

# DECAPEPTYL®

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## 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.

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### 1. Why am I using DECAPEPTYL?

DECAPEPTYL is used in assisted reproductive technology (ART) cycles to reduce the risk of cycle cancellation. It does this by preventing an early surge in luteinising hormone (LH), which can occur in women undergoing ART. DECAPEPTYL contains the active ingredient triptorelin acetate, which is a synthetic version of natural gonadotropin releasing hormone (GnRH).

For more information, see Section [1. Why am I using DECAPEPTYL?](#) in the full CMI starting from page 2.

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

Do not use DECAPEPTYL if you have ever had an allergic reaction to it or to any of the ingredients listed at the end of the CMI, see Section [7. Product details](#).

There are several circumstances in which a person should not use this medicine or may need to use with caution. It is important to understand if these circumstances apply to you before using DECAPEPTYL.

**Talk to your doctor if you have any other medical conditions or take any other medicines.** For more information, see Section [2. What should I know before I use DECAPEPTYL?](#) in the full CMI starting from page 2.

### **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.

Some medicines may interfere with DECAPEPTYL and affect how it works. For more information, see Section [3. What if I am taking other medicines?](#) in the full CMI starting from page 2.

### **4. How do I use DECAPEPTYL?**

You should only use DECAPEPTYL under the supervision of a doctor experienced in the treatment of infertility.

Always use this medicine exactly as your doctor has told you. You should check with your doctor if you are not sure. Your doctor will determine when to start your DECAPEPTYL treatment according to your cycle.

DECAPEPTYL is to be injected under the skin of your lower abdomen once a day. Before using DECAPEPTYL, you must be educated on how to use the injection and how to perform injections.

More instructions can be found in Section [4. How do I use DECAPEPTYL?](#) in the full CMI starting from page 2.

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

<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 DECAPEPTYL.</li><li>● Tell your doctor immediately if you become pregnant or if you have abnormal vaginal bleeding while using DECAPEPTYL.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>● Do not stop using this medicine or change the dosage without checking with your doctor.</li><li>● Do not give your medicine to anyone else, even if they have the same condition as you.</li></ul>

<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store in a refrigerator (2°C - 8°C). Do not freeze. Store in the original package to protect from light.</li></ul>
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For more information, see Section [5. What should I know while using DECAPEPTYL?](#) in the full CMI, starting from page 2.

## **6. Are there any side effects?**

All medicines can have side effects. Most of them are minor and temporary but some may need medical attention.

**Tell your doctor if you experience any side effects, including allergic reactions, abdominal pain, discomfort or swelling, diarrhoea, weight gain, difficulty breathing, decreased urination or visual impairment. These are very serious side effects. You may need urgent medical attention.**

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, starting from page 2.

# DECAPEPTYL®

**Active ingredient:** Triptorelin acetate

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## Consumer Medicine Information (CMI)

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

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

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

## 1. Why am I using DECAPEPTYL?

DECAPEPTYL is used in assisted reproductive technology (ART) cycles to reduce the risk of cycle cancellation. It does this by preventing an early surge in luteinising hormone (LH), which can occur in women undergoing ART.

DECAPEPTYL contains the active ingredient triptorelin acetate, which is a synthetic version of natural gonadotropin releasing hormone (GnRH). GnRH regulates the release of two hormones that are involved in the development of follicles and release of eggs from the ovaries: follicle-stimulating hormone (FSH) and luteinising hormone (LH).

**Ask your doctor if you have any questions about why DECAPEPTYL has been prescribed for you.** Your doctor may have prescribed DECAPEPTYL for another reason.

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

## **2. What should I know before I use DECAPEPTYL?**

### **Warnings**

#### **Do not use DECAPEPTYL if:**

- you are allergic to triptorelin acetate or any of the ingredients listed at the end of this leaflet
- you are allergic to GnRH, synthetic versions of GnRH, or similar medicines used in ART
- the expiry date printed on the pack has passed
- the packaging is torn or shows signs of tampering.

**Your doctor should make you aware of the signs and symptoms that may indicate allergic reaction when using DECAPEPTYL.**

**Check with your doctor if you:**

- have any other medical conditions
- take any medicines for any other condition
- are not sure whether you should use this medicine.

**Other medical conditions you need to tell your doctor about include:**

- mild to severe liver disease
- active allergies or being prone to allergies (women with severe allergies should not use DECAPEPTYL)
- Polycystic Ovarian Syndrome (fluid-filled sacs or pockets within or on the surface of the ovary)
- known risk of osteopenia (bone loss)
- mood changes or known depression.

