Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) – 1986
This medicine requires a doctor's prescription
Read the entire leaflet carefully before you start using this medicine

FOSTIMON 75 IU
FOSTIMON 150 IU

Powder and solvent for injection

Active ingredient and quantity:

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

FOSTIMON 150 IU: Urofollitropin (FSH) 150 IU/vial

Each ampoule (solvent) contains:
Sodium chloride 0.9%, water for injection.

Inactive ingredients and allergens: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

Therapeutic activity:
- 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.

Therapeutic group:
Gonadotropins.

2. Before using this medicine

Do not use this medicine if:

- You are pregnant or breast-feeding.
- You are sensitive (allergic) to the active ingredient (urofollitropin (FSH)) or to any of the other ingredients in this medicine (see section 6).
- You have enlarged ovaries or cysts not caused by a hormonal disorder (polycystic ovarian disease).
- You have bleeding of unknown cause.
- You have cancer of the ovaries, uterus or breast.
- You have abnormal swelling (tumour) of the pituitary gland or hypothalamus (brain).
- You have an early menopause, a malformation of the sexual organs or certain tumours of the womb that would make a normal pregnancy impossible.

Special warnings about using this medicine

Before treatment with FOSTIMON, tell your doctor if:
- You have an allergic reaction to a similar medicine.
- You are intolerant to certain sugars.
- You suffer or 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.
- You have an increased chance of having thrombosis or anyone in your immediate family have ever had a thrombosis.
- You are severely overweight.

This treatment increases your risk of developing a condition known as ovarian hyperstimulation syndrome (OHSS), see the “Possible side effects” section. If ovarian hyperstimulation occurs, you should stop treat immediately, contact your doctor and refrain from becoming pregnant. If this condition (OHSS) is developing, you should not have sexual intercourse, even if using barrier methods of contraception for at least 4 days. The first symptoms of ovarian hyperstimulation are pain in the lower abdominal region, nausea, 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 abdominal or chest cavity.

Use of the drug which helps release of the egg from the ovary (containing human chorionic gonadotropin-hCG) increases the likelihood of OHSS. It is therefore not advisable to use hCG in cases where OHSS is developing.

In patients receiving treatment to help ovulation, the occurrence of multiple pregnancies and births is increased compared to someone who is not receiving such treatment. 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.
There is a slightly increased risk of ectopic pregnancy in women with impaired/damaged fallopian tubes.

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

Treatment with FOSTIMON, just as pregnancy itself, may increase the chance of having thrombosis. Thrombosis is a medical condition in which a blood clot blocks a blood vessel in the body, most often in the veins of the legs or the lungs. Consult your doctor before starting treatment if you already have an increased risk of thrombosis or if anyone in your immediate family ever had a thrombosis or if you are severely overweight.

This medicine is prepared from human urine. The risk of passing on an organism that could cause an infection or disease cannot be definitely excluded. However, the risk is limited by steps in the manufacturing process designed to remove viruses, especially HIV, herpes virus and papillomavirus. No cases of viral contamination have been reported.

Tests and follow-up
The first injection of the medicine will be done under close medical supervision.
Close medical follow-up of the physician who is a fertility specialist is necessary during the treatment.
Your and your partner’s fertility should be evaluated before starting treatment.

Drug interactions
If you are taking or have recently taken other medicines including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

Pregnancy and breast-feeding
Do not be use the medicine if you are pregnant or breastfeeding.

Important information about some of this medicine's ingredients
This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free'.
This medicine contains lactose in the amount of 10 mg lactose monohydrate in each vial.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine.
Do not exceed the recommended dose.
Note!
Do not use FOSTIMON if the solution is not clear.

Instructions for use:
FOSTIMON is given by injection under the skin (subcutaneously) or into a muscle (intramuscular). Each vial should be used only once. The injection should be used as soon as it is prepared.

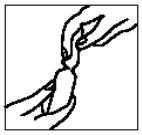
After suitable explanation and training, your doctor may ask you to inject FOSTIMON yourself.
First, your doctor must:
- let you practise giving yourself a subcutaneous injection,
- show you the possible places where you can inject yourself,
- show you how to prepare the solution for injection,
- explain how to prepare the right dose of injection.

Before injecting FOSTIMON yourself, read the following instructions carefully.

How to prepare and inject one 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 injection) included in each FOSTIMON pack.
Wash your hands, prepare a clean surface and make sure you have:
- two alcohol swabs (not included in this pack)
- one vial containing FOSTIMON powder
- one solvent ampoule
- one 1-5 ml syringe (not included in this pack)
- one 18G thick needle for preparing the solution (not included in this pack)
- one 27G or 29G fine bore needle for subcutaneous injection (not included in this pack)

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

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



Solvent ampoule

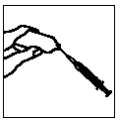
Withdraw the solvent:
Attach the withdrawing needle (18G) to the syringe. With the syringe in one hand, pick up the opened solvent ampoule, insert the needle and withdraw all of the solvent. Carefully set the syringe down on the surface, without touching the needle.

