

Package leaflet: Information for the user

Ovitrelle 250 micrograms solution for injection in pre-filled pen Choriogonadotropin alfa

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ovitrelle is and what it is used for
2. What do you need to know before you use Ovitrelle
3. How to use Ovitrelle
4. Possible side effects
5. How to store Ovitrelle
6. Contents of the pack and other information

1. What Ovitrelle is and what it is used for

What Ovitrelle is

Ovitrelle contains a medicine called ‘choriogonadotropin alfa’, made in a laboratory by a special recombinant DNA technique. Choriogonadotropin alfa is similar to a hormone found naturally in your body called ‘chorionic gonadotropin’, which is involved in reproduction and fertility.

What Ovitrelle is used for

Ovitrelle is used together with other medicines:

- To help develop and ripen several follicles (each containing an egg) in women undergoing Assisted Reproductive Techniques (procedure that may help you to become pregnant) such as ‘*in vitro* fertilisation’. Other medicines will be given first to bring about the growth of several follicles.
- To help release an egg from the ovary (ovulation induction) in women who cannot produce eggs (‘anovulation’), or women who produce too few eggs (‘oligo-ovulation’). Other medicines will be given first to develop and ripen the follicles.

2. What do you need to know before you use Ovitrelle

Do not use Ovitrelle

- if you are allergic to choriogonadotropin alfa or any of the other ingredients of this medicine (listed in section 6).
- if you have a tumour in a part of your brain called the ‘hypothalamus’ or ‘pituitary gland’.
- if you have large ovaries or sacs of fluid within the ovaries (ovarian cysts) of unknown origin
- if you have unexplained vaginal bleeding
- if you have cancer of your ovaries, womb or breast
- if you have had a pregnancy outside of your womb (ectopic pregnancy) within the last three months.
- if you have severe inflammation of your veins or blood clotting in your veins (active thromboembolic disorders).

- if you have any condition that usually makes a normal pregnancy impossible, such as menopause or early menopause (ovarian failure), or malformations of sexual organs.

Do not use Ovitrelle if any of the above applies to you. If you are not sure, talk to your doctor before using this medicine.

Warnings and precautions

Before the treatment is started, your and your partner's fertility should be evaluated by a doctor experienced in the treatment of fertility problems.

Ovarian Hyperstimulation Syndrome (OHSS)

This medicine may increase your risk of developing OHSS. This is when your follicles develop too much and become large cysts.

If you get lower abdominal pain, gain any weight rapidly, feel sick or are vomiting, or have difficulty in breathing, do not give yourself the Ovitrelle injection and talk to your doctor straight away (see section 4). If you are developing OHSS, you may be told not to have sex or to use a barrier contraceptive method for at least four days.

The risk of OHSS is reduced if the usual dose of Ovitrelle is used, and if you are monitored closely throughout your treatment cycle (e.g. blood tests for estradiol levels and ultrasound).

Multiple pregnancy and/or birth defects

When using Ovitrelle, you have a higher risk of being pregnant with more than one child at the same time ('multiple pregnancy', usually twins) than if you conceived naturally. Multiple pregnancy may lead to medical complications for you and your babies. When undergoing Assisted Reproductive Techniques, the risk of having a multiple pregnancy is related to the number of fertilised eggs or embryos placed inside you. Multiple pregnancies and specific characteristics of couples with fertility problems (e.g. age) may also be associated with an increased chance of birth defects.

The risk of multiple pregnancy is reduced if the usual dose of Ovitrelle is used, and if you are monitored closely throughout your treatment cycle (e.g. blood tests for estradiol levels and ultrasound).

Ectopic pregnancy

Pregnancy outside of the womb (an ectopic pregnancy) may occur in women with damaged fallopian tubes (the tubes which carry the egg from the ovary to the womb). Therefore, your doctor should perform an early ultrasound examination to rule out the possibility of pregnancy outside the womb.

Miscarriage

When undergoing Assisted Reproductive Techniques or stimulation of your ovaries to produce eggs, you are more likely to have a miscarriage than the average woman.

Blood clotting problems (thromboembolic events)

If you had in the past or recently blood clots in the leg or in the lung, or a heart attack or stroke, or if those happened in your family, then you might have a higher risk that these problems occur or become worse with Ovitrelle treatment.

Pregnancy tests

If you do a pregnancy test with serum or urine after use of Ovitrelle, and up to ten days later, it may happen that you get a false positive test result. If you are not sure, talk to your doctor.

