

Testosterone Implants

Testosterone

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Testosterone Implants. 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 receiving Testosterone Implants against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may wish to read it again.

What Testosterone Implants are used for

Testosterone Implants are used to treat confirmed testosterone deficiency in males.

The active substance of Testosterone Implants is testosterone. It is the natural male hormone produced by the testicles, necessary for the normal growth, development and function of the male sex organs and for secondary male sex characteristics. It is also necessary for the growth of body hair, the development of bones and muscles, and for the production of red blood cells. It also makes men's voice deepen. Preparations containing testosterone are used to replace testosterone in a person who

has low or no natural testosterone (a condition known as hypogonadism).

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

A doctor's prescription is required to obtain this medicine.

This medicine is not expected to affect your ability to drive a car or operate machinery.

Before you use Testosterone Implants

When you must not be given it

- * You have or have had a tumour of your prostate or breast
- * You are allergic to the active ingredient testosterone.

Before you are given it

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

- * heart disease
- * kidney disease
- * liver disease
- * high blood pressure
- * prostatic complaints such as problems passing urine

If you have sleep apnoea (temporarily stopping breathing during your sleep), this may get worse if you are using testosterone-containing products. Let your doctor know if you are worried about this.

Extra supervision by a doctor is necessary in the treatment of young boys.

This is because testosterone administration may cause early sexual development and disturb normal growth.

Extra supervision by a doctor is also necessary in elderly men.

This is because male hormones may increase the size of the prostate gland.

Misuse of androgens to enhance ability in sports carries serious health risks and is 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 Testosterone Implants may interfere with each other. These include:

- * anticoagulants or medicines used to prevent blood clots
- * anti-diabetic medicines such as insulin used to treat diabetes.

These medicines may influence the effects of Testosterone Implants or Testosterone Implants may affect other medication. You may need different amounts of your medicines, or you may need to take different medicines.

Do not use this product if it has passed the expiry date printed on the pack, or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Using Testosterone Implants

How much to use

The dose is chosen by your doctor. Usually in men a dose of 600 - 1200 mg testosterone is given, depending on individual requirements. In most hypogonadal men, a dose of 800 mg maintains the plasma testosterone levels within the normal male physiological range. The implants are effective for approximately 4 - 5 months.

How the implant is inserted

This medicine should only be given by a doctor or nurse.

Testosterone Implants are inserted under the skin (for example at the lower abdominal wall or buttock) to facilitate removal should it be necessary. A local anaesthetic is given in the area of implantation before the implants are inserted and the small cut made is dressed with a bandage afterwards.

Dosage should be adjusted by your doctor in response to individual requirements.

If you are given too much (overdose)

Testosterone Implants are given under medical supervision and it is very unlikely that you will be given too much.

You should consult your doctor if you feel the effect of the Testosterone Implants are too strong or too weak as side-effects are dependent on dosage, dose interval and your individual sensitivity.

While you are using Testosterone Implants

Keep all of your appointments so that your progress can be checked.

Your doctor may do some blood tests at regular intervals to make sure the medicine is working and to prevent unwanted side effects.

As far as known, Testosterone Implants have no adverse effects on alertness and concentration.

Side Effects of Testosterone Implants

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

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

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Testosterone Implants.

The side effects which are reported with testosterone therapy in general are:

- * changes in sexual desire
- * itching (pruritis)
- * acne
- * nausea
- * changes in liver function tests
- * depression, nervousness, mood disturbances
- * muscle pain (myalgia)
- * fluid retention in the tissues, usually marked by swelling of ankles or feet
- * high blood pressure (hypertension)
- * changes in cholesterol levels (changes in lipid metabolism)
- * increase in number of red blood cells (the cells which carry the oxygen in your blood)
- * prolonged abnormal, painful erection of the penis

- * disturbed formation of sperm
- * prostatic growth to a size representative for the concerned age group
- * increased growth of a small prostate cancer which had not been detected yet (progression of a sub-clinical prostatic cancer)
- * increased levels of a blood marker which is associated with prostate cancer (PSA increased)
- * feminisation (gynaecomastia)
- * local reaction at the insertion site.

Some side effects have no symptoms. These side effects e.g. changes in cholesterol levels, changes in liver function tests, increase in the number of red blood cells or increased blood pressure can only be found when your doctor does tests to check your progress.

Tell your doctor if you notice any other side effects.

Other side effects not listed in this leaflet also occur in some people.

Due to the nature of Testosterone Implants, side effects cannot be quickly reversed by discontinuing medication.

After Using Testosterone Implants

The effects of Testosterone Implants do not stop immediately after discontinuation, but gradually subside.

Storage

Keep Testosterone Implants in the original box in order to protect from light.

Keep it in a cool dark place where the temperature stays below 30 degrees C.

Do not use Testosterone Implants after the expiry date stated on the carton after the term 'exp.'

Keep it where children cannot reach it.

A locked cupboard at least 1.5 meters above the ground is a good place to store medicines.

Disposal

Return any unused medicine to your pharmacist.

For further information please ask your doctor or pharmacist.

Product Description

What it looks like

Testosterone Implants are white to pale yellow, opaque or translucent and have a common cylindrical shape with a diameter of 4.5 millimetre and a length of 6mm (100 mg) or a length of 12 millimetre (200 mg).

Each sterile implant is supplied singly in a sealed glass tube, positioned between plugs of non-absorbent wool.

Ingredients

Testosterone Implants consist of pure testosterone without any other ingredients.

Supplier

Schering-Plough Pty Limited
Level 4, 66 Waterloo Road,
North Ryde NSW 2113
Australia

This leaflet was prepared in:
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100 mg: AUST R 14523

200 mg: AUST R 14524

The information supplied relates only to Testosterone Implants and should not be used in relation to any other product which may also contain the same active ingredients.