

# PRIMOTESTON DEPOT

## 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 PRIMOTESTON DEPOT?

PRIMOTESTON DEPOT contains the active ingredient testosterone enantate. PRIMOTESTON DEPOT is used to replace the body's natural testosterone when not enough is made by the body.

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

### 2. What should I know before I use PRIMOTESTON DEPOT?

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

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

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

### 3. What if I am taking other medicines?

Some medicines may interfere with PRIMOTESTON DEPOT 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 PRIMOTESTON DEPOT?

- It is injected slowly into the muscle by your doctor.
- Your doctor will determine the time period between injections.

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

### 5. What should I know while using PRIMOTESTON DEPOT?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using PRIMOTESTON DEPOT.</li><li>• Contact your doctor if you experience prolonged stomach pain, blood in the stools or vomit or yellowing of the skin and eye during treatment.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine suddenly as you may experience withdrawal symptoms.</li><li>• Do not abuse this medicine by taking too much or use with other anabolic androgenic steroids.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store in a cool, dry place out of direct sunlight where the temperature stays below 25°C.</li><li>• Keep in the pack until it is time to use it.</li></ul>

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

### 6. Are there any side effects?

Common side effects include pain, redness, swelling, heat and itching at the injection site, cough, shortness of breath, difficulty in breathing, rash, itching or hives, acne, hair loss or growth, changes in libido, breast development, fluid retention, weight gain and hostility/aggression. Serious side effects include severe stomach pain or tenderness, weakness, tiredness, headache, light-headedness, fainting, signs of allergy such as rash, swelling of the face, lips, mouth, throat, wheezing or trouble breathing, chest pain, yellowing of the skin and eyes and unwanted, frequent or prolonged and painful erections.

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.

# PRIMOTESTON DEPOT (PREE mo TEST on)

Active ingredient(s): *testosterone enantate*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using PRIMOTESTON DEPOT. **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 PRIMOTESTON DEPOT.**

Where to find information in this leaflet:

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

### 1. Why am I using PRIMOTESTON DEPOT?

PRIMOTESTON DEPOT contains the active ingredient **testosterone enantate**. PRIMOTESTON DEPOT provides testosterone which is a natural hormone known as an androgen, which controls normal sexual development and function in men.

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

### 2. What should I know before I use PRIMOTESTON DEPOT?

#### Warnings

**Do not use PRIMOTESTON DEPOT if:**

- you are allergic to testosterone enantate, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have prostate cancer.
- you have breast cancer (males).
- you have high blood calcium levels associated with malignant tumours.
- you have previous or existing liver tumours.

**Check with your doctor if you:**

- have tendency to retain fluid (signs may include swollen feet or ankles).
- have high blood pressure or if you are being treated for high blood pressure as testosterone may cause a rise in blood pressure.

- have sleep apnoea (abnormal pauses in breathing during sleep).
- have a bleeding disorder.
- have thrombophilia (an abnormality of blood coagulation that increases the risk of thrombosis – blood clots in blood vessels).
- you are suffering from severe heart, liver or kidney disease (as testosterone may cause severe complications in the form of water retention in your body and sometimes accompanied by congestive heart failure).

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?](#)

### Pregnancy and breastfeeding

PRIMOTESTON DEPOT is intended for use in men only.

### 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 PRIMOTESTON DEPOT and affect how it works. These include:**

- barbiturates, medicines used to treat nervousness or sleeping problems.
- oxyphenbutazone, a medicine used to treat pain and inflammation.
- oral anticoagulants, 'blood thinning' medications to treat or prevent blood clots such as warfarin.
- medicines used to control blood sugar levels in diabetes, including oral antidiabetic drugs and insulin.
- ciclosporin, a medicine used to suppress the immune system.
- corticosteroids such as prednisolone or hydrocortisone, or adrenocorticotrophic hormone (ACTH), used to control inflammation.

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

### 4. How do I use PRIMOTESTON DEPOT?

#### How much to take / use

- PRIMOTESTON DEPOT is injected slowly into the muscle by your doctor.
- Experience shows that the short-lasting reactions (urge to cough, coughing fits, difficulty in breathing)

which occur in very rare cases during or immediately after the injection of oily solutions can be avoided by injecting the solution slowly.

