This medicine is sensitive to additional monitoring. This will allow prediction of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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 find any side effects not listed on this leaflet.

1. WHAT MERIOFERT IS AND WHAT IT IS USED FOR

Meriofert is used to promote ovulation in women, is added to contribute to the total LH

Human Chorionic Gonadotrophin (hCG), a follicle stimulating hormone activity (FSH) and activity.

Women undergoing ovulation 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 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 a rule, a sufficient number of follicles has developed, the treatment with Meriofert is withheld and ovulation is triggered by injecting another hormone (chorionic gonadotrophin, hCG).

How Meriofert should be given:

Meriofert is given by injection under your skin (by the subcutaneous route) or into your muscles (intramuscular injection). The injection site 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 small dose of injection.
- show you the possible places where you can inject yourself.
- show you how to prepare the solution for injection,
- explain 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 only be reconstituted with the solvent provided in the package.

Prepare a clean 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:

- one 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.

Prepare the solution for injection:

1. The ampoule neck is specifically designed to be broken more easily below the coloured dot. Gently flick the top of the ampoule to dislodge any liquid remaining at the tip. Hold the ampoule with the coloured dot facing away from you and snap off the top of the ampoule as shown above. Alternatively, use a hypodermic 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 in ampoule, insert the needle and draw up all the solvent into the syringe.

Attach the protective cap of the needle. Carefully set the syringe down on the surface.

Remove the coloured plastic cap (75 IU light green, 150 IU dark green) from the vial by gently pushing it off.

Disinfect the top of the rubber stopper by wiping it with an alcohol swab and allow to dry.
Disposing of all used items:
- If you have used the medicine as instructed, all the powder and empty syringes should be disposed of in an appropriate container. Any unused solution should be disposed of in accordance with local requirements.

If you use more Meriofert than you should:
- If you think you have used more Meriofert than you should, speak to your doctor or pharmacist as soon as possible. This may be because you are allergic to any of the ingredients in it, or you may have overestimated your requirements.

In case of overdose:
- If you or another person takes more Meriofert than is prescribed, speak to your doctor immediately. 

If you forget to use Meriofert:
- Take it at the next normal time for an injection. Do not take a double dose to make up for a missed one.

If you stop using Meriofert:
- Do not stop your treatment without consulting your doctor. Your doctor will tell you how much to inject and when.

The reconstituted solution is:
- A clear and colourless solution.

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
  - the side of your thigh or buttock.

Injecting the needle:
- 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 syringe:
- Push the fine needle firmly on to a complete 5 ml bull’s eye, then twist it slightly to ensure it is fully screwed on and to create a firm seal.
- Push the fine needle firmly on to a complete 5 ml bull’s eye, then twist it slightly to ensure it is fully screwed on and to create a firm seal.

Dosage:
- Once you have filled 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:
- If you have used Meriofert for 10 days and are not pregnant, consult your doctor as there is a risk of ovarian hyperstimulation syndrome.

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. By reporting side effects you can help provide more information on the safety of this medicine.

INFORMATION

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

Austria: Meriofert
Belgium: Fertinorm
Bulgaria: Meriofert
Cyprus: Meriofert
Denmark: Meriofert
Greece: Meriofert
Hungary: Fertinorm
Ireland: Meriofert
Luxembourg: Fertinorm
Malta: Meriofert
Netherlands: Meriofert

Meriofert is presented as a powder and solvent for solution injection.

1. 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. 

2. Press the plunger down firmly to squirl all the solution onto the powder. 

3. Do NOT shake, but gently roll the vial between the hands until the powder is reconstituted, taking care to avoid creating foam.

Once the powder is dissolved (which, in general, occurs immediately), slowly draw the solution into the syringe:
- With the plunger 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.

Preparation of higher doses, using more than 1 vial of powder:

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. The amounts in 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, up to a maximum of 6562.5 IU. If multiple vials of powder are used, the total amount of menotrophin contained in 1 ml of reconstituted solution will be as follows:

- Meriofert 75 IU powder and solvent for solution 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 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: sodium chloride and water for injections.

What Meriofert looks like and contents of the pack:
- Powder: white to almost white lyophilized powder
- Solvent: clear and colourless solution.

Marketing Authorisation Holder:
IBSA Farmaceutici srl Via Martiri di Cefalonia, 2
26900 Lodri - Italy

Manufacturer:
IBSA Farmaceutici srl Via Martiri di Cefalonia, 2
26900 Lodri - Italy

This leaflet was last revised in April 2017

Buon appetito di Meriofert