

PACKAGE LEAFLET: INFORMATION FOR THE USER

MERIOFERT PFS 900 IU
powder and solvent for solution for injection

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, please ask your doctor, pharmacist or nurse
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4
- In this leaflet, MERIOFERT PFS 900 IU powder and solvent for solution for injection is called MERIOFERT PFS.

What is in this leaflet:

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

1. What <MERIOFERT PFS > is and what it is used for

- MERIOFERT PFS is used to promote ovulation in women who are not ovulating and who have not responded to other treatment (clomiphene citrate)
- MERIOFERT PFS is used to bring about the development of several follicles (and therefore several eggs) in women receiving fertility treatment.

MERIOFERT PFS is a highly purified human menopausal gonadotrophin, belonging to a group of medicines called gonadotrophins.

Each multidose vial contains freeze-dried powder with 900 IU human follicle stimulating hormone activity (FSH) and 900 IU human luteinising hormone activity (LH).

Human menopausal gonadotrophin (HMG) is extracted from urine of post-menopausal women. Human chorionic gonadotrophin (hCG), a hormone extracted from urine of pregnant women, is added to contribute to the total LH activity.

This medicinal product must be used under the supervision of your doctor.

2. What you need to know before you use MERIOFERT PFS

You and your partner's fertility will be evaluated before your treatment is started.

Do not use MERIOFERT PFS if you have any of the following:

- Enlarged ovaries or cysts not caused by a hormonal disorder (polycystic ovarian disease)
- Bleeding of unknown cause
- Cancer of the ovaries, uterus or breast
- Abnormal swelling (tumour) of the pituitary gland or hypothalamus (brain)
- If you are allergic to menotrophin or any of the ingredients in this medicine (listed in section 6).

This medicine should not be used if you have an early menopause, a malformation of the sexual organs or certain tumours of the womb that would make a normal pregnancy impossible.

Warnings and Precautions

Although no allergic reactions to MERIOFERT PFS have yet been reported, you should tell your doctor if you have an allergic reaction to similar medicines.

This treatment increases your risk of developing a condition known as **ovarian hyperstimulation syndrome (OHSS)** (see Possible side effects). If ovarian hyperstimulation occurs then your treatment will be stopped and pregnancy will be avoided. The first signs of ovarian hyperstimulation are pain in the lower abdominal region as well as nausea (feeling sick), vomiting and weight gain. If these symptoms occur you should be examined by your doctor as soon as possible. In serious, but rare cases, the ovaries can become enlarged and fluid can build up in the abdomen or chest.

The drug used to bring about the final release of mature eggs (containing hCG) can increase the likelihood of OHSS. It is therefore not advisable to use hCG in cases where OHSS is developing and you should not have sexual intercourse even if using a barrier method of contraception for at least 4 days.

It should be noted that women with fertility problems have a higher rate of miscarriages than the normal population.

In patients having treatment to help ovulation, the occurrence of multiple pregnancies and births is increased compared to natural conception. However, this risk can be minimised by using the recommended dose.

There is a slightly increased risk of extra-uterine pregnancy (an ectopic pregnancy) in women with damaged fallopian tubes.

Multiple pregnancies and characteristics of the parents undergoing fertility treatments (e.g. maternal age, sperm characteristics) may be associated with an increased risk of birth defects.

Treatment with MERIOFERT PFS, just as pregnancy itself, may increase the chance of having thrombosis. Thrombosis is the formation of a blood clot in a blood vessel, most often in the veins of the legs or the lungs.

Please discuss this with your doctor, before starting treatment, especially:

- If you already know you have an increased chance of having thrombosis
- If you, or anyone in your immediate family, have ever had a thrombosis
- If you are severely overweight.

Children

The medicine is not intended for use in children.

Other medicines and MERIOFERT PFS

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

Pregnancy, breast-feeding and fertility

MERIOFERT PFS should not be used if you are pregnant or breast-feeding.

Driving and using machines

MERIOFERT PFS has no or negligible influence on the ability to drive and use of machinery.

MERIOFERT PFS contains sodium

This medicine contains less than 1 mmol of sodium (23 mg) per reconstituted solution, that it is to say essentially “sodium free”.

3. How to use MERIOFERT PFS

Dosage and duration of the treatment:

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

Women who are not ovulating and are having irregular periods or no periods at all:

As a general rule, the first injection of 75 IU of menotrophin is given during the first week of the cycle after spontaneous or induced menses.

Subsequently, MERIOFERT PFS is injected daily at the dosage prescribed by the physician and the treatment will continue until one or more ripe follicle have developed in the ovary. Your physician will adjust the MERIOFERT PFS dosage depending on the ovarian response, which is determined by clinical examinations.

As soon as one follicle reaches the required development stage, the MERIOFERT PFS treatment will be withheld and ovulation will be triggered with another hormone (chorionic gonadotropin, hCG).

Ovulation generally takes place after 32 to 48 hours.

