OVIDREL®

(choriogonadotropin alfa (rch)) solution for injection pre-filled pen

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about OVIDREL.

It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you using OVIDREL against the benefits it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this information with your medicine.
You may want to read it again later.

What OVIDREL is used for

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.

OVIDREL is used in women undergoing assisted reproductive techniques such as in vitro fertilisation (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 (oligo-ovulation). 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.

Before you use OVIDREL

When you must not use it

Do not use OVIDREL if you have or have had an allergy to:

- choriogonadotropin alfa or any of the 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 take OVIDREL if:

- your ovaries are unable to be stimulated to produce eggs (primary ovarian failure or premature menopause)
- you have uncontrolled thyroid or adrenal gland disease
- you have a tumour of the hypothalamus or pituitary gland
- you have ovarian enlargement or one or more large ovarian cysts
- you have cancer of your ovaries, uterus (womb) or breasts
- you have fibroid tumours in your uterus which would make pregnancy impossible
- you have been through menopause
- you have active blood clots disorders
- you have unexplained vaginal or uterine bleeding

If you are not certain whether these conditions apply to you, or you are worried about anything on this list, talk to your doctor.

Do not take OVIDREL after the expiry date printed on the pack. Do not take 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 a condition called ovarian hyperstimulation syndrome (OHSS). This is when the ovaries overreact 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 patients 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.

There may be a slightly increased risk of birth defects in women using assisted reproductive technologies. This may be due to maternal age, genetic factors, multiple pregnancies or the assisted reproductive technologies.

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.

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.

How OVIDREL is given

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 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 pen is for single use in one patient only. Discard any residue.

How to inject

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

OVIDREL is usually given in 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 OVIDREL

If you forget an injection, contact your doctor or nurse immediately for advice.

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

Immediately contact your doctor or the Poisons Information Centre (In Australia telephone 131 126. In New Zealand telephone 0800 764 766) if you are

concerned that you have given yourself too much OVIDREL.

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 symptoms unless your doctor says to.

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

Things to be careful of

Be careful driving or operating machinery until you know how OVIDREL affects you.

Side effects

Tell your doctor as soon as possible if you do not feel well while you are taking OVIDREL.

All medicines can have side effects. Sometimes they are serious, most of the times they are not.

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

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor immediately, or go to Accident and Emergency section of your nearest hospital if you experience any of the following:

- signs of allergic reactions including swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty breathing, severe skin rash, itching or hives
- signs of severe OHSS such as severe lower abdominal pain, severe pelvic pain, nausea, vomiting, diarrhoea followed by rapid weight gain, reduced amount of urine and shortness of breath
- signs of blood clots (such as pain, warmth, redness, numbness or tingling in arm or leg) and strokes

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

- local reactions at the injection site, such as pain, redness or swelling
- headache
- nausea, vomiting, diarrhoea, abdominal pain or discomfort

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

Tell your doctor if you notice anything else that is making you feel unwell.

After using 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. Protect from light.

Disposal

After injecting, you should discard the pen even if you have not injected all its contents. Pen and needle should be discarded in an appropriate disposal unit.

Product description

What it looks like

OVIDREL is supplied as solution for injection in a pre-filled pen. It contains no antimicrobial preservative.

Ingredients

Active ingredient:

- choriogonadotropin alfa

Inactive Ingredients:

- mannitol
- monobasic sodium phosphate monohydrate
- dibasic sodium phosphate dihydrate
- phosphoric acid
- sodium hydroxide
- poloxamer
- methionine
- water for injections

Manufacturer/Supplier

OVIDREL is supplied in Australia by:

Merck Healthcare Pty Ltd
Suite 1, Level 1, Building B
11 Talavera Road
Macquarie Park NSW 2113
E-mail: medinfo.australia@merckgroup.com
Phone: 1800 633 463

OVIDREL is supplied in New Zealand by:

Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks, Auckland
E-mail: medinfo.australia@merckgroup.com
Phone: 0800 426 252

The Australian registration number for:

OVIDREL choriogonadotropin alfa (rch) 250 microgram/0.5mL solution for injection pre-filled pen is AUST R 170446.

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