

## 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 OVALEAP?

OVALEAP contains the active ingredient follitropin alfa. OVALEAP is used to stimulate development of follicles in women who do not ovulate and women undergoing assisted reproductive technologies (ART) such as in vitro fertilisation (IVF) and in men in combination with hCG to stimulate the production of sperm. For more information, see Section [1. Why am I using OVALEAP?](#) in the full CMI.

### 2. What should I know before I use OVALEAP?

Do not use if you have ever had an allergic reaction to OVALEAP 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, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I use OVALEAP?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with OVALEAP 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 OVALEAP?

- Your doctor will decide the correct dose of OVALEAP for you. Your dose of OVALEAP may be adjusted depending on your individual response to treatment. Please consult your doctor if you are in any doubt.
- OVALEAP is given as a course of daily injections. You should have your injection at the same time each day.

More instructions can be found in Section [4. How do I use OVALEAP?](#) in the full CMI.

### 5. What should I know while using OVALEAP?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist, or pharmacist you visit that you are using OVALEAP.</li><li>• See your doctor regularly. Your doctor will monitor you closely throughout your treatment.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine suddenly.</li><li>• Do not use OVALEAP if you are pregnant or breastfeeding</li><li>• Do not use OVALEAP if your ovaries are enlarged, you have an unexplained ovarian cyst, you have unexplained vaginal or uterine bleeding, you have cancer of the ovaries, uterus or breasts, your ovaries have failed or you have fibroids in your uterus which would make pregnancy impossible</li><li>• Do not use OVALEAP if you have increased levels of gonadotrophins indicating failure of the testes or your infertility is due to disorders other than hypogonadotropic hypogonadism (low levels of gonadotrophins)</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how OVALEAP affects you.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Tell your doctor if you drink alcohol.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Prior to use, store OVALEAP in the original package at 2°C to 8°C (Refrigerate. Do not freeze.). Protect from light. Should refrigeration be unavailable, OVALEAP can be stored below 25°C for up to 3 months and away from light. OVALEAP must be discarded if it has not used for 3 months.</li></ul>

For more information, see Section [5. What should I know while using OVALEAP?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects include injection site reactions, headache, dizziness, stomach pain, abdominal distension or abdominal discomfort, nausea, vomiting, diarrhoea, acne, weight gain and an increase in breast tissue (in men). 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.

# OVALEAP

Active ingredient(s): *folliotropin alfa*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using OVALEAP. **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 OVALEAP.**

**Where to find information in this leaflet:**

- [1. Why am I using OVALEAP?](#)
- [2. What should I know before I use OVALEAP?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use OVALEAP?](#)
- [5. What should I know while using OVALEAP?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using OVALEAP?

**OVALEAP contains the active ingredient follitropin alfa which is similar to follicle stimulating hormone (FSH) found naturally in humans.** OVALEAP belongs to a class of hormones called gonadotrophins. FSH is necessary for the growth and development of egg cells (follicles) in women, and sperm production in men.

**OVALEAP is an approved biosimilar to the reference product Gonal-f®.**

**In women OVALEAP is used to bring about the development of follicles in women who are not ovulating and who have not responded to treatment with clomiphene citrate.**

**OVALEAP is also used to stimulate the development of several follicles in women undergoing assisted reproductive technologies (ART) such as in vitro fertilisation (IVF).**

**In men OVALEAP is used in combination with human chorionic gonadotrophin (hCG) to stimulate the production of sperm.**

## 2. What should I know before I use OVALEAP?

### Warnings

**Do not use OVALEAP if:**

- you are allergic to follitropin 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.

**Do not use OVALEAP if you have tumours of the hypothalamus or pituitary gland.**

**For women, do not use OVALEAP if:**

- you are pregnant
- you are breastfeeding
- your ovaries are enlarged
- you have an unexplained ovarian cyst
- you have unexplained vaginal or uterine bleeding
- you have cancer of the ovaries, uterus or breasts

- your ovaries have failed
- you have fibroids in your uterus or malformations of the sexual organs which would make pregnancy impossible

**For men, do not use OVALEAP if:**

- you have increased levels of gonadotrophins indicating failure of the testes
- your infertility is due to disorders other than hypogonadotrophic hypogonadism (low levels of gonadotrophins)

**Check with your doctor if you:**

- have any other medical conditions
- take any medicines for any other condition

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

**Do not use OVALEAP if you are pregnant.**

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

**Do not use OVALEAP if you are breastfeeding.**

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

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

### Use in children and the elderly

**Do not give this medicine to a child or elderly person**

### Before you start using OVALEAP

Your doctor will assess you and your partner's fertility. 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 including OVALEAP.

**Tell your doctor if you have or have had any of the following medical conditions:**

- disorders of the thyroid gland
- disorders of the adrenal glands
- high prolactin levels in the blood
- porphyria or a family history of porphyria

### For women

Your doctor will assess if you have any medical conditions which interfere with your ability to become pregnant.