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?](#)

Treatment with this medicine in very rare cases can uncover an underlying condition (pituitary adenoma) which can be associated with brain haemorrhage.

## **Pregnancy and breastfeeding**

Pregnancy must be excluded before treatment with DECAPEPTYL. DECAPEPTYL should be discontinued if you become pregnant while using it.

Undergoing treatment for infertility with hormones, like this medicine, has been associated with increased risk of:

- Ectopic pregnancy (pregnancy outside of the womb)
- Miscarriage
- Multiple pregnancy (twins, triplets, etc.)
- Congenital malformations (physical defects present in a baby at birth).

## **Ovarian hyperstimulation syndrome**

Some people have an exaggerated response to hormones used in ART, including when used with DECAPEPTYL. This may lead to ovarian hyperstimulation syndrome (OHSS). This is when your follicles develop too much causing your ovaries to swell and become painful.

OHSS is an emergency medical condition. Talk to your doctor as soon as possible if you have:

- abdominal pain, discomfort or swelling
- nausea
- vomiting
- diarrhoea
- weight gain

- difficulty in breathing
- decreased urination
- pain, warmth, redness, numbness, or tingling in your arm or leg
- confusion, extreme dizziness or severe headache

### **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.**

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

Your doctor or pharmacist has more information on medicines to be careful with or avoid while are you receiving this medicine.

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

### **4. How do I use DECAPEPTYL?**

**How much to use**

**Always use this medicine exactly as your doctor has told you. You should check with your doctor if you are not sure.**

DECAPEPTYL contains a solution of triptorelin acetate provided in a disposable syringe for single use.

The usual dosage is one injection under the skin of your lower abdomen once-daily.

If your doctor or nurse decides you can give the injections to yourself, they will train you on the right injection technique.

**Do not self-inject DECAPEPTYL until you are sure how to do it.**

The first injection of DECAPEPTYL should be under medical supervision because of the possibility of an allergic reaction (e.g. difficulty in breathing or swelling of the lips).

## **When to use DECAPEPTYL**

- DECAPEPTYL treatment can be started on day 2 or 3, or on day 21 to 23, of the menstrual cycle.
- After 2 to 4 weeks of DECAPEPTYL treatment, you will be given other hormones to stimulate follicle growth.
- In general, DECAPEPTYL treatment will continue until follicles have reached a suitable size, usually 4 to 7 weeks.
- If enough follicles are present, DECAPEPTYL treatment will be stopped and you will be given a medicine to induce ovulation.
- Your doctor will monitor your progress closely during your treatment.

## **How to Inject DECAPEPTYL**

- Remove the protective foil and take the syringe out of the blister packaging.
- Keep the syringe upright with the grey protective cap facing up.
- Remove the grey protective cap.
- Gently push the plunger until the first drops of liquid appear at the needle tip.
- Clean the injection site on the lower abdomen with an antiseptic swab immediately prior to injection. Allow to air-dry before proceeding.
- Lift up a fold of skin between the thumb and forefinger. With your free hand hold the syringe at a right angle to the skin like a dart and quickly insert the needle all the way into the skin fold. Press down slowly on the plunger to inject the contents of the syringe.
- Remove the syringe and needle from the skin and discard this immediately into a sharps disposal unit.
- For each dose, choose a different injection site along the lower abdomen.

## **Other important information**

- Each pre-filled syringe is for single-use only.
- Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you experience signs or symptoms of an allergic reaction (e.g. difficulty in breathing or swelling of the lips).

- The first injection of this medicine should be supervised by your doctor or nurse.
- The syringe with needle attached should be disposed of into a sharps disposal unit.

An instruction leaflet is supplied with your medicine.

## **If you forget to use DECAPEPTYL**

It is important that you do not miss a dose of DECAPEPTYL.

**If you miss a dose, contact your doctor or nurse.**

**Do not use a double dose to make up for the dose you missed.**

## **If you use too much DECAPEPTYL**

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

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Accident and Emergency at your nearest hospital.

## **5. What should I know while using DECAPEPTYL?**

### **Things you should do**

See your doctor regularly so you can be monitored closely throughout your treatment.

Tell every doctor, nurse or pharmacist that you visit that you are using DECAPEPTYL.

