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Ovitrelle (*choriogonadotropin alfa*)

An overview of Ovitrelle and why it is authorised in the EU

What is Ovitrelle and what is it used for?

Ovitrelle is a medicine used in women who have received treatment to stimulate their ovaries, to trigger ovulation (the release of an egg from 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).

Ovitrelle contains the active substance choriogonadotropin alfa.

How is Ovitrelle used?

Ovitrelle can only be obtained with a prescription and treatment 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 the ovaries (such as with a follicle stimulating hormone [FSH] or human menopausal gonadotrophin [hMG] medicine). The woman or her partner may carry out the injection if they have been trained to do so and have access to expert advice.

For more information about using Ovitrelle, see the package leaflet or contact your doctor or pharmacist.

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.

What benefits of Ovitrelle have been shown in studies?

Ovitrelle has mainly been studied in women undergoing fertility treatment (1,140 patients). Ovitrelle (250 or 500 micrograms) was compared with the natural hCG hormone that had been extracted from

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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.

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 occurred in 92% of the women treated with Ovitrelle.

What are the risks associated with Ovitrelle?

The most common side effects with Ovitrelle (which may affect up to 1 in 10 women) are reactions at the injection site, headache, vomiting, nausea (feeling sick), abdominal (belly) pain, abdominal distension (feeling of bloating) 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 must not be used in patients with tumours in 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 unrelated to polycystic ovarian disease or who have unexplained vaginal bleeding. Ovitrelle must also not be used in patients with active thromboembolic disorders (problems with blood clotting). For the full list side effects and restrictions of Ovitrelle, see the package leaflet.

Why is Ovitrelle authorised in the EU?

The European Medicines Agency decided that Ovitrelle's benefits are greater than its risks and recommended that it can be authorised for use in the EU.

Other information about Ovitrelle

Ovitrelle received a a marketing authorisation valid throughout the EU on 2 February 2001.

Further information on Ovitrelle can be found on the Agency's website: https://www.ema.europa.eu/en/medicines/human/EPAR/ovitrelle

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