Prepare the solution for injection:

1. Remove the plastic cap from the vial containing the FOSTIMON powder and wipe the rubber area of the stopper with an alcohol swab. Allow it to dry.

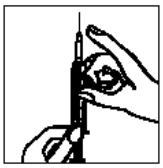
Vial of powder

2. Pick up the syringe and slowly inject all the solvent into the vial of powder through the middle of the rubber stopper.
3. Once the powder is dissolved (which, in general, occurs immediately; do not shake the vial to avoid creating foam), slowly draw the solution into the syringe: Make sure that the solution is clear and colourless.

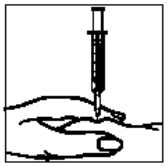


Subcutaneous injection of FOSTIMON solution:

- Remove the needle intended for withdrawal and replace it with the fine bore needle for subcutaneous injection (27G or 29G)
- Now complete the safety check: Remove any air bubbles by holding the syringe with the needle pointing upwards. Gently flick the syringe to remove 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 recommended.
- 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 wait a few seconds for it to dry. Firmly pinch the skin together and insert the needle at a 90-degree **angle with a rapid motion. Inject under the skin as you were shown. Do not inject directly into a vein. Inject the solution by gently pushing the plunger. Take as much time as you need to inject all the solution prescribed. Take the needle out immediately and clean the skin at the injection site with a swab containing disinfectant.**



Disposal of all used items:
Once you have finished injecting, put all the needles and ampoules into the sharps container you have been given. Any leftover solution you have not used should be thrown away.

If you have accidentally taken a higher dose, the effect of an overdose is unknown, nevertheless, one could expect ovarian hyperstimulation syndrome to occur (see section 4 “Side effects). If you have taken a higher dose, refer to your doctor or pharmacist for advice.

If you forget to take the medicine at the intended time, take the next dose at the next normal time for an injection. Do not take additional quantities to make up for forgotten doses.

Adhere to the treatment as recommended by your doctor.
Even if your health improves, do not stop taking this medicine without consulting your doctor.

If you stop taking this medicine
Do not stop taking the medicine without consulting your doctor in advance. Contact your doctor or pharmacist with any question about this medicine and how it is used.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using FOSTIMON may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

You should stop taking this medicine and contact your doctor immediately if any of the following symptoms appears, which may be so severe that you will require urgent medical care:

Common side effect (affects up to 1 in 10 patients):
- Ovarian hyperstimulation syndrome (OHSS). The first symptoms of ovarian hyperstimulation are pain in the lower abdominal region, nausea, vomiting and weight gain (see section 2 under "Special warnings"). If these symptoms occur, you should be examined by your doctor as soon as possible.

Additionally, the following side effects have been reported:
Common side effects (affects 1 to -10 in 100 patients):
- Headache
- Feeling bloated and abdominal discomfort
- Constipation
- Pain at the injection site

Uncommon side effects (affects 1 to -10 in 1,000 patients):
- Overactive thyroid gland
- Mood swings
- Tiredness
- Dizziness
- Breathlessness
- Nosebleeds
- Nausea, abdominal pain, indigestion
- Skin redness, itching
- Hot flushes
- Cystitis
- Breast enlargement, breast pain
- Difficulty stopping bleeding

Redness, pain and bruising at the injection site may appear (unknown frequency).
See section 2, Special warnings section, regarding the risk of blood clots, ectopic pregnancy, multiple pregnancy and miscarriages.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il), which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants If you have taken an overdose or if a child has accidentally swallowed some medicine, immediately go to a hospital emergency room and bring the medicine package with you. Do not induce vomiting unless explicitly instructed to do so by a doctor!
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.

Storage conditions:
Do not store above 25°C. Store in the outer carton in order to protect from light.
Even according to the recommended package/storage conditions, medicines keep 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 medicines in the same package.
Use immediately after preparing the solution.
Do not use if the solution is not clear.

6. Additional information

In addition to the active ingredient, this medicine also contains:
Powder vial: lactose monohydrate
Solvent ampoule: sodium chloride, water for injection

What the medicine looks like and contents of the pack
The pack contains:
- A vial with a plastic cap that contains white dry powder
- An ampoule that contains 1 ml of clear, colourless and odourless solvent solution.

Amount in pack: 1 or 10 (vial+ampoule). Not all pack sizes may be marketed.

Registration holder's name and address: Tzamal Bio-Pharma Ltd., 20 Hamagshimim St., Petah Tikva.

Manufacturer's name and address: IBSA Institut Biochimique SA, Switzerland.

Revised in August 2022 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
FOSTIMON 75 IU/ml - 137 15 30175
FOSTIMON 150 IU/ml - 137 16 30176

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