

IVIDREL[®] SOLUTION FOR INJECTION

Choriogonadotropin alfa (250mcg/0.5ml)

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What Ovidrel is used for

Ovidrel is used in women undergoing assisted reproductive techniques such as in vitro fertilization (IVF). Other medicines are given first to bring about the growth and development of several follicles to produce eggs. Follicles are the structures in your ovaries that contain the egg.

Ovidrel is then used to ripen (mature) these follicles. Ovidrel is also used in women who do not produce eggs (anovulation), or who produce too few eggs (oligoovulation). It is used to trigger the release of eggs (ovulation), after other medicines have been used to develop the follicles.

Your doctor may prescribe Ovidrel for another reason. Ask your doctor if you have any questions about why Ovidrel has been prescribed for you. Ovidrel is not addictive. This medicine is available only with a doctor's prescription.

How Ovidrel works

Ovidrel belongs to a family of hormones known as gonadotrophins, which are involved in the normal control of reproduction.

The active substance of Ovidrel is choriogonadotropin alfa that is produced in mammalian cells modified by recombinant DNA technology.

Before you use Ovidrel

- *When you must not use it*

Do not use Ovidrel if:

- you have a history of allergy to choriogonadotropin alfa, or a similar medicine, or any other inactive ingredients (listed at the end of this leaflet).

Symptoms of an allergic reaction to Ovidrel may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not use Ovidrel if you have, or have had, any of the following medical conditions:

- your ovaries are unable to be stimulated to produce eggs (primary ovarian failure).
- excessive bleeding in the female reproductive system of unknown origin
- extrauterine pregnancy (pregnancy outside uterus) in the previous 3 months
- active blood clot disorders
- pregnancy and breastfeeding
- a tumour of the hypothalamus or pituitary gland.
- ovarian enlargement or one or more large ovarian cysts.
- cancer of your ovaries, uterus (womb) or breasts.
- fibroid tumours or malformations of sexual organs in your uterus which would make pregnancy impossible.
- if you have been through menopause.

Ovidrel should not be used in the elderly or in children.

Do not use Ovidrel after the expiry date printed on the pack.

Do not use Ovidrel if the packaging is torn or shows signs of tampering. If your medicine has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using Ovidrel, contact

your doctor.

- *Before you start to use it*

Your doctor will assess you and your partner's infertility. This may include tests for other medical conditions, which may interfere with your ability to become pregnant. If necessary, other medical conditions may be treated before starting infertility treatments and Ovidrel.

Tell your doctor if you have or have had any other pre-existing medical conditions.

Treatment with Ovidrel may increase your risk of developing underactive thyroid gland, dysfunction of adrenal glands, high prolactin levels and a condition called *ovarian hyperstimulation syndrome* (OHSS). This is when the ovaries over react to the hormonal treatment and develop too many follicles.

The most common symptom is stomach pain. During stimulation your doctor will monitor your treatment by use of ultrasound and blood tests to measure oestrogen levels. This will help to indicate if you are likely to develop OHSS. If necessary, your doctor will delay or cancel your Ovidrel injection.

Compared to natural conception, the frequency of multiple pregnancies and births is increased in people receiving this treatment. The majority of these are twins. In assisted reproduction techniques, the number of babies is related to the number of embryos replaced. Please discuss with your doctor.

The rate of miscarriage in people who receive this treatment is higher than those with natural conception. Please talk to your doctor about your concerns.

The incidence of ectopic pregnancies might be increased. Therefore, it is

important to have early ultrasound confirmation that a pregnancy is in the uterus.

There may be a slight increased risk of birth defects in women using assisted reproductive technologies. This may be due to differences in maternal age, sperm characters and higher incidence of multiple pregnancies. Talk to your doctor about any concerns you may have before undergoing treatment. Tell your doctor if you or your family have or have had increased risk of developing blood clots e.g. stroke, heart attacks.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without prescription from your pharmacy, supermarket or health food shop.

How to use Ovidrel

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet. Treatment with Ovidrel should be started under the supervision of a specialist doctor experienced in fertility treatment.

- How much to inject

The dose of Ovidrel is one pre-filled syringe or pre-filled pen (250 microgram in 0.5 mL) given as a single injection after stimulation of follicle growth by other medicines. Dosage may need to be varied on the instruction of your doctor and you should be confident in your ability to adjust the dose.

Please consult your doctor or pharmacist if you are in any doubt. Your doctor will explain exactly when to give the injection. Each pre-filled syringe or pre-filled pen is for single use only.