### **Call your doctor straight away if you:**

- become pregnant
- have abnormal vaginal bleeding
- have symptoms of OHSS, such as abdominal pain, discomfort or swelling, nausea, vomiting, diarrhoea, weight gain, difficulty in breathing or decreased urination

**Be sure to keep all your doctor's appointments so your progress can be checked.**

Your doctor will normally arrange for you to have ultrasound scans and sometimes blood tests to monitor your response to treatment.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using DECAPEPTYL.

### **Things you should not do**

- Do not use DECAPEPTYL to treat any other complaints unless your doctor tells you to.

- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop using your medicine or change the dosage without checking with your doctor.

## **Driving or using machines**

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

DECAPEPTYL should not normally interfere with your ability to drive or operate machinery.

## **Looking after your medicine**

- Keep DECAPEPTYL in the original pack until it is time to use it.
- Store DECAPEPTYL in a refrigerator (2°C to 8°C).
- Do not freeze.

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

**Keep DECAPEPTYL where young children cannot reach it.**

## **Getting rid of any unwanted medicine**

If you have any DECAPEPTYL that has expired or is left over from your treatment take it to any pharmacy for safe disposal.

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

## **6. Are there any side effects?**

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

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

### **Side effects**

<b>Side Effects</b>	<b>What to do</b>
<b>Injection site inflammation (common) (affect more than 1 in 100 users):</b> <ul style="list-style-type: none"><li>• Redness</li><li>• Itchiness</li><li>• Tenderness</li><li>• Pain or discomfort</li><li>• Warmth or burning</li><li>• Stinging</li><li>• Swelling</li></ul>	<b>These side effects are not usually serious but can become serious.</b> <b>Seek immediate medical care if you have any concerns.</b>

<b>Side Effects</b>	<b>What to do</b>
<p><b>Common side effects (affect more than 1 in 100 users):</b></p> <ul style="list-style-type: none"> <li>• Headache</li> <li>• Heavy, more painful periods, which may be prolonged or irregular</li> </ul> <p><b>Uncommon side effects (affect less than 1 in 100 users):</b></p> <ul style="list-style-type: none"> <li>• Abdominal pain, nausea or vomiting</li> <li>• Cold and flu-like symptoms or sore throat</li> <li>• Tiredness</li> <li>• Mood alterations</li> <li>• Dizziness</li> <li>• Hot flushes</li> <li>• Back or pelvic pain</li> <li>• Ovarian cysts, a fluid-filled sac or pocket within or on the surface of the ovary</li> </ul> <p><b>Side effects (unknown frequency):</b></p>	

<b>Side Effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• Breast pain</li> <li>• Vaginal bleeding/spotting</li> <li>• Vaginal dryness</li> <li>• Painful sexual intercourse</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• Abortion (common) (affect more than 1 in 100 users)</li> </ul> <p><b>Ovarian hyperstimulation syndrome related (common) (affect more than 1 in 100 users):</b></p> <ul style="list-style-type: none"> <li>• Abdominal pain, discomfort or swelling</li> <li>• Nausea</li> <li>• Vomiting</li> <li>• Diarrhoea</li> <li>• Weight gain</li> <li>• Difficulty in breathing</li> <li>• Decreased urination</li> </ul>	<p><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, even if a few days have passed since your last injection, or you stop using DECAPEPTYL.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Allergic reaction related (unknown frequency):</b></p> <ul style="list-style-type: none"> <li>• Shortness of breath, wheezing or difficulty breathing</li> <li>• Swelling of the face, lips, tongue or other parts of the body</li> <li>• Rash, itching or hives on the skin</li> </ul> <p><b>Other (unknown frequency):</b></p> <ul style="list-style-type: none"> <li>• Visual impairment</li> </ul>	

**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 DECAPEPTYL contains**

<b>Active ingredient (main ingredient)</b>	100 micrograms of triptorelin acetate (equivalent to 95.6 micrograms triptorelin).
<b>Other ingredients (inactive ingredients)</b>	Sodium chloride, glacial acetic acid and water for injections.

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

### **What DECAPEPTYL looks like**

DECAPEPTYL is supplied as a colourless solution in a glass syringe of 1 mL to which a needle is connected. The syringe and needle are closed with a rubber stopper

and a needle shield. This product is supplied in a pack size of 7 pre-filled syringes. (AUST R 219857).

## **Who distributes DECAPEPTYL**

DECAPEPTYL is distributed in Australia by:

Ferring Pharmaceuticals Pty Ltd

Suite 2, Level 1, Building 1,

20 Bridge Street, Pymble NSW 2073

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