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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. BEFORE YOU USE OVITRELLE

Do not use Ovitrelle:

- if you are allergic (hypersensitive) to choriogonadotropin alfa or any of the ingredients of Ovitrelle listed in section 6.
- if you have a tumor 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 (extra-uterine pregnancy) within the last three months.

- if you have severe inflammation of your veins or blood clotting in your veins (active thrombo- embolic 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 or pharmacist before using this medicine.

Take special care with Ovitrelle:

Before the treatment is started, you 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.

Using other medicines:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breastfeeding

Do not use Ovitrelle if you are pregnant or breastfeeding. Ask your doctor or pharmacist before you take any medicine.

Driving and using machines

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

Important information about some of the ingredients of Ovitrelle

This medicine contains less than 1 mmol sodium (23 mg), which means it is essentially "sodium-free".

3. HOW TO USE OVITRELLE

Always take Ovitrelle exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure

How much to use

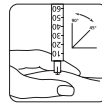
- The usual dose of Ovitrelle is 1 pre-filled syringe (250 micrograms/0.5 ml) given as a single injection.
- Your doctor will have explained exactly when to give the injection.

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 needle 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

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, Ovitrelle 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 (affects less than 1 user in 10,000).
- Lower abdominal pain together with nausea (feeling sick) or vomiting may be the symptoms of Ovarian Hypostimulation Syndrome (OHSS). This may indicate that the ovaries over-reacted to the treatment and that large ovarian cysts developed (see also section 2 'Take special care with Ovitrelle'). This event is common (affects 1 to 10 users in 100).
- 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 (affects 1 to 10 users in 1,000).

- Serious blood clotting complications (thromboembolic events) independent of OHSS may be found very rarely. This could cause chest pain, breathlessness, stroke or heart attack (see also section 2 "Take special care with Ovitrelle").

Other side effects

Common

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

Uncommon

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

Very rare

- 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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE OVITRELLE

Keep out of the reach and sight of children.

Do not use 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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER 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 in EU

Merck Serono Europe Limited
56 Marsh Wall London E14 9TP United Kingdom

Manufacturer

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

DATE OF INFORMATION

March 2013

For further inquiries inside Egypt, Call 16935

This is a medicine

- A medicine is a product which affects your health and its consumption, contrary to instructions, is dangerous for you.
- Closely follow your doctor's prescription, the method of use and the instructions of the pharmacist who sold the product.
- Your doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not interrupt the period of treatment prescribed without your doctor's permission.
- Do not repeat the same prescription without consulting your doctor.

Keep medicines out of reach of children.

Council of Arab Health Ministers

Union of Arab Pharmacists

Merck Serono



PACKAGE LEAFLET: INFORMATION FOR THE USER

OVITRELLE® 250 micrograms/0.5ml

solution for injection in pre-filled syringe

Choriogonadotropin alfa

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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