- How to inject it

Ovidrel is given as an injection under the skin (subcutaneously), usually near your stomach. Ovidrel is intended to be injected by yourself or by your partner.

Your doctor or nurse will instruct and assist you in learning the procedure and technique of self-injection. Do not attempt self-injection until you are sure of how to do it. Your partner may be trained to give the injection at home. Your doctor or nurse can also give the injection to you.

- Where to inject it

Ovidrel is usually given under the skin of the stomach area (except around navel and waistline) or the front of your thigh

Do not inject into any areas in which you feel lumps, firm knots, depressions, pain or discolouration.

Talk to your doctor if you find anything unusual when injecting.

- If you forget to inject it

You should contact your doctor immediately. It is important that Ovidrel is injected on the correct day and at the correct time as instructed by your doctor. You must inform your doctor if your injection was not given when directed. Ask your doctor if you are not sure what to do or have trouble remembering to inject your medicine.

- If you inject too much (overdose)

Immediately telephone your doctor for advice if you think that you or anyone else may have injected too much Ovidrel. Do this even if there are no signs of discomfort or poisoning. Nevertheless, there is a possibility that ovarian hyperstimulation syndrome (OHSS) may result from an overdosage of Ovidrel. You may need urgent medical attention.

While you are using Ovidrel

- Things you must do

Tell your doctor if you start taking any new medication while using Ovidrel.

- Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours or if they have the

same condition as you.

Do not use Ovidrel to treat any other complaints unless your doctor advise.

Do not stop Ovidrel or change the dose without checking with your doctor

- Things to be careful of

Ovidrel may interfere with the results of a blood or urinary hCG (pregnancy) test for up to 10 days. This may lead to a false positive pregnancy test.

Side effects

If you do not feel well while you are taking Ovidrel then tell your doctor or pharmacist as soon as possible. All medicines can have side effects. Most of the time they are not serious but sometimes they can be.

Tell your doctor immediately if you experience any of the following: Early signs of ovarian hyperstimulation syndrome (OHSS) which include severe stomach pain, nausea, vomiting, diarrhea, shortness of breath and low urine production.

Tell your doctor if you notice any of the following and they worry you:

Common side effects:

- injection site reactions
- headache
- tiredness
- nausea/vomiting, abdominal pain
- rash
- mild or moderate OHSS

Other side effects not listed above may also occur in some people.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Ovidrel

- Storage

Keep this medicine where young children cannot reach it.

Ovidrel must be stored at 2°C to 8°C (Refrigerate. Do not freeze) in its original container. Product is for single person only.

Contains no antimicrobial preservative. Discard any residue. Ovidrel can also be stored for up to 30 days below 25°C in its original container and protected from light. Discard any residue. After opening, the product should be used immediately.

- Disposal

After injecting, you should discard the syringe even if you have not injected all its contents. Syringes should be discarded in an appropriate disposal unit.

Product description

- What it looks like

Pre-filled syringe: 0.5 ml of clear, colorless to slightly yellowish solution contained in a pre-filled syringe (type I glass) with a plunger stopper (halobutyl rubber) and plunger (plastic), and with a stainless steel needle for injection.

Pack size: Each box contains 1mL glass pre-filled syringe.

Pre-filled pen: 3ml cartridge (type I glass, with a bromobutyl rubber plunger stopper and an aluminium crimp cap with bromobutyl rubber) preassembled in a prefilled pen. Each prefilled pen contains 0.5 ml of solution for injection and one injection needle

- Ingredients

- Active ingredient:
choriogonadotropin alfa
- Inactive ingredients:
mannitol, phosphoric acid, sodium hydroxide, poloxamer, methionine and water for injections

- MAL Number:

MAL20041216AZ

Manufacturer

Merck Serono S.p.A.
Via delle Magnolie 15
(loc. frazione Zona Industriale)
70026 - Modugno (BA), Italy.

Product Registration Holder

Merck Sdn Bhd (178145-V)
Level 3, Menara Sunway Annexe,
Jalan Lagoon Timur
Bandar Sunway
46150, Petaling Jaya
Selangor Darul Ehsan

Date of Revision:

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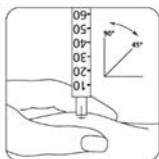
Instructions for use, handling and disposal

Ovidrel® is given by injection under the skin. Each pre-filled syringe or prefilled pen is for single use only. Only clear solution without particles should be used. Any unused product or waste material should be disposed of in accordance with local requirements.

If you inject Ovidrel® to yourself, please carefully read the following instructions:

Prefilled syringe:

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



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.

Prefilled pen:

Please carefully read and follow the “Instructions for use” provided in the carton.

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.