31 July 2013
EMA/422789/2013
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ovaleap

follitropin alfa

On 31 July 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ovaleap, 600 IU/ml, solution for injection intended for the treatment of fertility disorders. The applicant for this medicinal product is Teva Pharma B.V. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion. Ovaleap is a biosimilar medicinal product, i.e. a medicinal product that has been demonstrated to be similar in quality, safety and efficacy to the reference medicinal product GONAL-f.

The active substance of Ovaleap is follitropin alfa, recombinant human follicle-stimulating hormone [r-hFSH](G03GA05). Follitropin alfa is essential for normal female gamete growth and maturation, and induction of normal gonadal steroid production. Deficient endogenous production of FSH is a known cause of infertility and administration of exogenous gonadotropins is used to treat this condition.

The benefits with Ovaleap are its ability for the treatment of fertility disorders. The most common side effects are headache, ovarian cysts and local injection site reactions. Mild or moderate Ovarian Hyperstimulation Syndrome (OHSS) has been commonly reported and should be considered as an intrinsic risk of the stimulation procedure. Thromboembolism may occur very rarely, usually associated with severe OHSS.

A pharmacovigilance plan for Ovaleap will be implemented as part of the marketing authorisation.

The approved indication is:

In adult women

- Anovulation (including polycystic ovarian syndrome) in women who have been unresponsive to treatment with clomifene citrate.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

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- Stimulation of multifollicular development in women undergoing superovulation for assisted reproductive technologies (ART) such as in vitro fertilisation (IVF), gamete intra-fallopian transfer and zygote intra fallopian transfer.
- Ovaleap in association with a luteinising hormone (LH) preparation is recommended for the stimulation of follicular development in women with severe LH and FSH deficiency. In clinical trials these patients were defined by an endogenous serum LH level < 1.2 IU/L.

In adult men

- Ovaleap is indicated for the stimulation of spermatogenesis in men who have congenital or acquired hypogonadotropic hypogonadism with concomitant human chorionic gonadotropin (hCG) therapy.

It is proposed that Ovaleap be prescribed by physicians experienced in the treatment of fertility disorders.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Ovaleap and therefore recommends the granting of the marketing authorisation.