Children and adolescents

Ovitrelle is not for use in children and adolescents.

Other medicines and Ovitrelle

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

Do not use Ovitrelle if you are pregnant or breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines

It is not expected that Ovitrelle will affect your ability to drive and use machines.

Ovitrelle contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially “sodium-free”.

3. How to use Ovitrelle

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How much to use

- The recommended dose is 1 pre-filled pen (250 micrograms/0.5 mL) given as a single injection.
- Your doctor will explain to you exactly when to give the injection.

Using this medicine

- If you administer Ovitrelle to yourself, please carefully read and follow the separate “Instructions for use” provided in the carton.
- Ovitrelle is intended to be given by injection under the skin (subcutaneously).
- Each pre-filled pen is for single use only.
- Your doctor or nurse will show you how to use the Ovitrelle pre-filled pen to inject the medicine.
- Inject Ovitrelle as your doctor or nurse taught you.
- After the injection, dispose of the used needle safely, and discard the pen.

If you use more Ovitrelle than you should

If too much Ovitrelle is used, there is a possibility that ovarian hyperstimulation syndrome may occur. See your doctor straight away if you get lower abdominal pain, gain any weight rapidly, feel sick or are vomiting, or have difficulty in breathing.

If you forget to use Ovitrelle

If you forget to use Ovitrelle, please talk to your doctor as soon as you notice.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using Ovitrelle and see a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

- Allergic reactions such as fast or uneven pulse, swelling of your tongue and throat, sneezing, wheezing, or serious breathing difficulty are very rare (may affect up to 1 in 10,000 people).
- Lower abdominal pain together with nausea (feeling sick) or vomiting may be the symptoms of Ovarian Hyperstimulation Syndrome (OHSS). This may indicate that the ovaries over-reacted to

the treatment and that large ovarian cysts developed (see also in section 2. under “Ovarian Hyperstimulation Syndrome”). This event is common (may affect up to 1 in 10 people).

- The OHSS may become severe with clearly enlarged ovaries, decreased urine production, weight gain, difficulty in breathing and possible fluid accumulation in your stomach or chest. This event is uncommon (may affect up to 1 in 100 people).
- Serious blood clotting complications (thromboembolic events) sometimes independent of OHSS may be found very rarely. This could cause chest pain, breathlessness, stroke or heart attack (see also in section 2. under “Blood clotting problems”).

Other side effects

Common (may affect up to 1 in 10 people)

- Headache, feeling tired.
- Local reactions at the injection site, such as pain, redness or swelling.

Uncommon (may affect up to 1 in 100 people)

- Diarrhoea.
- Feeling depressed, irritable or restless.
- Breast pain.

Very rare (may affect up to 1 in 10,000 people)

- Mild skin allergic reactions such as rash.

Pregnancy outside your womb, ovarian torsion (a condition affecting the ovaries) and other complications may arise from the assisted reproductive techniques your doctor may use.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

Malta

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ovitrelle

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C-8°C). Do not freeze.

Do not use Ovitrelle if you notice any signs of deterioration, if the liquid contains particles or is not clear.

Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines no longer used. These measures will help to protect the environment.

6. Contents of the pack and other information

What Ovitrelle contains

- The active substance is choriogonadotropin alfa, produced by recombinant DNA technology.
- Each pre-filled pen contains 250 micrograms choriogonadotropin alfa in 0.5 mL (equivalent to approximately 6,500 International Units, IU).
- The other ingredients are mannitol, methionine disodium phosphate dihydrate, sodium dihydrogen phosphate monohydrate, poloxamer 188, phosphoric acid (for pH adjustment), sodium hydroxide (for pH adjustment) and water for injections.

What Ovitrelle looks like and contents of the pack

- Ovitrelle comes as a clear, colourless to slightly yellow liquid for injection in a pre-filled pen.
- Each pen contains 0.5 mL of solution.
- It is supplied in packs of 1 pre-filled pen and 1 injection needle.

Marketing Authorisation Holder

Merck Europe B.V., Gustav Mahlerplein 102, 1082 MA Amsterdam, The Netherlands

Manufacturer

Merck Serono S.p.A., Via delle Magnolie 15, 70026 Modugno (Bari), Italy

This leaflet was last revised in October 2018

Detailed information on this medicine is available on the European Medicines Agency web site:

<http://www.ema.europa.eu>.