Meriofert 75 IU
Meriofert 150 IU
powder and solvent for solution for injection

menotrophin

FI/158 (UK) 5000003264 Rev. 05 07.24

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 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.
- In this leaflet Meriofert 75 IU powder and solvent for solution for injection and Meriofert 150 IU powder and solvent for solution for injection are called Meriofert.

What is in this leaflet:

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

1. WHAT MERIOFERT IS AND WHAT IT IS USED FOR

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

Meriofert is a highly purified human menopausal gonadotrophin, belonging to a group of medicines called gonadotrophins.
Each vial contains freeze-dried powder with 75 IU human follicle stimulating hormone activity (FSH) and 75 IU human luteinising hormone activity (LH).
Human menopausal Gonadotrophin (HMG) is extracted from urine of post-menopausal women.Human Chorionic Gonadotrophin (hCG), a hormone naturally extracted from urine of pregnant women, is added to contribute to the total LH activity.

Each vial contains freeze-dried powder with 150 IU human follicle stimulating hormone activity (FSH) and 150 IU human luteinising hormone activity (LH).
Human menopausal Gonadotrophin (HMG) is extracted from urine of post-menopausal women.
Human Chorionic Gonadotrophin (hCG), a hormone naturally 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

You and your partner's fertility will be evaluated before your treatment is started.
Do not use Meriofert 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).
- Hypersensitivity (allergy) to menotrophin or any of the ingredients in Meriofert

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 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 human chorionic gonadotrophin-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, 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
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 should not be used if you are pregnant or breast-feeding.

Driving and using machines
Meriofert has no or negligible influence on the ability to drive and use of machinery.

Meriofert 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

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 one Meriofert 75 IU vial is given during the first week of the cycle after spontaneous or induced menses.
Subsequently, Meriofert 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 dosage depending on the ovarian response, which is determined by clinical examinations.
As soon as one follicle reaches the required development stage, the Meriofert 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 (1-2 vials of Meriofert 150 IU). Your physician may decide to administer higher dosages if required. The injected dosage of Meriofert 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 is withheld and ovulation is triggered by injecting another hormone (chorionic gonadotropin, hCG).

How Meriofert should be given:

Meriofert is given by injection under your skin (by the subcutaneous route) or into your muscle (intramuscular injection).
Each vial should be used only once and the injection should be used as soon as it is prepared.

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

For the first time, 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 yourself, read the following instructions carefully.

How to prepare and inject Meriofert using 1 vial of powder:
The solution must be prepared just before injection. One vial is for single use only. The medicinal product must be reconstituted under aseptic conditions.
Meriofert must only be reconstituted with the solvent provided in the package.

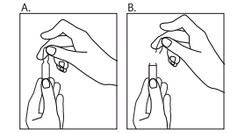
Prepare a clean surface and wash your hands before the solution is reconstituted. It is important that your hands and the items you use are as clean as possible.

Set out all the following items on the clean surface:

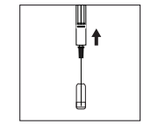
- two cotton wool alcohol swabs (not provided),
- one vial containing Meriofert powder,
- one solvent in ampoule,
- one syringe (not provided),
- one needle for preparing the injection (not provided),
- a fine bore needle for subcutaneous injection (not provided).

<u>Reconstitution of the solution for injection using 1 vial of powder</u>

Prepare the solution for injection:

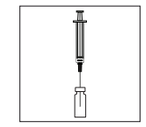


1.
The ampoule neck is specifically designed to break more easily below the coloured dot. Gently flick the top of the ampoule to dislodge any liquid remaining in the tip. Hold the ampoule with the coloured dot facing away from you and snap off the top of the ampoule as shown in the picture. Using a cloth or ampoule-snapper to hold the ampoule will help protect your fingers.
Carefully place the opened ampoule upright on the cleaned surface.



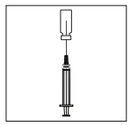
Remove the protective cap of the needle. Attach the reconstitution needle (large needle) to the syringe.
With the syringe in one hand, pick up the opened solvent ampoule, insert the needle and draw up the entire content of the ampoule into the syringe.
Attach the protective cap of the needle.
Carefully set the syringe down on the surface.