Treatment with OVALEAP may increase your risk of developing a condition called ovarian hyperstimulation syndrome (OHSS). This is when the ovaries over-react to the hormonal treatment and become larger.

The most common symptom is lower abdominal pain. During stimulation your doctor will monitor your treatment by the use of ultrasound and/or blood tests to help determine if you are likely to develop OHSS. If necessary your doctor will delay or cancel your OVALEAP injection. You may also be advised to

refrain from sexual intercourse until the end of the cycle if this occurs.

Compared to natural conception, the frequency of multiple pregnancies and births is higher in patients receiving treatments that stimulate follicle growth for ovulation induction. The majority of these are twins. Your doctor will monitor your response to treatment to minimise the chance of multiple pregnancies, because of the greater risks they carry for mothers and babies.

Compared to natural conception, the frequency of pregnancy loss is higher in patients undergoing treatments to stimulate follicle growth for ovulation induction

There may be a slightly increased risk of birth defects in women using assisted reproductive technologies. This may be due to increased maternal age, genetic factors, multiple pregnancies or the procedures. An effect of medicines used to induce ovulation has not been excluded.

**Tell your doctor if you or a family member have or have had signs of blood clots (e.g. pain, warmth, redness, numbness or tingling in the arm or leg).**

Treatment with OVALEAP and hCG may increase the risk of blood clots forming in your blood vessels.

**Talk to your doctor about any concerns you may have before undergoing treatment or before you start using OVALEAP.**

#### For men

Elevated FSH blood levels are indicative of testicular failure. Your doctor may ask you for a semen analysis to assess your response to treatment.

**Talk to your doctor about any concerns you may have before you start using OVALEAP**

### 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.

Tell your doctor if you have any allergies to foods, dyes, preservatives, or any other medicines.

**Some medicines may interfere with OVALEAP and affect how it works.**

Your doctor has more information on medicines to be careful with or avoid while using OVALEAP

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

### 4. How do I use OVALEAP?

#### How much to take/use

- Your doctor will decide the correct dose of OVALEAP for you.
- Your dose of OVALEAP may be adjusted depending on your individual response to treatment.
- Please consult your doctor if you are in any doubt.
- The following is a guide to the common dose.

#### Women who are not ovulating

- The common dose usually starts at 75IU (5.5 microgram) daily. The dose may be adjusted as your treatment

progresses. The maximal daily dose is usually not higher than 225 IU (16.5 microgram)

#### Women undergoing assisted reproductive technologies

- The common dose usually starts at 150 IU (11 microgram) daily, commencing on day 2 or 3 of the cycle. The dose may be adjusted as your treatment progresses. The maximal daily dose is usually not higher than 450 IU (33 microgram)

#### Men with hypogonadotropic hypogonadism

- OVALEAP is commonly given with hCG. The common dose usually starts at 150 IU (11 microgram) three times a week.

#### When to take OVALEAP

- You should have your injection at the same time each day.
- OVALEAP is given as a course of daily injections.
- Treatment with OVALEAP should be started under the supervision of a specialist doctor experienced in fertility treatment.
- Do not use OVALEAP on anyone else. It is for your use only.

#### How to inject OVALEAP

- OVALEAP is given as a subcutaneous (under your skin) injection in the lower abdominal area or thigh.
- OVALEAP is intended to be injected by you or your partner. OVALEAP cartridges should only be administered using the OVALEAP Pen which is available separately.
- Alternatively your doctor or a nurse may give you these injections.
- If your doctor or nurse decides you can give the injections yourself, the doctor or nurse will teach you the injection technique. You can also find separate instructions for use provided with the OVALEAP Pen.
- **Do not self-inject until you are sure of how to do it.**
- **Read the Instructions for Use provided in the pack carefully before commencing injections.**
- Your partner may be trained to give the injection at home.

#### Where to inject OVALEAP

- OVALEAP is usually given in the lower abdominal area (except around the navel and waistline) or the front of your thigh. The injection site should be changed daily to lessen possible injection site reactions.
- **Do not inject into any areas in which you feel lumps, firm knots, depressions, pain, or see any discolouration.**
- **Talk to your doctor if you find anything unusual when injecting.**

#### How long to use OVALEAP for

##### For women

- The length of treatment varies with each patient. It is possible to have more than one treatment cycle of OVALEAP

##### For men

- The combination treatment of OVALEAP and hCG could continue for at least 4 months and may continue for up to 18-24 months

### If you forget to use OVALEAP

OVALEAP should be used regularly at the same time each day. If you forget an injection or are not sure what to do, contact your doctor or nurse immediately for advice.

### Do not inject a double dose on any day.

**Ask your doctor if you are not sure what to do or have any trouble remembering to inject your medicine.**

### If you use too much OVALEAP

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

### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 or in New Zealand call 0800 764 766), 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 OVALEAP?

