

# REANDRON 1000

*Testosterone undecanoate*

---

## Consumer Medicine Information

---

### What is in this leaflet

---

This leaflet answers some common questions about Reandron 1000.

It does not contain all the available information.

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

All medicines have risks and benefits. Your doctor has weighed the risks of you using Reandron 1000 against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

---

### What Reandron 1000 is used for and how it works

---

Reandron 1000 is used to replace the body's natural hormone testosterone when not enough is made by the body.

Testosterone is a natural male hormone, known as an androgen, which controls normal sexual development in men.

Testosterone is essential for the development and maintenance of the male reproductive organs as well as other male characteristics, such as deep voice, increased muscle strength, hair growth etc.

Reandron 1000 contains testosterone undecanoate, a so-called androgen as the active ingredient. Reandron 1000 is injected into a location in your body (buttock muscle) where it can be stored and the testosterone is gradually released over a period of time.

The testosterone obtained from Reandron 1000 is identical to the naturally occurring testosterone present in the body.

Your doctor may prescribe Reandron 1000 for other reasons. Ask your doctor if you have any questions about why Reandron 1000 has been prescribed for you.

A doctor's prescription is required to obtain this medicine.

This medicine is not addictive.

This medicine is not expected to affect your ability to drive a car or operate machinery.

For further information please talk to your doctor or pharmacist.

---

## **Before you use Reandron 1000**

---

### ***When you must not use Reandron 1000***

**Do not use Reandron 1000 if you have or are suspected to have:**

- prostate cancer
- breast cancer
- high blood calcium levels associated with tumours

**Do not use Reandron 1000 if you have an allergy to:**

- testosterone undecanoate
- any of the ingredients listed at the end of this leaflet

**Reandron 1000 must not be used by children.**

The safety of Reandron 1000 in children under 18 years of age has not been established.

**Pregnancy: Reandron 1000 must not be used by women.**

**Do not use it after the expiry date printed on the pack.**

If you use it after the expiry date has passed, it may not work as well.

**Do not use if it or the packaging does not look quite right, or if the packaging is torn or shows signs of tampering.**

### ***Before you start to use Reandron 1000***

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

- high blood pressure or heart problems
- a tendency to retain fluid (signs may include swollen feet or ankles)
- liver or kidney disease
- epilepsy
- migraine
- diabetes
- any form of cancer
- high levels of calcium in the blood (hypercalcaemia)
- high levels of calcium in the urine (hypercalciuria)
- enlargement of the prostate (signs may include difficulty passing urine or frequent passing of urine)
- any form of blood clotting disorder

Reandron 1000 may increase the risk of benign prostatic hypertrophy (enlargement of the prostate gland) and/or prostate cancer. During treatment, your doctor may monitor the effects of this medicine on the prostate gland.

Worsening of breathing problems during sleep has been reported during treatment with testosterone replacement in predisposed people. This is especially true in overweight people or people with lung problems.

People using testosterone replacement over long periods of time may develop polycythaemia (an abnormal increase in the number of red blood cells in the blood). Your doctor may organise regular blood tests to check this is not happening.

### ***Sportsmen and women***

Athletes should note that the active substance testosterone undecanoate may produce a positive reaction in anti-doping tests.

### ***Taking other medicines***

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

Also tell any doctor or dentist who prescribes another medicine for you that you are using Reandron 1000.

Some medicines may be affected by Reandron 1000 or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

#### **In particular:**

- oral anticoagulants ('blood thinning' medications to treat or prevent blood clots)
- insulin (a medicine used to control blood sugar in diabetes)
- corticosteroids

---

## **How to use Reandron 1000**

---

### **Reandron 1000 is for use by adult men only.**

Reandron 1000 (1 ampoule corresponding to 1000mg testosterone undecanoate) will be injected by your doctor every 10-14 weeks.

The injection will be administered very slowly into your buttock muscle. Reandron 1000 is strictly for intramuscular injection. Special care will be given to avoid injection into a blood vessel.

### ***Start of treatment***

Your doctor will measure your blood testosterone levels before start of treatment. The first injection interval may be reduced to a minimum of 6 weeks. With this initial shortened interval, the necessary testosterone level will be reached quickly.

For Reandron 1000 to work best it is very important that Reandron 1000 is given exactly as your doctor tells you.

### ***If you use too much (overdose)***

As Reandron 1000 is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However if you experience any side effects after being given Reandron 1000, tell your doctor immediately.

---

## **Side effects**

---

**Tell your doctor or pharmacist if you notice any unwanted effect, especially if severe or persistent, or if there is a change in your health that you think might be caused by Reandron 1000.**

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

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

- Diarrhoea
- Leg pain
- Pain affecting a joint
- Dizziness
- Increased sweating
- Headache
- Respiratory disorder
- Painful, tender or enlarged breasts
- Skin reactions such as: irritation, redness, acne, dry or stinging skin
- Testicular pain (prostate disorder)
- Injection site pain
- Increased blood pressure
- Blood clot beneath the skin at the injection site

These are the most common side effects of Reandron 1000. Mostly these are mild and short-lived.

**The following side effects have been observed during treatment with other testosterone preparations. These may also occur with Reandron 1000. You may need urgent medical attention. Serious side effects are rare.**

- Weight gain
- Muscle cramps
- Depression/nervousness/irritability

- Sleep apnoea
- Jaundice (yellowing of the skin)
- Changes in the results of tests that check how your liver is working
- Skin reactions (acne, itchy skin)
- Hair loss
- Unwanted increased sex drive
- Oligospermia (reduction in the number of sperm)
- Unwanted priapism (frequent or prolonged and painful erections)
- Injection site reactions

**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.

### ***Storage***

Please note the expiry date on the pack. Do not use after this date.

Store all medicines out of the reach of children.

Reandron 1000 should be kept in a cool dry place where the temperature stays below 30° C.

---

### **Product description**

---

#### ***What it looks like***

Reandron 1000 is contained in a 5mL glass ampoule:

#### ***Ingredients***

Each 5mL glass ampoule of Reandron 1000 contains 4mL oily solution with 1000mg testosterone undecanoate as active ingredient.

Reandron 1000 also contains benzyl benzoate and castor oil.

#### ***Supplier***

Reandron 1000 is distributed in Australia by:

Schering Pty Ltd

Locked Bag 4

Alexandria NSW 1435

ABN 50 000 023 361

#### ***Date of information***

This leaflet was prepared in August 2005.

Reandron 1000  
AUST R: 106946