

REANDRON® 1000

(Ree-ANNE-dron)

testosterone undecanoate

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Reandron. 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 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 IS USED FOR

Male hypogonadism is the condition where there are low levels of testosterone in the body.

Reandron 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 hair growth, deep voice, sexual drive, muscle mass and body fat distribution.

Reandron contains testosterone undecanoate, as the active ingredient. Reandron is injected into a location

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

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

BEFORE YOU ARE GIVEN REANDRON

When you must not be given it

Do not use Reandron if you 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.

Do not use Reandron if you have an allergy to:

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

Some of the symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

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

Do not use this medicine after the expiry date printed on the carton and vial.

The expiry date is printed on the carton and on each vial after "EXP" (e.g. 11 18 refers to November

2018). The expiry date refers to the last day of that month. If it has expired return it to your pharmacist for disposal.

Do not use this medicine if the packaging is torn or shows signs of tampering.

If the packaging is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use it

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

Tell your doctor if you have, or have 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)

If you are suffering from 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.

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.

If you have not told your doctor about any of the above, tell them before you are given Reandron.

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.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get 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

These medicines may be affected by Reandron 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.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

HOW REANDRON IS GIVEN

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions printed on the pharmacist label, ask your doctor or pharmacist for help.

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 it is given

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

If you are given too much (overdose)

As 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.

Immediately telephone the Poisons Information Centre on 13 11 26 for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have been given too much Reandron. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

WHILE YOU ARE RECEIVING REANDRON

Things you must 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.

SIDE EFFECTS

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

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

Do not be alarmed by the list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

High doses of Reandron may affect sperm cell development (spermatogenesis), which reduces the size of the testes. This is reversible once treatment is stopped.

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

- weight gain
- acne
- enlarged prostate
- hot flushes
- injection site reactions such as pain or discomfort, itching, bruising, redness or irritation

These are the most common side effects of Reandron.

Tell your doctor as soon as possible if you notice any of the following:

- depression, irritability or aggression

The above list includes serious side effects that may require urgent medical attention.

Tell your doctor immediately, or go to the Accident and Emergency department at your nearest hospital if you notice any of the following:

- weakness, tiredness, headache, light-headedness
- 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
- coughing, increased sweating, chest pain, feeling faint
- yellowing of the skin and eyes, also called jaundice
- unwanted frequent or prolonged and painful erections
- severe stomach pain or tenderness which do not disappear within a short time

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

AFTER RECEIVING REANDRON

Storage

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Store Reandron in a cool dry place where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a window-sill.

Do not leave it in the car.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Return any unused medicine to your pharmacist.

PRODUCT DESCRIPTION

What it looks like

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

Ingredients

Active ingredient:

- Reandron 1000 – 1000 mg testosterone undecanoate per ampoule/vial

Inactive ingredients:

- benzyl benzoate

- castor oil

Supplier

Bayer Australia Ltd
ABN 22 000 138 714
875 Pacific Highway
Pymble NSW 2073

Bayer New Zealand Limited
3 Argus Place, Hillcrest,
North Shore
Auckland 0627

Australian Registration Number

Reandron 1000 (ampoule) – AUST R 106946

Reandron 1000 (vial) – AUST R 213942

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See TGA website (www.ebs.tga.gov.au) for latest Australian Consumer Medicine Information.

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