### Things you should do

**See your doctor regularly. Your doctor will monitor you closely throughout your treatment.**

**If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using OVALEAP.**

**If you plan to have surgery, tell your doctor or dentist that you are using OVALEAP.**

**Your doctor will carefully monitor your response to OVALEAP by using ultrasound, blood tests or semen analysis.**

### Call your doctor straight away if you:

- Become pregnant while using OVALEAP

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

### Things you should not do

#### If you are self-injecting do not:

- Stop using this medicine suddenly.
- Change the dose unless your doctor tells you to. Changing your dose without advising your doctor can increase your risk of unwanted side effects or can prevent the drug from working properly.
- Give this medicine to anyone else, even if their symptoms seem similar to yours or if they have the same condition as you.

### Driving or using machines

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

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

### Looking after your medicine

- Prior to using, store OVALEAP in the original package at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light.
- Should refrigeration be unavailable, OVALEAP can be stored below 25°C for up to 3 months and away from light. OVALEAP must be discarded if it has not been used after 3 months.

### Do not use OVALEAP if the solution contains particles or is not clear.

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 windowsills.

### Keep it where young children cannot reach it.

### When to discard your medicine

**After first piercing OVALEAP pen with a needle, OVALEAP may be stored below 25°C for a maximum of 28 days with the cap on, in order to protect the product from light.**

### 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.

If you are self-injecting, you should discard all sharps into a disposal unit.

Do not use this medicine after the expiry date.

Do not use OVALEAP if you notice any visible signs of deterioration or damage to the container.

## 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.

### Less serious side effects

Less serious side effects	What to do
<b>Head related:</b> <ul style="list-style-type: none"><li>• Headaches, dizziness</li></ul> <b>Stomach or bowel related:</b> <ul style="list-style-type: none"><li>• stomach pain, abdominal distension or abdominal discomfort</li><li>• nausea, vomiting</li><li>• diarrhoea</li></ul> <b>Skin related:</b> <ul style="list-style-type: none"><li>• pain, redness, itching or swelling at the site of injection during your treatment with OVALEAP</li><li>• acne (for men)</li></ul> <b>Hormone related:</b>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>weight gain (in men)</li> </ul> <b>Reproductive system:</b> <ul style="list-style-type: none"> <li>vaginal bleeding</li> <li>some breast development (in men)</li> </ul>	

### Serious side effects

Serious side effects	What to do
<b>Allergic reactions:</b> <ul style="list-style-type: none"> <li>swelling of the face, lips, tongue, or other parts of the body</li> <li>shortness of breath, wheezing or difficulty breathing;</li> <li>severe skin rash, itching or hives.</li> </ul> <b>Heart and blood related:</b> <ul style="list-style-type: none"> <li>warning signs of stroke or heart attack</li> <li>warning signs of blood clots such as pain, warmth, redness, numbness or tingling in your arm or leg</li> <li>inflammation, swelling or pain in your legs</li> </ul> <b>Reproductive system:</b> <ul style="list-style-type: none"> <li>signs of severe OHSS such as severe lower abdominal pain, severe pelvic pain, nausea, vomiting, diarrhoea followed by rapid weight gain, reduced amounts of urine and shortness of breath</li> <li>Ectopic pregnancy (embryo implanted outside the womb) may occur, especially in women with prior tubal disease.</li> </ul>	<b>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.</b>

**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](http://www.tga.gov.au/reporting-problems). 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 OVALEAP contains

<b>Active ingredient (main ingredient)</b>	Each cartridge contains the active ingredient follitropin alfa (rch) (recombinant human follicle stimulating hormone) 300
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	IU/0.5 mL or 450 IU/0.75 mL or 900 IU/1.5 mL.
<b>Other ingredients (inactive ingredients)</b>	Mannitol Monobasic sodium phosphate dihydrate Sodium hydroxide Benzyl alcohol Polysorbate 20 Methionine Benzalkonium chloride Water for injections

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

### What OVALEAP looks like

OVALEAP contains sterile solution for injection in a cartridge.

OVALEAP solution for injection is available in the following strengths and pack sizes:

- 300 IU/0.5 mL (22 microgram). The pack contains 1 cartridge of solution for injection and 10 needles for administration (AUST R 328122)
- 450 IU/0.75 mL (33 microgram). The pack contains 1 cartridge of solution for injection and 10 needles for administration (AUST R 328120)
- 900 IU/1.5 mL (65.52 microgram). The pack contains 1 cartridge of solution for injection and 20 needles for administration (AUST R 328121)

The OVALEAP cartridge is designed for use in conjunction with the OVALEAP pen only, which is available separately.

### Who distributes OVALEAP

Theramex Australia Pty Ltd

60 Margaret Street,

Sydney, NSW 2000

For enquiries call: 1800 THERAMEX or 1800 843 726

This leaflet was prepared in March 2021.