2.
Remove the coloured plastic cap (75 IU light green, 150 IU dark green) from the powder vial by gently pushing it upwards.
Disinfect the top of the rubber stopper by wiping it with an alcohol swab and allow to dry.



3.
Pick up the syringe, remove the needle shield and slowly inject the solvent into the powder vial through the middle of the top of the rubber stopper.
Press the plunger down firmly to squirt all

the solution onto the powder.
DO NOT SHAKE, but gently roll the vial between the hands until the powder is completely dissolved, taking care to avoid creating foam



4.
Once the powder is dissolved (which, in general, occurs immediately), slowly draw the solution into the syringe:
- With the needle still inserted, turn the vial upside down.
- Make sure the needle tip is underneath the level of the liquid.
- Gently pull the plunger to draw all the solution up into the syringe.
- Check that the reconstituted solution is clear and colourless.

<u>Preparation of higher doses, using more than 1 vial of powder</u>

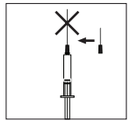
If your doctor has recommended higher doses for you, this can be achieved by using more than one vial powder with one ampoule of solvent.

When reconstituting more than 1 vial of Meriofert , at the end of step 4 above, draw the reconstituted contents of the first vial back into the syringe and slowly inject into a second vial. Repeat steps 2 to 4 for the second and subsequent vials, and until the contents of the required number of vials equivalent to the prescribed dosage are dissolved (within the limit of the maximum total dosage of 450 IU, corresponding to a maximum of 6 vials of Meriofert 75 IU or 3 vials of Meriofert 150 IU).

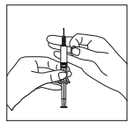
Your doctor may increase your dose by 37.5 IU which represents half a vial of Meriofert 75 IU. For this you should reconstitute the contents of the 75 IU vial according to steps 2 to 3 described above and draw half of this reconstituted solution (0.5 ml) back into the syringe according to step 4.
In that situation you will have two preparations to be injected: the first preparation reconstituted in 1 ml and the second containing 37.5 IU in 0.5 ml.
Both preparations will be injected with their own syringe according to the following steps.

The solution must be clear and colourless.

Injecting your medicine subcutaneously:



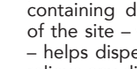
- When the syringe contains the described dose, attach the protective cap of the needle. Remove the needle from the syringe and replace it with the fine bore needle for subcutaneous injection including its protective cap.



- Push the fine bore needle firmly onto the syringe barrel, then twist it slightly to ensure it is fully screwed on and to create a firm seal.
- Remove the protective cap of the needle. 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 until a bead of liquid appears at the tip of the needle.
- Do not use if it contains any particles or is cloudy.

<u>The injection site:</u>
- 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.

<u>Inserting the needle:</u>



- Firmly pinch the skin together. With the other hand, insert the needle with a dart-like motion at an angle of 45° or 90°.

<u>Injecting the solution:</u>
- 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. As described for the preparation of the solution, depending on the dosage prescribed by your doctor, you may not use the entire volume of the solution.

<u>Removing the needle:</u>
- Pull the syringe out quickly and apply pressure to the injection site with a swab containing disinfectant. A gentle massage of the site – while still maintaining pressure – helps disperse the Meriofert solution and relieve any discomfort.

Injecting your medicine intramuscularly:
For intramuscular injections your healthcare provider will prepare and then inject Meriofert into the side of your thigh or buttock.
Dispose of all used items:
Once you have finished your injection, all the needles and empty syringes should be disposed of in an appropriate container. Any unused solution or waste material should be disposed of in accordance with local requirements.

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

If you forget to use Meriofert :
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 :
Do not stop on your own initiative: Always consult your doctor if you are considering 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 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 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).

<u>Reporting of side effects</u>
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 the Yellow Card Scheme 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

Keep this medicine out of the sight and reach of children.

Do not store above 25° C. Keep the vial and the ampoule of solvent in the outer carton in order to protect from light.

Do not use this medicine after the expiry date which is stated on the outer carton, the vial and the ampoule of solvent. If the expiry date is reported as month/year, the expiry date refers to the last day of that month.

Use immediately after reconstitution.

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

Do not throw away any medicines via wastewater. 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 contains
The active substance is menotrophin.

