

## Package leaflet: Information for the user

### Ovitrelle 250 micrograms/0.5 mL solution for injection in pre-filled syringe 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 technologies (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 your hypothalamus or pituitary gland (both are parts of the brain).
- 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 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 technologies, the risk of having a multiple pregnancy is related to your age, the quality and 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 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 technologies 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)

Talk to your doctor before using Ovitrelle if you or a member of your family have ever had blood clots in the leg or in the lung, or a heart attack or stroke. You may be at a higher risk of serious blood clots or existing clots might become worse with Ovitrelle treatment.

### Tumours of sexual organs

There have been reports of tumours in the ovaries and other sex organs, both benign and malignant, in women who have undergone multiple regimens for infertility 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, 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 syringe (250 micrograms/0.5 mL) given as a single injection.
- Your doctor will have explained exactly when to give the injection.

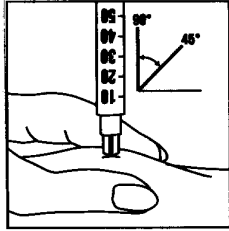
### **Using this medicine**

- Ovitrelle is intended for subcutaneous use that means given by injection under the skin.
- Each pre-filled syringe is for single use only. Only clear solution without particles should be used.
- Your doctor or nurse will show you how to use the Ovitrelle pre-filled syringe to inject the medicine.
- Inject Ovitrelle as your doctor or nurse taught you.
- After the injection, dispose of the used syringe safely.

If you administer Ovitrelle to yourself, please carefully read the following instructions:

1. Wash your hands. It is important that your hands and the items you use are as clean as possible.
2. Assemble everything you need. Please note that alcohol swabs are not contained in the package. Find a clean area and lay out everything:
  - two alcohol swabs,
  - one pre-filled syringe containing the medicinal product.

3. Injection:



Immediately inject the solution: Your doctor or nurse will have already advised you where to inject (e.g. tummy, front of thigh). Wipe the chosen area with an alcohol swab. Firmly pinch the skin together and insert the needle for injection at a 45° to 90° angle using a dart-like motion. Inject under the skin, as you were taught. Do not inject directly into a vein. Inject the solution by pushing gently on the plunger. Take as much time as you need to inject all the solution. Immediately withdraw the needle and clean the skin with an alcohol swab using a circular motion.

4. Dispose of all used items:  
Once you have finished your injection, immediately discard the empty syringe in a sharps container. Any unused solution must be discarded.

#### **If you use more Ovitrelle than you should**

The effects of an overdose of Ovitrelle are unknown, nevertheless there is a possibility that ovarian hyperstimulation syndrome (OHSS) may occur, which is further described in section 4.

#### **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 rash, 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, abdominal distension or abdominal discomfort 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.
- Local reactions at the injection site, such as pain, redness or swelling.

Uncommon (may affect up to 1 in 100 people)

- Diarrhoea.

### **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](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

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). Store in the original package. Ovitrelle 250 micrograms solution for injection may be stored at room temperature (at or below +25°C) for up to 30 days without being refrigerated again during this period, and must be discarded if not used during these 30 days.

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 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 syringe contains 250 micrograms / 0.5 mL (equivalent to 6500 IU).
- The other ingredients are mannitol, methionine, poloxamer 188, phosphoric acid, sodium hydroxide, water for injections.

### **What Ovitrelle looks like and contents of the pack**

Ovitrelle is provided as solution for injection. It is available as a single pre-filled syringe (pack of 1).

**Marketing Authorisation Holder**

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