European Medicines Agency

EMEA/H/C/86

EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

PUREGON

EPAR summary for the public

This document is a summary of the European Public Assessment Report (EPAR). It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the studies performed, to reach their recommendations on how to use the medicine.
If you need more information about your medical condition or your treatment, read the Package Leaflet (also part of the EPAR) or contact your doctor or pharmacist. If you want more information on the basis of the CHMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Puregon?
Puregon is a powder and solvent to be made up into a solution for injection. It is also available as a solution for injection in a vial or a cartridge. Puregon contains the active substance follitropin beta.

What is Puregon used for?
Puregon is used to treat infertility in women in the following situations:
- women who are anovulatory (do not produce eggs) and do not respond to treatment with clomiphene citrate (another medicine that stimulates ovulation).
- women who are undergoing fertility treatment (assisted reproductive techniques, such as *in vitro* fertilisation). Puregon is administered to stimulate the ovaries to produce more than one egg at a time

Puregon can also be used to stimulate sperm production in men who have hypogonadotrophic hypogonadism (a rare hormone deficiency disease).
Puregon can only be obtained with a prescription.

How is Puregon used?
Treatment with Puregon should be carried out by a doctor who has experience in the treatment of fertility problems. Puregon is given as a 'subcutaneous' injection (under the skin) or into a muscle. The powder should be mixed with the solvent provided just before use. The patient or their partner may carry out the injections. Puregon should only be administered by people who have been trained by the doctor and have access to expert advice. The dose and frequency of administration of Puregon depend on its use (see above) and the patient's response to treatment. For a full description of the doses, please see the Package Leaflet.

How does Puregon work?
The active substance in Puregon, follitropin beta, is a copy of the natural hormone follicle stimulating hormone (FSH). In the body, FSH regulates the reproductive function: in women, it stimulates the production of eggs, and in men, it stimulates the production of sperm by the testicles. Previously, the FSH used as a medicine was extracted from urine. The follitropin beta in Puregon is produced by a method known as 'recombinant DNA technology'. It is made by a cell that has received a gene (DNA), which makes it able to produce human FSH.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 16
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

How has Puregon been studied?
Puregon's use in women undergoing fertility treatment has been studied in 981 patients. The number of eggs recovered and the ongoing pregnancy rate were the main measures of effectiveness. Puregon was studied in 172 anovulatory women, measuring how many cycles of treatment were needed for these women to ovulate. In men, Puregon was studied to see its effect on sperm production in 49 patients. In all of the studies, Puregon was compared to the natural FSH hormone that was extracted from urine.

What benefit has Puregon shown during the studies?
Puregon was as effective as the comparator in all of the studies. Puregon was as effective as urinary FSH as a fertility treatment, in producing ovulation and in producing sperm.

What is the risk associated with Puregon?
The most common side effects reported are a reaction and pain at the injection site. In 4 % of the women treated with Puregon in clinical studies, signs and symptoms related to ovarian hyperstimulation syndrome (e.g. feeling sick, weight gain, and diarrhoea) have been reported. Ovarian hyperstimulation syndrome occurs when the ovaries over-respond to treatment. Doctors and patients must be aware of this possibility. For a full list of all side effects reported with Puregon, see the Package Leaflet.
Puregon should not be used in people who may be hypersensitive (allergic) to follitropin beta or any of the other ingredients. Puregon must not be used in patients with tumours of the ovary, breast, womb, testicle, pituitary gland or hypothalamus. It must not be used in men with testicular failure. In women, it must not be used when there is ovarian failure, ovarian enlargement or the presence of cysts that are not due to polycystic ovarian disease, or vaginal bleeding. For the full list of restrictions, see the Package Leaflet.

Why has Puregon been approved?
The Committee for Medicinal Products for Human Use (CHMP) decided that Puregon's benefits are greater than its risks in the female for the treatment of infertility, and in the male for deficient spermatogenesis due to hypogonadotrophic hypogonadism. The Committee recommended that Puregon be given marketing authorisation.

Other information about Puregon:
The European Commission granted a marketing authorisation valid throughout the European Union, for Puregon on 3 May 1996. The marketing authorisation holder is N.V. Organon. The marketing authorisation was renewed on 3 May 2001 and on 3 May 2006.

The full EPAR for Puregon is available here.

This summary was last updated in 03-2009.