

REREANDRON® 1000

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 REANDRON?

REANDRON contains the active ingredient testosterone undecanoate. REANDRON is used to replace the body's testosterone in male hypogonadism a condition where there are low levels of testosterone in the body.

For more information, see Section [1. Why am I using REANDRON?](#) in the full CMI.

2. What should I know before I use REANDRON?

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

Talk to your doctor if you have any other medical conditions such as diabetes, fluid retention, bleeding disorders, high blood pressure, prostate tumours, epilepsy or if you take any other medicines

For more information, see Section [2. What should I know before I use REANDRON?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with REANDRON and affect how it works. Let your doctor know if you take medicines to thin the blood, control blood sugar levels, suppress the immune system, for pain and inflammation or for treatment of sleeping problems and nervousness.

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 REANDRON?

REANDRON is injected by your healthcare professional every 10-14 weeks.

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

5. What should I know while using REANDRON?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using REANDRON.Keep all of your doctor's appointments. Your doctor may monitor your blood pressure, examine your prostate and conduct other tests from time to time.
Looking after your medicine	<ul style="list-style-type: none">Store it in a cool dry place away from moisture, heat or sunlight where the temperature stays below 30°C

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

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Reandron.

- Less severe side effects may include weight gain, acne, enlarged prostate, hot flushes, injection site reactions
- Severe side effects including chest pains, sweating, signs of an allergic reaction, jaundice, prolonged painful erections, severe stomach pains or blood clots require immediate 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.

REANDRON[®] 1000 (Ree·ANNE·dron)

Active ingredient(s): *testosterone undecanoate*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using REANDRON?

REANDRON contains the active ingredient testosterone undecanoate. Testosterone undecanoate 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 hair growth, deep voice, sexual drive, muscle mass and body fat distribution.

REANDRON is used to replace the body's testosterone in male hypogonadism a condition where there are low levels of testosterone in the body.

Reandron is injected into a location in your body (buttock muscle) where it can be stored and gradually released over a period of time.

2. What should I know before I use REANDRON?

Warnings

Do not use REANDRON if:

- you are allergic to testosterone undecanoate, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- have or are suspected to have:
 - prostate cancer
 - male breast cancer
 - high blood calcium levels associated with tumours
 - past or present liver tumours
- **Do not use REANDRON if you are a woman.**

Check with your doctor if you:

- Have or had any of the following medical conditions:
 - diabetes
 - a bleeding disorder
 - thrombophilia (an abnormality of blood coagulation that increases the risk of thrombosis - blood clots in blood vessels)
 - a tendency to retain fluid (signs may include swollen feet or ankles)
 - high blood pressure or if you are being treated for high blood pressure as testosterone may cause a rise in blood pressure
 - epilepsy
 - migraines
 - sleep apnoea (abnormal pauses in breathing during sleep)
 - **severe heart, liver or kidney disease.** Treatment with REANDRON may cause severe complications in the form of water retention in your body and sometimes accompanied by (congestive) heart failure. Please inform your doctor immediately if you notice any signs of water retention.
- take any medicines for any other condition

REANDRON may increase the rate of progression of prostatic tumours including benign prostatic hypertrophy (enlargement of the prostate gland) and/or prostate cancer. Before treatment, your doctor will conduct tests to ensure that you do not have prostate cancer.

People using testosterone replacement over long periods of time may develop an abnormal increase in the number of red blood cells in the blood (polycythaemia). Your doctor may organise regular blood counts to monitor this.

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

Use of androgens for reasons other than what your doctor prescribed carries a serious health risk and is strongly discouraged.

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?](#)

Children and Adolescents

- It is not recommended to give this medicine to a child under the age of 18 years.

