

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Primoteston Depot. 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 Primoteston Depot 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.

You may need to read it again.

WHAT PRIMOTESTON DEPOT IS USED FOR

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

Testosterone is a natural hormone, known as an androgen, which controls normal sexual development and function in men.

Testosterone is essential for the development and maintenance of the male reproductive organs as well as other male characteristics, such as facial and body hair growth, deep voice, sexual drive, muscle mass and body fat distribution.

The depot effect of testosterone enantate permits long intervals between injections. An injection of Primoteston Depot can maintain its effect for 2-4 weeks, depending on your initial hormonal status.

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 PRIMOTESTON DEPOT

When you must not be given it

Do not use Primoteston Depot if you have an allergy to:

- testosterone enantate, the active ingredient in Primoteston Depot
- 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

Do not use Primoteston Depot if you have:

- prostate cancer
- breast cancer in males
- high blood calcium levels associated with malignant tumours
- previous or existing liver tumours

Do not use this medicine after the expiry date printed on the pack 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 be given 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.

Primoteston Depot is recommended for use in men only.

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

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

Primoteston Depot may quicken the growth of existing prostatic tumours and prostatic hyperplasia (enlargement of the prostate gland), particularly if you are an older patient.

Before treatment, your doctor should conduct tests to check that you do not have existing prostate cancer. In addition, your doctor will regularly check your prostate while you are using Primoteston Depot.

If you use Primoteston Depot over long periods of time, you 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.

Tell your doctor if you have, or have had, any of the following medical conditions:

- 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
- sleep apnoea (abnormal pauses in breathing during sleep)
- a bleeding disorder
- thrombophilia (an abnormality of blood coagulation that increases the risk of thrombosis - blood clots in blood vessels)

If you are suffering from severe heart, liver or kidney disease, treatment with Primoteston 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.

If you have not told your doctor about any of the above, tell them before you start using Primoteston Depot.

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 Primoteston Depot may interfere with each other. 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

These medicines may be affected by Primoteston Depot or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

HOW PRIMOTESTON DEPOT 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 it is given

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.

How much is given

Before treatment with Primoteston Depot, your doctor will measure your blood 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.

Your doctor will decide how often your injection interval is, based on results from blood testosterone tests conducted during treatment with Primoteston Depot.

If you are given too much (overdose)

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.

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 Primoteston Depot. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

WHILE YOU ARE RECEIVING PRIMOTESTON DEPOT

Things you must do

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

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

Keep all of your doctor's appointments.

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 "Side effects".

Primoteston Depot helps control the symptoms of your condition, but does not cure it. Therefore, your doctor must administer Primoteston Depot every 3 – 4 weeks.

If you experience prolonged stomach pain, blood in the stools or vomit, or yellowing of the skins and eyes during treatment with Primoteston Depot, tell your doctor immediately.

There have been cases reported of patients developing liver tumours while using Primoteston Depot. Your doctor may tell you to stop 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.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are receiving Primoteston Depot.

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 following lists of side effects. You may not experience any of them.

Ask your doctor to answer any questions you may have.

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

- pain, redness, swelling, heat or 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
- hostility/aggression

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.

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

- severe stomach pain or tenderness which do not disappear within a short time
- weakness, tiredness, headache, light-headedness, fainting
- signs of allergy such as rash, swelling of the face, lips, mouth, throat or other parts of the body, wheezing or trouble breathing
- chest pain
- yellowing of the skin and eyes, also called jaundice
- unwanted, frequent or prolonged and painful erections

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 PRIMOTESTON DEPOT

Storage

Keep Primoteston Depot in the pack until it is time to use it.

Keep Primoteston Depot in a cool, dry place out of direct sunlight where the temperature stays below 25°C.

Do not store Primoteston Depot or any other medicine in the bathroom or near a sink.

Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

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.

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

Primoteston Depot is a clear, yellowish oily solution and comes in 1 mL prefilled syringes. Each pack contains 3 syringes.

Ingredients

Active ingredient:

Primoteston Depot – 250 mg testosterone enantate per prefilled syringe.

Inactive ingredients:

- benzyl benzoate
- castor oil

Supplier

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

Australian Registration Number

Primoteston Depot
– AUST R 10707

Date of preparation

January 2021

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

® Registered trademark of the Bayer group, Germany

© Bayer Australia Ltd

All rights reserved.

