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EPAR summary for the public

Ovitrelle

choriogonadotropin alfa

This is a summary of the European public assessment report (EPAR) for Ovitrelle. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Ovitrelle.

What is Ovitrelle?

Ovitrelle is a medicine that contains the active substance choriogonadotropin alfa. It is available as a powder and solvent to be made up into a solution for injection and as a solution in a pre-filled syringe or pre-filled pen.

What is Ovitrelle used for?

Ovitrelle is used in women who have received treatment to stimulate their ovaries, to trigger ovulation (the release of eggs by the ovaries) and the development of a special structure on the ovary (the *corpus luteum*) that helps pregnancy.

It can be used in women who are undergoing fertility treatment (such as *in vitro* fertilisation), and in women who are anovulatory (do not produce eggs) or oligo ovulatory (rarely produce eggs).

The medicine can only be obtained with a prescription.

How is Ovitrelle used?

Treatment with Ovitrelle should be carried out under the supervision of a doctor who has experience in the treatment of fertility problems.

Ovitrelle is given by injection under the skin. A dose of 250 micrograms is given 24 to 48 hours after the ovaries have produced follicles that are mature enough (eggs ready for ovulation). In women undergoing fertility treatment, this is generally 24 to 48 hours after stopping treatment to stimulate

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the ovaries (such as a follicle stimulating hormone [FSH] or human menopausal gonadotrophin [hMG] preparation). The patient or their partner may carry out the injection if they have been trained and have access to expert advice.

How does Ovitrelle work?

The active substance in Ovitrelle, choriogonadotropin alfa, is a copy of the natural hormone human chorionic gonadotropin (hCG), also known as the 'pregnancy' hormone, which helps to maintain pregnancy. Because of its similarity to luteinising hormone (LH), Ovitrelle is also used to trigger ovulation.

The choriogonadotropin alfa in Ovitrelle is produced by a method known as 'recombinant DNA technology': it is made by a cell that has received a gene (DNA), which makes cell able to produce it.

How has Ovitrelle been studied?

Ovitrelle has mainly been studied in women undergoing fertility treatment (1,140 patients). Ovitrelle (250 micrograms or 500 micrograms) was compared with the natural hCG hormone that had been extracted from urine. The effectiveness of Ovitrelle was measured by looking at how many eggs were released. One study was also carried out in women who could not ovulate.

What benefit has Ovitrelle shown during the studies?

Ovitrelle was as effective as urinary hCG in triggering ovulation, and the 250-microgram dose of Ovitrelle was as effective as the 500-microgram dose. In anovulatory women, ovulation was seen in 92% of the women treated with Ovitrelle.

What is the risk associated with Ovitrelle?

The most common side effects with Ovitrelle (seen in between 1 and 10 patients in 100) are reactions at the injection site, headache, tiredness, vomiting, nausea (feeling sick), abdominal pain (stomach ache) and ovarian hyperstimulation syndrome (such as feeling sick, weight gain and diarrhoea). Ovarian hyperstimulation syndrome occurs when the ovaries over respond to treatment, especially when medicines to trigger ovulation have been used.

Ovitrelle should not be used in people who may be hypersensitive (allergic) to choriogonadotropin alfa or any of the other ingredients. It must not be used in patients with tumours of the hypothalamus, pituitary gland, ovary, womb or breast. It must not be used when a response cannot be obtained (such as in ovarian failure). It must not be used in women with ovarian enlargement or cysts not due to polycystic ovarian disease, unexplained vaginal bleeding, or who have had an ectopic pregnancy (a pregnancy that develops outside the womb) in the previous three months. Ovitrelle must also not be used in patients with active thromboembolic disorders (problems with blood clotting). For the full list of restrictions, see the package leaflet.

Why has Ovitrelle been approved?

The CHMP decided that Ovitrelle's benefits are greater than its risks and recommended that it be given marketing authorisation.

Other information about Ovitrelle

The European Commission granted a marketing authorisation valid throughout the European Union for Ovitrelle on 2 February 2001.

The full EPAR for Ovitrelle can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Ovitrelle, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 05-2011.