

## **Prescribing information for Fostimon (Urofollitropin)**

75 IU and 150 IU powder and solvent for solution for injection, highly purified lyophilised Human Follicle Stimulating Hormone (FSH).

**Presentation:** Fostimon 75 IU, as a white lyophilised pellet containing urofollitropin 75 IU and providing 75 IU of follicle stimulating hormone (FSH) activity. Fostimon 150 IU, as a white lyophilised pellet containing urofollitropin 150 IU and providing 150 IU of follicle stimulating activity.

**Indication:** Anovulation (including polycystic ovarian syndrome, PCOS) in women who have been unresponsive to treatment with clomiphene citrate. Controlled ovarian hyperstimulation to induce the development of multiple follicles in Assisted Reproductive Technologies (ART) such as in vitro fertilisation (IVF), Gamete Intra-fallopian Transfer (GIFT) and Zygotes Intra-fallopian Transfer (ZIFT).

**Dosage and administration:** Fostimon is intended for subcutaneous or intramuscular administration. The powder should be reconstituted immediately prior to use with the solvent provided. Care must be taken when reconstituting more than 1 vial (in 1ml solvent) to avoid foaming of the reconstituted solution. Treatment should be adjusted to the individual patient's response as assessed by measuring follicular development by ultrasound and/or measurement of oestrogen levels. A commonly used regimen for treating anovulation starts at 75 to 150 IU of FSH per day and is increased if necessary by 37.5 IU (up to 75 IU), with intervals of 7 or 14 days preferably, in order to achieve an adequate but not excessive response. An example of controlled ovarian hyperstimulation during ART commences at 150 IU – 225IU of Fostimon daily and is increased according to the patient's response. The maximum daily dose in ART is usually not higher than 450IU (Refer to Summary of Product Characteristics (SPC) for full information).

**Contraindications:** Hypersensitivity to FSH or any of the excipients. Tumours of the hypothalamus or pituitary gland and in females who have either ovarian enlargement or a cyst not due to polycystic ovarian disease. Gynaecological bleeding of unknown origin. Ovarian, uterine or mammary carcinoma. Primary ovarian failure. Malformations of sexual organs incompatible with pregnancy. Fibroid tumours of the uterus incompatible with pregnancy.

**Undesirable effects:** Some adverse reactions (ADRs) such as headache, abdominal distension and ovarian hyperstimulation syndrome were reported in clinical trials with FOSTIMON. Most events were of mild to moderate severity. (Refer to Summary of Product Characteristics (SPC) for complete list of adverse reactions).

**Precautions:** Use only under specialist supervision; to minimise the risks of Ovarian Hyperstimulation Syndrome (OHSS) or of multiple pregnancy, ultrasound scans as well as oestradiol measurements are recommended.

**Interactions:** No drug interaction studies have been conducted in humans.

**Pharmaceutical Precautions:** Do not store above 25°C, use immediately after reconstitution.

**Legal Category:** POM.

**Marketing Authorisation Numbers:** Fostimon 75 IU – PL 21039/0005, Fostimon 150 IU – PL 21039/0006. Basic NHS price: Fostimon 75 IU 10 vials - £279.00, Fostimon 150 IU 10 vials - £558.00.

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

**Distributor in UK:** Pharmasure Ltd., 4 – 6 Colonial Business Park, Colonial Way, Watford WD24 4PR, UK.

**Date of last revision of PI text:** October 2018.

**Approval code:** UK/201810/00007/01