In this phase of the treatment, fertilization is possible. You will be advised to have sexual intercourse every day starting from the day preceding the administration of hCG. If pregnancy is not achieved in spite of ovulation, the treatment can be repeated.

Women undergoing ovarian stimulation for multiple follicular development prior to in vitro fertilisation or other assisted reproductive techniques:

The aim of this method is to obtain concomitant multiple follicular development. The treatment will start on the 2nd or 3rd day of the cycle with injections of 150-300 IU of MERIOFERT PFS. Your physician may decide to administer higher dosages if required. The injected dosage of MERIOFERT PFS is higher than in the method used for natural fertilization. The continuation of the treatment is adjusted individually by the physician.

As soon as a sufficient number of follicles has developed, the treatment with MERIOFERT PFS is withheld and ovulation is triggered by injecting another hormone (chorionic gonadotropin, hCG).

How MERIOFERT PFS should be given:

MERIOFERT PFS is given by injection under your skin (by the subcutaneous route)

Each vial should be reconstituted only once and each single injection should be performed as soon as the needed dose is drawn up.

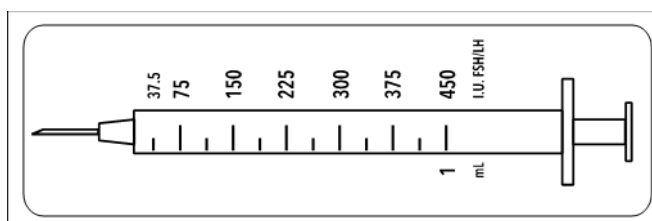
After suitable advice and training your doctor may ask you to inject MERIOFERT PFS yourself.

Before your first injection, your doctor must:

- Let you practise giving yourself a subcutaneous injection
- Have shown you the possible places where you can inject yourself
- Have shown you how to prepare the solution for injection
- Have explained how to prepare the right dose of injection.

Before injecting MERIOFERT PFS yourself, read the following instructions carefully.

As 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 MERIOFERT PFS in IU (units). To obtain the correct dose you should use one of the 12 administration syringes graduated in FSH/LH IU units provided.



These syringes are intended for single use only and should be disposed of after each administration according to local requirements and in an appropriate container.

How to prepare and inject 1 vial of MERIOFERT PFS :

The solution for injection containing 900 IU of menotrophin must be prepared just before you are ready take your first dose, by adding the solvent for reconstitution in prefilled syringe, (included in each pack) to the vial containing powder.

Prepare a clean surface and wash your hands with soap and warm water. It is important that your hands and the items you use are as clean as possible.

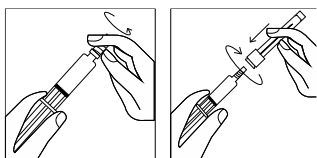
Gather the following supplies:

- the vial containing MERIOFERT PFS powder
- the prefilled syringe containing solvent for reconstitution
- the needle for preparing the reconstitution
- one disposable syringe with staked-in needle for subcutaneous administration graduated in FSH/LH units
- one alcohol swab
- cotton and disinfectant solution (not provided in the pack)

REMEMBER Prior to reconstitution and each administration, disinfect the rubber top of the vial containing the reconstituted solution with cotton and disinfectant (i.e. alcoholic solution) and allow to dry.

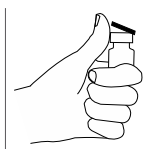
Reconstitution of the solution for injection

Preparing the pre-filled syringe:

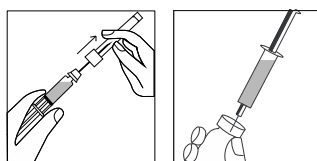


1.
 - Remove the cap from the pre-filled syringe containing solvent; attach the reconstitution needle with its protective cap still on to the syringe.
 - Carefully place the syringe on the clean surface.

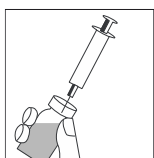
Preparing the vial:



2.
 - Remove the coloured plastic flip-off cap from the vial by gently pushing it upwards with your thumb.
 - Wipe the rubber top with cotton and disinfectant solution and allow to dry.



3.
 - Pick up the syringe, remove the protective cap of the needle and push the needle through the rubber middle of the vial top.
 - Press the plunger down firmly to empty all the solution onto the powder.
 - 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 overpressure in the vial.



DO NOT SHAKE the reconstituted solution, but gently swirl until the solution is clear.

Generally, MERIOFERT PFS dissolves immediately.

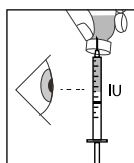
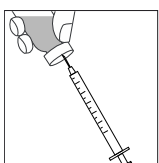
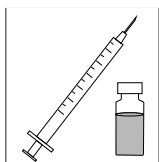
Check that the reconstituted solution is clear.

Before the injection:

4.
 - Check whether the reconstituted solution is clear, colourless and free from particles. DO NOT USE if the solution contains particles, is cloudy or is not colourless.
 - Clean the rubber stopper of the vial with cotton and a disinfectant solution.