Drug abuse and dependence

- Always take this medicine exactly as your doctor or pharmacist has told you.
- Abuse of testosterone, especially if you take too much of this medicine alone or with other anabolic androgenic steroids, can cause serious health problems to your heart and blood vessels (that can lead to death), mental health and/or the liver.
- Individuals who have abused testosterone may become dependent and may experience withdrawal symptoms when the dosage changes significantly or is stopped immediately. You should not abuse this medicine alone or with other anabolic androgenic steroids because it carries serious health risks. (See [6. Are there any side effects?](#))

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 and REANDRON may interfere with each other. These include:

- oral anticoagulants, 'blood thinning' medications to treat or prevent blood clots
- medicines used to control blood sugar levels in diabetes
- oxyphenbutazone, a medicine used to treat pain and inflammation
- cyclosporin, a medicine used to suppress the immune system
- barbiturates, medicines used to treat nervousness and sleeping problems

4. How do I use REANDRON?

How much is given

REANDRON (1 ampoule/vial corresponding to 1000 mg testosterone undecanoate) will be injected by your healthcare professional every 10-14 weeks.

At the start of treatment your doctor will measure your blood testosterone levels. Depending on the results, the second injection may be given before 10 weeks. This is so that the necessary testosterone levels can be reached more quickly.

How REANDRON is given

The injection will be administered very slowly into your buttock muscle by your doctor.

If you use too much REANDRON

Since REANDRON 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 it, tell your doctor immediately. Side effects such as irritability, nervousness, weight gain, or prolonged

or frequent erections may indicate the need for dosage adjustment.

If you suspect you have received too much REANDRON you should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), 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 REANDRON?

Things you should do

- **If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using REANDRON.**
- **Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.**
- **Keep all of your doctor's appointments.** REANDRON helps control the symptoms of your condition, but does not cure it. Therefore, your doctor must administer REANDRON every 10 – 14 weeks. Your doctor may monitor your blood pressure, examine your prostate and conduct other tests from time to time, particularly if you are elderly. This is to make sure the medicine is working and to check for unwanted side effects.

Looking after your medicine

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 where the temperature stays below 30°C;

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.

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.

Less serious side effects

Less serious side effects	What to do
<p>Skin related</p> <ul style="list-style-type: none"> injection site reactions such as pain or discomfort, itching, bruising, redness or irritation acne <p>Metabolism related</p> <ul style="list-style-type: none"> weight gain <p>Reproductive system related</p> <ul style="list-style-type: none"> enlarged prostate reduction in the size of the testes - high doses of REANDRON may affect sperm cell development (spermatogenesis). This is reversible once treatment is stopped. <p>Vascular system related</p> <ul style="list-style-type: none"> hot flushes 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Mood Related</p> <ul style="list-style-type: none"> depression, irritability, or aggression <p>Nervous system related</p> <ul style="list-style-type: none"> weakness, tiredness, headache, light-headedness <p>Allergy related</p> <ul style="list-style-type: none"> signs of allergy such as rash, swelling of the face, lips, mouth, throat or other parts of the body, shortness of breath, wheezing or trouble breathing <p>Liver related</p> <ul style="list-style-type: none"> yellowing of the skin and eyes, also called jaundice <p>Reproductive system related</p> <ul style="list-style-type: none"> unwanted frequent or prolonged and painful erections <p>Stomach related</p> <ul style="list-style-type: none"> severe stomach pain or tenderness which do not disappear within a short time <p>Vascular system related</p> <ul style="list-style-type: none"> pain, swelling, redness, and enlarged veins in the affected area (thromboembolism) 	<p>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.</p>

<ul style="list-style-type: none"> coughing, increased sweating, chest pain, feeling faint 	
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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. 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 REANDRON contains

Active ingredient (main ingredient)	1000 mg testosterone undecanoate per ampoule/vial
Other ingredients (inactive ingredients)	benzyl benzoate castor oil

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

What REANDRON looks like

REANDRON is a clear, yellowish oily solution contained in a 5 mL glass ampoule or 6 mL glass vial.

REANDRON 1000 (ampoule) – AUST R 106946

REANDRON 1000 (vial) – AUST R 213942

Who distributes REANDRON

Bayer Australia Ltd

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875 Pacific Highway

Pymble NSW 2073

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