PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS REGULATIONS (PREPARATIONS) – 1986

The dispensing of this medicine requires a doctor's prescription.

Read this package insert carefully in its entirety before using this medicine.

FOSTIMON 75 IU/ml

Powder and solvent for solution for injection

FOSTIMON 150 IU/ml

Powder and solvent for solution for injection

Composition:

Each vial (powder) contains:
Urofollitropin (FSH) 75 IU/ml

In addition each vial contains:
Lactose 10 mg

Each vial (powder) contains:
Urofollitropin (FSH) 150 IU/ml

In addition each vial contains:
Lactose 10 mg

Each ampoule (solvent) contains:
Sodium chloride 0.9 %
water for injections

Therapeutic group:
Gonadotrophins.

Therapeutic activity:
FOSTIMON is used to stimulate women who are not ovulating and who have not responded to other treatment (clomiphene citrate).

It is used to bring about the development of several follicles (and therefore several eggs) in women receiving fertility treatments.

When should the preparation not be used?

Do not use this medicine if you are pregnant or breast-feeding.
Do not use this medicine if you are hypersensitive (allergic) to Urofollitropin (FSH) or to any other ingredients of this medicine.
Do not use this medicine if you suffer from enlarged ovaries or cysts not caused by a hormonal disorder (polycystic ovarian disease).
Do not use this medicine if you have bleeding of unknown cause.
Do not use this medicine if you have cancer of the ovaries, uterus or breast.
Do not use this medicine if you suffer from abnormal swelling (tumour) of the pituitary gland or hypothalamus (brain).
Do not use this medicine 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.

Do not take this medicine without consulting a doctor before starting treatment:
If you are intolerant to some sugars.
If you suffer of have suffered in the past from impaired function of the fallopian tubes, thyroid gland, pituitary gland, adrenal gland, blood system (e.g. coagulation etc.), hyperprolactinaemia.

Warnings:
The first injection should be given under close medical supervision.
Close medical follow-up of the physician who is a fertility specialist is necessary during the treatment.
This treatment increases your risk of developing a condition known as ovarian hyperstimulation syndrome (OHSS). This is uncommon if you are not ovulating and your treatment is given in the recommended way.
In the event of a severe ovarian hyperstimulation syndrome, the treatment should be discontinued immediately, and you should proceed to a hospital. In cases where OHSS is developing you should not have sexual intercourse even if using barrier methods of contraception for at least 4 days.
In patients treated 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.
It should be noted that women with fertility problems have a higher rate of miscarriages than the normal population.
General:
Your and your partner's fertility should be evaluated before your treatment is started.
If you have an allergic reaction to a similar medicine, inform your doctor before commencing treatment with this medicine.

Drug interactions:
If you are taking another drug concomitantly or if you have just finished treatment with another medicine, inform the attending doctor, in order to prevent hazards or lack of efficacy arising from drug interactions.

Side effects:
In addition to the desired effect of the medicine, during the course of treatment adverse reactions may occur, such as: headache, feeling bloated and stomach discomfort, constipation, ovarian hyperstimulation syndrome, breast sensitivity and pain at the injection site.

Side effects which require special attention:
nausea, abdominal pain, tiredness, dyspnoea, other local reactions at the injection site (redness and itching), breast enlargement, breast pain, hot flushes, dizziness, lethargy, mood swings, slowness, cystitis, increased activity of the thyroid gland, redness, itching, nosebleeds, and increased bleeding time.
Side effects when Fostimon is used in combination with hCG:
Abnormal blood clots, ectopic pregnancy, overstimulation of the ovaries – large ovarian cysts can form. First signs of this 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 the event that you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult your doctor immediately.

Dosage:
The dosage is according to doctor's instructions only.
Do not exceed the recommended dosage.
If you forget to take this medicine at the specified time, take the dose at the next normal time for an injection. Do not take additional quantities to make up for any doses you have forgotten.

Attention!
Do not use FOSTIMON if the solution does not look clear.

Directions for use:

FOSTIMON is given by injection either under your skin (by the subcutaneous route) or into a muscle (by the intramuscular route).
Each vial should be used only once. The injection should be used immediately after its preparation.

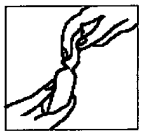
After suitable advice and training your doctor may ask you to inject FOSTIMON yourself.
At first, your doctor must:
- let you practise giving yourself a subcutaneous injection,
- have shown you the possible places where you can inject yourself,
- have shown you how to prepare the solution for injection,
- have explained how to prepare the right dose of injection.