Each vial contains freeze-dried powder with 75 IU human follicle stimulating hormone activity (FSH) and 75 IU human luteinising hormone activity (LH).
Human menopausal Gonadotrophin (HMG) is extracted from urine of post-menopausal women.
Human Chorionic Gonadotrophin (hCG), an hormone extracted from urine of pregnant women, is added to contribute to the total LH activity.

Each vial contains freeze-dried powder with 150 IU human follicle stimulating hormone activity (FSH) and 150 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.

If multiple vials of powder are used, the amount of menotrophin contained in 1 ml of reconstituted solution will be as follows:

Meriofert 75 IU powder and solvent for solution for injection	
Number of vials used	Total amount of menotrophin in 1 ml of solution
1	75 IU
2	150 IU
3	225 IU
4	300 IU
5	375 IU
6	450 IU

Meriofert 150 IU powder and solvent for solution for injection	
Number of vials used	Total amount of menotrophin in 1 ml of solution
1	150 IU
2	300 IU
3	450 IU

The other excipients are
For the powder: lactose monohydrate.
For the solvent: 9 mg/ml sodium chloride and water for injections.

What Meriofert looks like and contents of the pack
Powder: white freeze-dried plug or powder
Solvent: clear and colourless solution.

Meriofert is presented as a powder and solvent for solution for injection.
1 set contains the following:
- One vial containing a white freeze-dried plug or powder
- One ampoule (1 ml) containing a clear and colourless solution

It comes in pack sizes of 1, 5 or 10 sets.
Not all pack sizes may be marketed.

<u>Marketing Authorisation Holder:</u>
IBSA Farmaceutici Italia srl
Via Martiri di Cefalonia, 2
26900 Lodi – Italy

<u>Manufacturer:</u>
IBSA Farmaceutici Italia srl
Via Martiri di Cefalonia, 2
26900 Lodi – Italy

<u>Batch release for UK(NI) only:</u>
IBSA Pharma Limited
Units 4-6 Colonial Business Park,
Colonial Way,
Watford WD24 4PR, UK

This medicinal product is authorized in the Member States of the EEA under the following names: (The strength and pharmaceutical form are identical in all countries, only the trade name changes)

<u>Austria:</u> Meriofert
<u>Belgium:</u> Fertinorm
<u>Bulgaria:</u> Meriofert
<u>Cyprus:</u> Meriofert
<u>Czech Republic:</u> Meriofert
<u>Denmark:</u> Meriofert
<u>Estonia:</u> Meriofert
<u>Finland:</u> Meriofert
<u>France:</u> Fertistart
<u>Greece:</u> Meriofert
<u>Hungary:</u> Meriofert
<u>Italy:</u> Meriofert
<u>Latvia:</u> Meriofert
<u>Lithuania:</u> Meriofert
<u>Luxembourg:</u> Fertinorm
<u>Norway:</u> Meriofert
<u>Poland:</u> Mensinorm
<u>Romania:</u> Meriofert
<u>Slovakia:</u> Meriofert
<u>Spain:</u> Meriofert
<u>Sweden:</u> Meriofert
<u>The Netherlands:</u> Meriofert
<u>United Kingdom:</u> Meriofert

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder via medinfo.uk@ibsagroup.com.

This leaflet was last revised in 05/2024

APPROVAZIONE
APPROVAL

Technical Packaging:	Livelli *Levels* Si/ Yes [X] NO [ ] Testo in traccia *Outline text* Si/ Yes [X] NO [ ] Sovrastampa *Overprinting* Si/ Yes [ ] NO [X] File conforme *Compliant file* Si/ Yes [X] NO [ ] Data/ Date 17.07.2024 Firma/ Signature Elena Moretti
Marketing/ Client:	Grafica *Graphic* [ ] Colori *Colors* [ ] Richiesta prova stampa *Printing proof required* [ ] Presenza avvio stampa *Start printing presence required* [ ] Data/ Date _____ Firma/ Signature _____
Regulatory Affairs:	Testo *Text* [ ] Conformità testo con layout/grafica registrata e approvata nel dossier [ ] *Text and Compliance to the product dossier* Data/ Date _____ Firma/ Signature _____

DIMENSIONE E POSIZIONE DEL BRAILLE SULLA BOZZA GRAFICA SONO INDICATIVI
BRAILLE DIMENSIONS AND POSITION ARE INDICATIVE

Note/ Notes