Preparing the injection:

5.



- Take one of the provided disposable syringes with staked-in needle, remove the protective cap of the needle and insert the needle vertically into centre of the vial top.
- Push the plunger till it is completely depressed.
- Turn the vial upside down. Ensure that the needle is under the surface of the medicine and draw the prescribed dose of MERIOFERT PFS into the administration syringe.
- Remove the needle from the vial. Hold the syringe with the needle pointing upwards and gently tap the side of the syringe to force any air bubbles up to the top.
- Push the plunger slowly until a bead of liquid appears at the tip of the needle.

REMEMBER: As this vial contains medication for several days of treatment, you must make sure you only draw up the amount of medication that was prescribed by your doctor.

Administering the injection

The injection site:



- Your doctor or nurse will have already advised you where on your body to inject your medicine. The usual places are the thigh or the lower abdominal wall below the navel
- Wipe the injection site with an alcohol swab.
- Firmly pinch the skin together. With the other hand, insert the needle with a dart-like motion at an angle of 45° or 90°.

Injecting the solution:

- Inject under the skin as you were shown. Do not inject directly into a vein. Push the plunger slowly and steadily, so the solution is correctly injected and the skin tissues are not damaged.

Take as much time as you need to inject the volume of solution prescribed.

Pull the needle straight out and apply pressure to the injection site with cotton and disinfectant. Gentle massage the site – while still maintaining pressure – this will help disperse the medicine and relieve any discomfort.

Next further injections:

For the next injections with the reconstituted solution of MERIOFERT PFS repeat from step 4 onwards.

If you use more MERIOFERT PFS than you should:

The effects of an overdose of MERIOFERT PFS are unknown, nevertheless, one could expect ovarian hyperstimulation syndrome to occur (see Possible side effects). If you use more MERIOFERT PFS than you should, speak to your doctor or nurse.

If you forget to use MERIOFERT PFS:

Take it at the next normal time for an injection. Do not take double dose to make up for a forgotten dose.

If you stop using MERIOFERT PFS:

Do not stop on your own initiative. Always consult your doctor before stopping this medicine.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, MERIOFERT PFS can cause side effects, although not everybody gets them.

The following side effect is important and will require immediate action if you experience it. You should stop taking MERIOFERT PFS and see your doctor immediately if the following occurs:

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

- Ovarian Hyperstimulation Syndrome (symptoms include ovarian cyst formation or enlargement of existing cysts, lower stomach pain, feeling thirsty and sick, and sometimes being sick, passing reduced quantities of concentrated urine and weight gain) (see Section 2 for additional information).

The following side-effects have also been reported:

Very Common (may affect more than 1 in 10 people):

- Headache
- Swollen or bloated stomach.

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

- Abdominal pain or discomfort
- Pelvic pain
- Back pain
- Sensation of heaviness

- Breast discomfort
- Dizziness
- Hot flushes
- Thirst
- Feeling sick
- Tiredness
- Feeling generally unwell
- Injection site reaction such as pain and inflammation (frequency higher with IM than SC).

Rare: (may affect up to 1 in 1,000 people):

- Ovarian torsion (twisting of the ovary which causes extreme pain in the lower abdomen).
- Thromboembolism (formation of a clot in a blood vessel that breaks loose and is carried by the blood stream to block another vessel).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store MERIOFERT PFS

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 outer carton, the vial and the prefilled syringe of solvent. If the expiry date is reported as month/year, the expiry date refers to the last day of that month.

Before reconstitution: Store 2-8°C.

After reconstitution, the solution may be stored for a maximum of 28 days at not more than 25°C.

Do not freeze before or after reconstitution.

Do not use MERIOFERT PFS if you notice the solution does not look clear. After reconstitution the solution must be clear and colourless.

Do not dispose of 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 MERIOFERT PFS contains

The active substance is menotrophin.

Each multidose vial contains freeze-dried powder with 900 IU human follicle stimulating hormone activity (FSH) and 900 IU human luteinising hormone activity (LH). Human menopausal gonadotrophin (HMG) is extracted from urine of post-menopausal women. Human chorionic gonadotrophin (hCG), a hormone extracted from urine of pregnant women, is added to contribute to the total LH activity.

The other excipients are

For the powder: lactose monohydrate, polysorbate 20, disodium phosphate dihydrate, phosphoric acid and sodium hydroxide.

For the solvent: metacresol and water for injection.

What MERIOFERT PFS looks like and contents of the pack

Powder: white to almost white lyophilized powder.

Solvent: clear and colourless solution.

MERIOFERT PFS is presented as a powder and solvent for solution for injection.

1 set contains the following:

- 1 vial containing MERIOFERT PFS powder
- 1 prefilled syringe containing solvent for reconstitution
- 1 needle for reconstitution
- 12 alcohol swabs for multiple injections
- 12 disposable syringes with staked-in needles for multiple injections

Marketing Authorisation Holder:

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