

REJUNON 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 REJUNON 1000?

REJUNON 1000 contains the active ingredient testosterone undecanoate. REJUNON 1000 is used to replace the body's natural hormone testosterone when not enough is made by the body.

For more information, see Section [1. Why am I using REJUNON 1000?](#) in the full CMI.

2. What should I know before I use REJUNON 1000?

Do not use if you have ever had an allergic reaction to REJUNON 1000 or any of the ingredients listed at the end of the CMI.

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 REJUNON 1000?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with REJUNON 1000 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 REJUNON 1000?

- REJUNON 1000 (1 vial corresponding to 1000 mg testosterone undecanoate) will be injected by your healthcare professional every 10-14 weeks.
- The injection will be administered very slowly into your buttock muscle by your doctor.

More instructions can be found in Section [4. How do I use REJUNON 1000?](#) in the full CMI.

5. What should I know while using REJUNON 1000?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using REJUNON 1000. • 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.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how REJUNON 1000 affects you. • As far as is known, this medicine REJUNON 1000 has no influence on driving and using machines.
Looking after your medicine	• REJUNON 1000 will be stored by your doctor or pharmacist in a cool dry place below 25°C and protected from light.

For more information, see Section [5. What should I know while using REJUNON 1000?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, REJUNON 1000 can cause side effects, although not everybody gets them. Your doctor will discuss these with you and will explain the risks and benefits of using REJUNON 1000.

- 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.

REJUNON 1000

Active ingredient: *testosterone undecanoate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using REJUNON 1000. **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 REJUNON 1000.**

Where to find information in this leaflet:

- [1. Why am I using REJUNON 1000?](#)
- [2. What should I know before I use REJUNON 1000?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use REJUNON 1000?](#)
- [5. What should I know while using REJUNON 1000?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using REJUNON 1000?

REJUNON 1000 contains the active ingredient testosterone undecanoate. REJUNON 1000 is 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.

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

REJUNON1000 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 REJUNON 1000?

Warnings

Do not use REJUNON 1000 if:

- you are allergic to testosterone undecanoate, or any of the ingredients listed at the end of this leaflet including benzyl benzoate
- always check the ingredients to make sure you can use this medicine
- you are a woman.
- you have, or have had any of these medical conditions:
 - prostate cancer
 - male breast cancer
 - high blood calcium levels associated with tumours
 - past or present liver tumours

Check with your doctor if you:

Have, or have had, any other medical conditions such as:

- 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 REJUNON 1000 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.

REJUNON 1000 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.

Improper use

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

The misuse of this medicine to enhance ability in sports carries serious health risks and is to be discouraged.

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.

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.

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 REJUNON 1000 and affect how it works.

- 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
- ciclosporin, a medicine used to suppress the immune system
- barbiturates, medicines used to treat nervousness and sleeping problems

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect REJUNON 1000.

4. How do I use REJUNON 1000?

How much is given

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

When will REJUNON 1000 be given

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.

If you forget to use REJUNON 1000

As REJUNON 1000 is given to you under the supervision of your doctor, it is very unlikely that you will forget to receive it.

How REJUNON 1000 is given

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

If you use too much REJUNON 1000

As REJUNON 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 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.

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 REJUNON 1000?

Things you should do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using REJUNON 1000.

Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.

Keep all of your doctor’s appointments.

REJUNON 1000 helps control the symptoms of your condition but does not cure it. Therefore, your doctor must administer REJUNON 1000 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

REJUNON 1000 will be stored by your doctor or pharmacist in a cool dry place below 25°C and protected from light.

When to discard your medicine

REJUNON 1000 will be discarded by your doctor or pharmacist.

Getting rid of any unwanted medicine

REJUNON 1000 will be discarded by your doctor or pharmacist. 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.

High doses of REJUNON 1000 may affect sperm cell development (spermatogenesis), which reduces the size of the testes. This is reversible once treatment is stopped.

Less serious side effects

Less serious side effects	What to do
Skin related: • injection site reactions such as pain or discomfort, itching, bruising, redness or irritation • acne Metabolism related • weight gain Reproductive system related • enlarged prostate • reduction in the size of the testes- high doses of REJUNON 1000 may affect sperm cell development (spermatogenesis). This is a reversible once treatment is stopped. Vascular system related • hot flushes	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Mood disorders: • depression • irritability • aggression Nervous system related • weakness, tiredness, headache, light-headedness Allergy related • 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	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.

Liver related

- yellowing of the skin and eyes, also called jaundice

Reproductive system related

- unwanted frequent or prolonged and painful erections

Stomach related

- severe stomach pain or tenderness which do not disappear within a short time

Vascular system related

- pain, swelling, redness, and enlarged veins in the affected area (thromboembolism)
- coughing, increased sweating, chest pain, feeling faint.

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 REJUNON 1000 contains

Active ingredient (main ingredient)	Testosterone undecanoate
Other ingredients (inactive ingredients)	benzyl benzoate castor oil
Potential allergens	benzyl benzoate

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

What REJUNON 1000 looks like

REJUNON 1000 testosterone undecanoate 1000 mg / 4 mL solution for injection is a clear yellowish oily solution in a vial containing 1000 mg / 4 mL of testosterone undecanoate (Aust R 407004).

Who distributes REJUNON 1000

Juno Pharmaceuticals Pty Ltd

15-17 Chapel Street

Cremorne VIC 3121

This leaflet was prepared in November 2023