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 listed in this leaflet. See section 4.

What is in this leaflet:
1. What Fostimon is and what it is used for
2. What you need to know before you use Fostimon
3. How to use Fostimon
4. Possible side effects
5. How to store Fostimon
6. Content of the pack and other information

1. WHAT FOSTIMON IS AND WHAT IT IS USED FOR

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

Urofollitropin is a highly purified human follicle stimulating hormone, belonging to a group of medicines called gonadotropins. This medicinal product must be used under the supervision of your doctor.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE FOSTIMON

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

DO NOT USE FOSTIMON if you have any of the following:
- Enlarged ovaries or cysts not caused by a hormonal disorder (polycystic ovarian disease).
- Infection on an organ that could cause an infection or disease cannot be definitely excluded; however, this is limited by steps in the manufacturing process to remove viruses, especially HIV, Hepes virus and Papillomavirus.
- No cases of viral contamination have been reported.

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

Pregnancy and breast-feeding
Fostimon should not be used if you are pregnant or breast-feeding.

3. HOW TO USE FOSTIMON

Dosage and duration of the treatment:
Always take 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:
If you are having periods, the treatment should start within 7 days of the start of your period (first 2 or 3 days of the menstrual cycle). You will be given 1 injection per day under your skin (subcutaneous).

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 Fostimon yourself. For the first time, your doctor must:
- let you practise giving yourself a subcutaneous injection,
- show you the possible places where you can inject yourself,
- show you how to prepare the solution for injection,
- have explained how to prepare the right dose of injection.

Presentations other than ampoules should be considered for self-administration by patients. Before injecting Fostimon yourself, read the following instructions carefully.

How to prepare and inject Fostimon, 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.

Fostimon must only be reconstituted with the solvent provided in the package.

Prepare a clean surface and wash your hands before the solution is constituted. 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 Fostimon powder,
- one solvent ampoule,
- one vial of solvent (not provided),
- one needle for preparing the injection (not provided),
- a fine bore needle for subcutaneous injection (not provided).

Reconstitution of the solution for injection using 1 vial of powder:
Prepare the solution for injection:

- 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.
Injecting the medicine subcutaneously:

1. 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.
2. 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.
3. Remove the protective cap of the needle. Hold the needle with the needle pointing upwards and gently tap the side of the syringe to force any air bubbles up to the top.
4. Press the plunger until a bead of liquid appears at the tip of the needle.
5. Do not use it if it contains any particles or is cloudy.

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.

Inserting 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 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 dispersed in the subcutaneous tissue.
- Withdraw the needle when the plunger is raised to the level of the liquid.

Removing the needle:

- Pull the syringe out quickly and apply pressure at the tip of the needle.
- Firmly pinch the skin together.
- Gently pull the plunger to draw all the solution up into the syringe.
- Attach the protective cap of the needle. Carefully set the syringe down on the surface.
- If 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 needle with the needle pointing upwards and gently tap the side of the syringe to force any air bubbles up to the top.
- Do not use it if it contains any particles or is cloudy.

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- 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 dispersed in the subcutaneous tissue. Withdraw the needle when the plunger is raised to the level of the liquid.
- 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.

Removing the needle:

- 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 Fostimon solution and relieve any discomfort.

Dispose of all used items:
Any unused product or waste material should be disposed of in accordance with local requirements. The syringes should be disposed of in an appropriate container.

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

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

If you stop using Fostimon:
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, Fostimon 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 Fostimon and see your doctor immediately if the following occurs:

- Common, affects 1 to 10 users in 100:
  - Ovarian Hyperstimulation Syndrome (see Section 2 for additional information)

The following side-effects have also been reported:

- Common, affects 1 to 10 users in 100:
  - Headache
  - Bloating of abdomen
  - Constipation
  - Pain at the injection site.

- Uncommon, effects 1 to 10 users in 1,000:
  - Overactive thyroid gland
  - Mood swings
  - Cystitis
  - Diarrhoea
  - Nausea, indigestion, abdominal pain
  - Skin rash, itch, redness
  - Hot flush
  - Nose bleed
  - Pain
  - Breast enlargement, breast pain
  - Difficulty stopping bleeding

Redness, pain and bruising at the injection site may occur (frequency not stated).

See section 2 for additional information on risk of blood clots, ectopic pregnancy, multiple pregnancy and miscarriage.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 direct (see details below).

IRELAND: HPRA Pharmacovigilance
Earlsfort Terrace, IRL – Dublin 2;
Tel: +353 1 6764971;
Fax: +353 1 6762517;
Website: www.hpra.ie
Email: medsafety@hpra.ie

UNITED KINGDOM: Yellow Card Scheme.
Website: www.mhra.gov.uk/yellowcard

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

5. HOW TO STORE FOSTIMON

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. The expiry date refers to the last day of the month.

Use immediately after reconstitution.

Do not use Fostimon 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 safely dispose of medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Fostimon contains

The active substance is Urofollitropin.

One vial contains 75 IU of urofollitropin (follicle-stimulating hormone FSH): 1 ml of reconstituted solution contains either 75 IU, 150 IU, 225 IU, 300 IU, 375 IU or 450 IU of urofollitropin when respectively 1, 2, 3, 4 or 5 vials are reconstituted in 1 ml of solvent.

One vial contains 150 IU of urofollitropin (follicle-stimulating hormone FSH): 1 ml of reconstituted solution contains either 150 IU, 300 IU or 450 IU of urofollitropin when respectively 1, 2, 3, 4 or 5 vials are reconstituted in 1 ml of solvent.

The specific in vivo activity is equal or superior to 5000 IU of FSH per mg of protein.

What Fostimon looks like and contents of the pack

Fostimon is presented as a powder and solvent for solution for injection. 1 set contains powder in vial (75 IU or 150 IU) and solvent in an ampoule (1mL) – Pack size of 1, 5 or 10 sets.

The powder is a white to off-white caked mass and the solvent is clear and colourless.

Marketing Authorisation Holder:
IBSA Farmaceutici Italia S.r.l.
Via Martiri di Cefalonia, 2
26900 Lodi
ITALY

Manufacturer:
IBSA Farmaceutici Italia Srl
Via Martiri di Cefalonia, 2
26900 LODI - ITALY

Batch Release (UK and Ireland):
PHARMASERVICE LIMITED
4-6 Colonial Business Park
Colonial Way
Warford WD24 4PR
UNITED KINGDOM

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

Austria: Fostimon
Belgium: Fostimon
Cyprus: Fostimon
Denmark: Fostimon
Finland: Fostimon
France: Fostimon
Lithuania: Fostimon
Netherlands: Fostimon
Norway: Fostimon
Portugal: Fostimon
Sweden: Fostimon
United Kingdom: Fostimon

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