

Gonadron

testosterone undecanoate

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 Gonadron?

Gonadron contains the active ingredient testosterone undecanoate. Gonadron is used to replace the body's natural hormone 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 Gonadron?](#) in the full CMI.

2. What should I know before I use Gonadron?

Do not use if you have ever had an allergic reaction to Gonadron 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 Gonadron?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Gonadron 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 Gonadron?

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

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

5. What should I know while using Gonadron?

Things you should do	- Remind any doctor, dentist or pharmacist you visit that you are using Gonadron. - 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, 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	Store Gonadron in a cool dry place where the temperature stays below 30°C.

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

6. Are there any side effects?

Common side effects include weight gain, acne, enlarged prostate, hot flushes and injection site reactions such as pain or discomfort, itching, bruising, redness or irritation.

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.

Gonadron

Active ingredient(s): testosterone undecanoate

Consumer Medicine Information (CMI)

This leaflet provides important information about using Gonadron. 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 Gonadron against the benefits they expect it will have for you. **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 Gonadron.** The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available. You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on this medicine. You can also download the most up to date leaflet from www.ebs.tga.gov.au in Australia, and from www.medsafe.govt.nz in New Zealand. Those updates may contain important information about the medicine and its use of which you should be aware.

Where to find information in this leaflet:

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

1. Why am I using Gonadron?

Gonadron 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.

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

Gonadron 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 Gonadron?

Warnings

Do not use Gonadron 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.
- Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.
- have or suspected to have
 - prostate cancer.
 - male breast cancer.
 - high blood calcium levels associated with tumours.
 - past or present liver tumours.
- you are a woman

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.

Check with your doctor if you have:

- 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,
- water retention in your body. This is sometimes accompanied by (congestive) heart failure.
- take any medicines for any other condition

Gonadron 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 Section [6. Are there any side effects?](#))

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.

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 Gonadron 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. It may be necessary to adjust the dose of your blood sugar reducing medicine. Like other androgens, testosterone may increase the effect of insulin. Taking SGLT-2 inhibitors (such as empagliflozin, dapagliflozin or canagliflozin) together with testosterone may increase the number of red blood cells in your blood. Your doctor may need to monitor your blood more regularly.
- 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
- Corticosteroids, medicines used to reduce inflammation or suppress the immune system

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

4. How do I use Gonadron?

How much is given

- Gonadron (1 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 Gonadron

As Gonadron 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 Gonadron you should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 in Australia or 0800 764766 in New Zealand), 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 Gonadron?

Things you should do

Remind any doctor, dentist or pharmacist you visit that you are using Gonadron.

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

Keep all of your doctor's appointments.

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

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

Protect from light.

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; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Getting rid of any unwanted medicine

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.

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.

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

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
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 Gonadron may affect sperm cell development (spermatogenesis). This is reversible once treatment is stopped. Vascular system related • hot flushes	Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Mood Related • depression, irritability, or 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 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. The patient should therefore be observed during and	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.

immediately after each injection in order to allow for early recognition of possible signs and symptoms of pulmonary oily microembolism.	
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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, in Australia you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems, or in New Zealand to Medsafe online at <https://pophealth.my.site.com/carmreportnz/s/>.

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 Gondaron contains

Active ingredient (main ingredient)	Testosterone undecanoate 1000 mg/4mL
Other ingredients (inactive ingredients)	Benzyl benzoate and castor oil
Potential allergens	Contains benzoates

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

What Gonadron looks like

Gonadron is a sterile clear yellowish oily solution for single-use intramuscular injection free from visible foreign particulate matter contained in 5 mL amber coloured glass vial with grey rubber stopper, sealed with light green flip off seal, and supplied as 1 vial pack size.

Vial stopper not made with natural rubber latex. (Aust R 414398).

Who distributes Gonadron

In Australia:

Sun Pharma ANZ Pty Ltd
12 Waterloo Road
Macquarie Park
Sydney NSW 2113

Email: customerservice.aus@sunpharma.com

Telephone: 1800 726 229

In New Zealand:

Max Health Ltd
PO Box 44452
Pt Chevalier, Auckland 1246
Telephone: (09) 815 2664

This leaflet was updated in June 2026.

