for about 10 seconds. This will remove the over-pressure in the vial.

Remove the syringe and the needle for reconstitution.



MENOPUR ® 1200 IU:

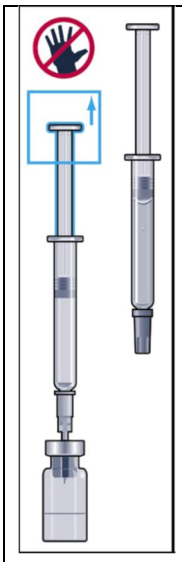
a) When adding the solvents a slight over-pressure is created in the vial. Therefore, let go of the syringe plunger to let it rise up by itself for about 10 seconds. This will remove the over-pressure in the vial.

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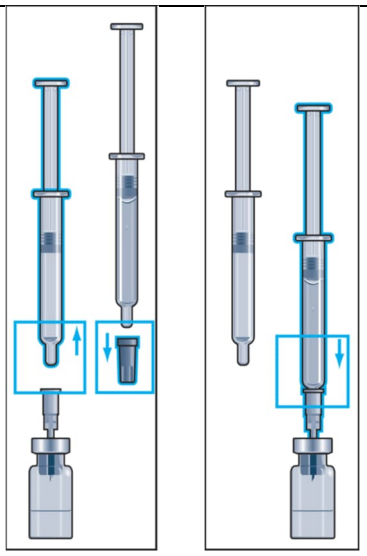
b) Gently remove the syringe from the needle with a twist, leaving the needle in the vial. Remove the rubber cap from the second pre-filled syringe with solvent and firmly attach the syringe to the needle fixed in the vial. Slowly inject all of the solvent to avoid creating bubbles.

c) Let go of the syringe plunger to let it rise up by itself for about 10 seconds. This will remove the over-pressure in the vial.

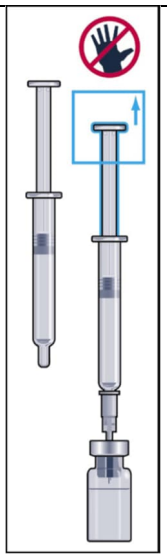
Remove the syringe and the needle for reconstitution.



a)



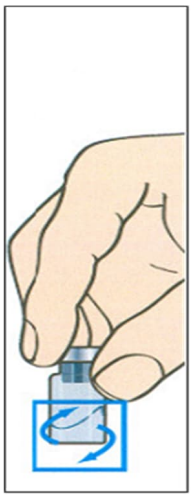
b)



c)

Step 5:

The powder should quickly dissolve (within 2 minutes) to form a clear solution. To help the powder dissolve, swirl the solution. Do not shake as this will cause air bubbles to form.



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If the solution is not clear or if it contains particles, it ***should not*** *be used.*

MENOPUR ® 600 IU:

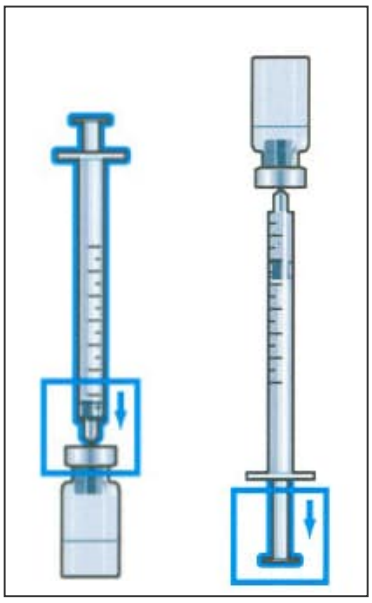
The vial with MENOPUR ® 600 IU powder is now dissolved with one syringe with solvent and ready to use.

MENOPUR ® 1200 IU:

The vial with MENOPUR ® 1200 IU powder is now dissolved with two syringes with solvent and ready to use.

Step 6:

Take the administration syringe with pre-fixed needle and insert the needle vertically into the centre of the vial. The administration syringe already contains a small amount of air, which should be injected in the vial above the liquid. Turn the vial upside down and draw the prescribed dose of MENOPUR ® into the administration syringe for injection.



Remember: as this vial contains medication for several days of treatment, you need to make sure you only draw up the amount that was prescribed by your doctor.

Step 7:

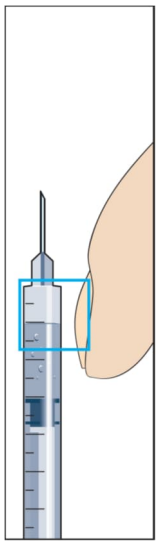
Remove the syringe from the vial and draw a small amount of air into the syringe.