Before injecting FOSTIMON yourself, read the following instructions carefully.

How to prepare and inject 1 vial of FOSTIMON:
The injection must be prepared just before you are ready to use it, using the solvent (a solution of 0.9% sodium chloride in water for injections) included in each FOSTIMON pack.
Wash your hands, prepare a clean surface and make sure you have:

- two alcohol swabs (not provided)
- one sterile gauze pad
- one vial containing FOSTIMON powder
- one solvent ampoule
- one 1-5 ml syringe (not provided)
- one 18G thick needle for preparing the solution (not provided),
- a One 27G or 29G fine bore needle for subcutaneous injection (not provided).

Preparing FOSTIMON for injection:
Open the solvent ampoule containing the clear liquid:


solvent

On the neck of the solvent ampoule, you will see a small coloured mark where it is designed to break easily. Gently tap the top of the ampoule to dislodge any liquid remaining in the tip. Firmly press the ampoule above the neck, and break the ampoule away from the coloured mark. Carefully place the opened ampoule upright on the cleaned surface.

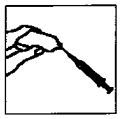
Withdraw the solvent:

Attach the needle intended for withdrawal of the solvent (18G) to the syringe. With the syringe in one hand, pick up the opened solvent ampoule, insert the needle and withdraw all of the solvent. Carefully set the syringe down on the surface, taking care not to touch the needle.

Prepare the solution for injection:


Vial of powder

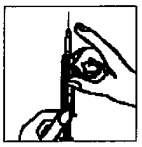
1 Remove the aluminium seal from the vial containing the FOSTIMON powder and wipe the rubber area of the cap with an alcohol swab.



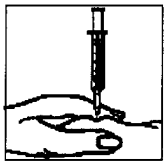
2 Pick up the syringe and slowly inject the solvent into the vial of powder through the rubber cap.
3 Once the powder has dissolved (which usually occurs immediately), slowly draw the solution up into the syringe.

Injecting of FOSTIMON solution by the subcutaneous route:

- Remove the needle intended for withdrawal of the solvent from the syringe and replace it with the fine bore needle for subcutaneous injection (27G or 29G).



- Now complete the Safety Check: Any air bubbles must be removed by holding the syringe with the needle pointing upwards. Gently flick the syringe to displace any air bubbles and push the plunger very slowly until a bead of liquid appears at the tip of the needle.
- Adjust the amount of Fostimon in the syringe for injection as your doctor has advised you.



- Your doctor or nurse will have already shown you where to inject Fostimon (e.g. tummy, front of thigh). Wipe the injection site with an alcohol swab and allow it to dry for a few seconds. Firmly pinch the skin together and insert the needle at a 90° angle using a dart-like motion. Inject under the skin as you were shown. Do not inject directly into a vein. Inject the solution by pushing gently on the plunger. Take as much time as you need to inject *all* the solution prescribed. Take out the needle immediately and clean the skin at the injection site with a sterile gauze pad.

Dispose of all used items:
Once you have finished your injection, put all needles and empty ampoules into the sharps container you have been given. Any unused solution must be thrown away.

How can you contribute to the success of the treatment?

Complete the full course of treatment as instructed by the doctor.

Avoid poisoning!
This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning.
If you have taken an overdose, or if a child has accidentally swallowed this medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.
Do not induce vomiting unless explicitly instructed to do so by a doctor!
This medicine has been prescribed for the treatment of your ailment; in another patient it may cause harm.
Do not give this medicine to your relatives, neighbors or acquaintances.
Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.

Storage:
Do not store above 25° C. Keep in the outer packaging in order to protect from light.
Even if kept in their original container and stored as recommended, medicines may be kept for a limited period only. Please note the expiry date of the medicine! In case of doubt, consult the pharmacist who dispensed the medicine to you.
Do not store different medications in the same package.

Drug registration number:
Fostimon 75 IU/ml - 137 15 30175
Fostimon 150 IU/ml – 137 16 30176

Manufacturer: IBSA Institut Biochimique SA, Switzerland.

Registration holder: Tzamal Bio-Pharma, 20 Hamagshimim St., Petah Tikva 49170.

The format of this leaflet was determined by the Ministry of Health and its content was checked and approved in November 2008.

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