OVIDREL®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using OVIDREL?

OVIDREL contains the active ingredient choriogonadotropin alfa (rch). OVIDREL is used in women undergoing assisted reproductive techniques such as in vitro fertilisation (IVF) and in women who do not produce eggs (anovulation) or who produce too few eggs (oligo-ovulation) to trigger the release of eggs (ovulation) after other medicines have been used to develop follicles.

For more information, see Section 1. Why am I using OVIDREL? in the full CMI.

2. What should I know before I use OVIDREL?

Do not use if you have ever had an allergic reaction to OVIDREL or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, are pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use OVIDREL? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with OVIDREL and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use OVIDREL?

- The dose of OVIDREL is one pre-filled pen (250 microgram in 0.5 mL) given as a single injection under the skin (subcutaneously) after stimulation of follicular growth with other medicines. Your doctor will explain how much and when to give the injection. Each pre-filled pen is for single use in one patient only.
- Follow all directions given to you by your doctor or pharmacist carefully, including the Instructions for Use provided in the pack.

More instructions can be found in Section 4. How do I use OVIDREL? in the full CMI.

5. What should I know while using OVIDREL?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using OVIDREL.
Things you should not do	• Do not stop using this medicine suddenly or change the dose without checking with your doctor. • Do not give this medicine to anyone else, even if they have the same condition as you.
Driving or using machines	• Be careful driving or operating machinery until you know how OVIDREL affects you.
Looking after your medicine	• Store OVIDREL at 2°C to 8°C (Refrigerate. Do not freeze) in its original container. Protect from light. • Prior to use and within its shelf life, OVIDREL pre-filled pen can also be stored below 25°C for up to 28 days in its original container and protected from light. It must be discarded if not used after these 28 days.

For more information, see Section 5. What should I know while using OVIDREL? in the full CMI.

6. Are there any side effects?

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Tell your doctor if you experience any side effects.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

OVIDREL®

Active ingredient(s): *choriogonadotropin alfa (rch)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using OVIDREL. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using OVIDREL.**

Where to find information in this leaflet:

1. Why am I using OVIDREL?

OVIDREL contains the active ingredient choriogonadotropin alfa (rch). OVIDREL belongs to a family of hormones known as gonadotrophins, which are involved in the normal control of reproduction.

OVIDREL is used in women undergoing assisted reproductive technique such as in vitro fertilisation (IVF) and in women who do not produce eggs (anovulation) or who produce too few eggs (oligo-ovulation) to trigger the release of eggs (ovulation) after other medicines have been used to develop follicles.

2. What should I know before I use OVIDREL?

Warnings

Do not use OVIDREL if:

- you are allergic to choriogonadotropin alfa, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- your ovaries are unable to be stimulated to produce eggs (primary ovarian failure).
- 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.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- or your family have had increased risk of developing blood clots, e.g. stroke, heart attacks.

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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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.

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.

3. What if I am taking other medicines?

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect OVIDREL.

4. How do I use OVIDREL?

How much to inject

- The dose of OVIDREL is one pre-filled pen (250 microgram in 0.5 mL) given as a single injection under the skin after stimulation of follicular growth with other medicines.
- Your doctor will explain how much and when to give the injection.
- Each pre-filled pen is for single use in one patient only. Discard any residue.

- Follow the instructions provided by your doctor, nurse or pharmacists.

When to inject OVIDREL

- OVIDREL is given as a single injection under the skin (subcutaneously), usually near your stomach. Your doctor will tell you when to inject OVIDREL.
- It is important that OVIDREL is injected on the correct day and at the correct time as instructed by your doctor.

How to inject OVIDREL

- Your doctor or nurse will instruct and assist you in learning the procedure and technique of self-injection.
- Your doctor or nurse can also give the injection to you.
- Follow the Instructions for Use provided in the pack.
- Do not attempt self-injection until you are sure of how to do it.
- Do not inject in which you feel lumps, firm knots, depression, pain or discolouration.
- Talk to your doctor if you find anything unusual when injecting.

If you forget to use OVIDREL

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

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 the medicine.

If you use too much OVIDREL

If you think that you have used too much OVIDREL, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26 in Australia or 0800 764 766 in New Zealand**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using OVIDREL?

Things you should do

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

Remind any doctor, dentist or pharmacist you visit that you are using OVIDREL.

Things you should not do

- Do not stop using this medicine suddenly without telling your doctor.
- Do not change the dose unless your doctor tells you to.
- Give this medicine to anyone else even if they have the same condition as you.

Ovarian Hyperstimulation Syndrome (OHSS)

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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how OVIDREL affects you.

Looking after your medicine

- OVIDREL must be stored at 2°C to 8°C (Refrigerate. Do not freeze) in its original container. Protect from light.
- Prior to use and within its shelf life, OVIDREL pre-filled pen can also be stored below 25°C for up to 28 days in its original container and protected from light. It must be discarded if not used after these 28 days.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

Side effects	What to do
• Local reactions at the injection site, such as pain, redness or swelling • Headache • Nausea, vomiting, diarrhoea, abdominal pain or discomfort	**Speak to your doctor if you have any of these side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Allergic reactions: • 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:** • Severe lower abdominal pain, severe pelvic pain, nausea, vomiting, diarrhoea followed by rapid weight gain, low urine output and shortness of breath **Signs of blood clots:** • Pain, warmth, redness, numbness or tingling in arm or leg and strokes	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. In New Zealand, you can report side effects to Medsafe online at https://pophealth.my.site.com/carmreportnz/s/.

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

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What OVIDREL contains

Active ingredient (main ingredient)	choriogonadotropin alfa (rch)
Other ingredients (inactive ingredients)	mannitol monobasic sodium phosphate monohydrate dibasic sodium phosphate dihydrate phosphoric acid sodium hydroxide poloxamer methionine water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What OVIDREL looks like

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

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

Who distributes OVIDREL

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

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