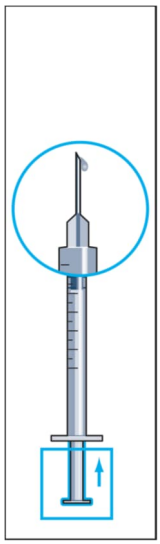
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Step 8:

Gently flick the administration syringe so that any air bubbles will be collected in the tip. Depress the plunger carefully until the first drop of solution comes out from the needle.





Your doctor or nurse will tell you where to inject (e.g. front of the thigh or abdomen). Before Injection, disinfect the injection site with alcohol pads.

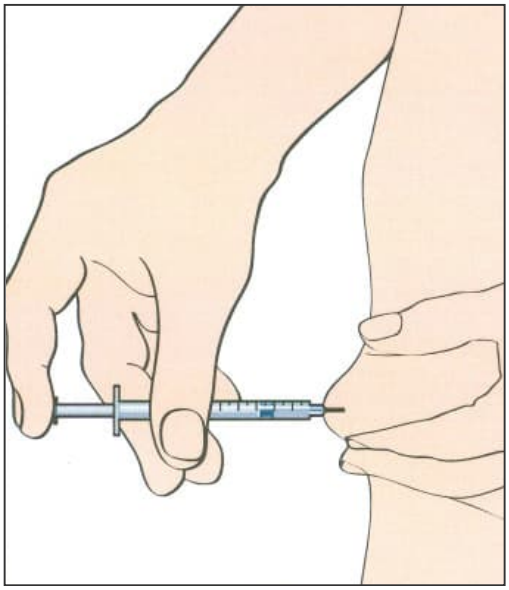
Step 9:

To inject, pinch the skin to produce a fold, and insert the needle in one swift motion at 90 degrees to the body. Press down on the plunger gently to inject the solution and then remove the administration syringe.

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After removing the syringe, apply pressure to the injection site to stop any bleeding. Gently massaging the injection site will help to disperse the solution under the skin.

Do not put used items into normal domestic waste; these should be disposed of appropriately.



Step 10:

For further injections with the reconstituted solution of MENOPUR ®, repeat step 6 to 9.

What MENOPUR ® looks like and contents of the pack

MENOPUR ® 75 IU: Powder for solution for injection is a white to off-white lyophilised cake.

MENOPUR ® SOLVENT: Solution for injection is a clear colourless solution.

The reconstituted solution is a clear colourless solution free from any foreign particles.

Contents of the pack:

MENOPUR ® 75 IU: 2 R (2 mL) x 1 colourless glass (Type 1) vials with rubber stopper closed with a cap.

MENOPUR ® SOLVENT: 1 mL colourless glass (Type 1) ampoule.

MENOPUR ® 75 IU is supplied in packs of 10 vials with the corresponding number of MENOPUR ® SOLVENT ampoules.

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MENOPUR ® 600 IU:

Powder: white to off-white lyophilisation cake.

Solvent: clear colourless solution free from any foreign particles.

Contents of the pack:

Powder: 2 mL colourless glass (type 1 glass) vial with a rubber stopper closed with a cap.

Solvent: 1 mL pre-filled syringe (type 1 glass) with rubber tip cap and plunger rubber stopper.

MENOPUR ® 600 IU is supplied as a pack of 1 vial of powder, 1 pre-filled syringe with solvent for reconstitution, 1 needle for reconstitution and 9 disposable syringes for administration graduated in FSH/LH units with prefixed needles.

MENOPUR ® 1200 IU:

Powder: white to off-white lyophilisation cake.

Solvent: clear colourless solution free from any foreign particles.

Contents of the pack:

Powder: 2 mL colourless glass (type 1 glass) vial with a rubber stopper closed with a cap.

Solvent: 1 mL pre-filled syringe (type 1 glass) with rubber tip cap and plunger rubber stopper

MENOPUR ® 1200 IU is supplied as a pack of 1 vial of powder, 2 pre-filled syringes with solvent for reconstitution, 1 needle for reconstitution and 18 disposable syringes for administration graduated in FSH/LH units with prefixed needles.

Holder of Certificate of Registration

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This leaflet was last revised in

12 May 2025

Registration numbers

MENOPUR ® 75 IU: A39/21.10/0357

MENOPUR ® SOLVENT: A39/34/0412

MENOPUR ® 600 IU: A44/21.10/0382

MENOPUR ® 1200 IU: A44/21.10/0383

Namibia		
NS2	MENOPUR ® 75 IU Powder and solvent for solution for injection	07/21.10/0085
NS2	MENOPUR ® 600 IU Powder for solution for injection	18/21.10/0118
NS2	MENOPUR ® 1200 IU Powder for solution for injection	18/21.10/0119
NS2	MENOPUR ® 600 IU & 1200 IU Solvent for solution for injection:	18/34/0128

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