### When to take / use PRIMOTESTON DEPOT

- Your doctor will determine how often to inject PRIMOTESTON DEPOT after measuring your testosterone levels.
- Initially, one prefilled syringe is injected into the muscle every 2-3 weeks by your doctor. The injection interval will depend on your testosterone levels.
- To maintain the effect of PRIMOTESTON DEPOT, 1 prefilled syringe is injected into the muscle every 3 – 4 weeks.
- PRIMOTESTON DEPOT helps control the symptoms of your condition but does not cure it.

### If you forget to use PRIMOTESTON DEPOT

PRIMOTESTON DEPOT will be injected by your doctor at regular interval. Keep your regular appointments to see the doctor.

### If you use too much PRIMOTESTON DEPOT

As PRIMOTESTON DEPOT 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.

If you think that you have used too much PRIMOTESTON DEPOT, you may need urgent medical attention.

#### 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 PRIMOTESTON DEPOT?

### Things you should do

Keep all of your doctor appointments.

#### Call your doctor straight away if you:

- experience prolonged stomach pain, blood in the stools or vomit, or yellowing of the skin and eyes during treatment with PRIMOTESTON DEPOT. There have been cases reported of patients developing liver tumours while using PRIMOTESTON DEPOT. Your doctor may tell you to stop using PRIMOTESTON DEPOT.

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

Your doctor may examine your prostate and conduct other tests (including blood 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.

### Things you should not do

- Do not abuse the use of testosterone, especially if you take too much of this medicine alone or with other anabolic androgenic steroids, as this 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 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 “Side effects”.

### Driving or using machines

Be careful before you drive or use any machines or tools until you know how PRIMOTESTON DEPOT affects you.

### Looking after your medicine

- Store below 25°C.
- Keep in the pack until it is time to use it.

Follow the instructions on 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.

Keep it where young children cannot reach it.

### When to discard your medicine

The doctor will discard the syringe after administration.

### 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
• pain, redness, swelling, heat or	Speak to your

## 7. Product details

This medicine is only available with a doctor's prescription.

### What PRIMOTESTON DEPOT contains

<b>Active ingredient (main ingredient)</b>	Testosterone enantate
<b>Other ingredients (inactive ingredients)</b>	Benzyl benzoate, castor oil
<b>Potential allergens</b>	n/a

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

### What PRIMOTESTON DEPOT looks like

PRIMOTESTON DEPOT is a clear, yellowish oily solution and comes in a 1 mL prefilled syringe. Each pack contains 1 prefilled syringe (AUST R 10707).

### Who distributes PRIMOTESON DEPOT

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

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<ul style="list-style-type: none"><li>itching at the injection site</li><li>cough, bronchitis, sinusitis, snoring</li><li>shortness of breath, difficulty in breathing</li><li>rash, itching or hives</li><li>acne</li><li>dry skin</li><li>hair loss or growth</li><li>changes in libido</li><li>mood changes</li><li>breast development, pain or induration</li><li>changes to the prostate</li><li>fluid retention</li><li>weight gain</li><li>hostility/aggression</li><li>urinary tract disorders</li><li>changes in appetite</li><li>increase in cholesterol and triglycerides</li><li>migraine, or tremor</li><li>muscle problems</li></ul>	<b>doctor if you have any of these less serious side effects and they worry you.</b>
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These side effects may occur during or immediately after the injection.

Long term treatment or treatment with high doses of PRIMOTESTON DEPOT can affect sperm production.

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>severe stomach pain or tenderness which do not disappear within a short time</li><li>weakness, tiredness, headache, light-headedness, fainting</li><li>signs of allergy such as rash, swelling of the face, lips, mouth, throat or other parts of the body, wheezing or trouble breathing</li><li>chest pain</li><li>yellowing of the skin and eyes, also called jaundice</li><li>unwanted, frequent or prolonged and painful erections</li></ul>	<b>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.</b>

**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](http://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.**