

Testosterone

testosterone

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about TESTOSTERONE. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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

Keep this leaflet with the medicine. You may need to read it again.

What TESTOSTERONE is used for

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

TESTOSTERONE can be used by both males and females.

TESTOSTERONE is naturally made by the body, however sometimes your body's ability to make enough is reduced. Testosterone is a natural hormone, known as an androgen, which controls normal sexual development in men and many other functions in women. Testosterone is essential for the development and maintenance of the male reproductive organs as well as other male characteristics, such as deep voice, increased muscle strength, hair growth etc.

The testosterone in TESTOSTERONE is identical to the naturally occurring testosterone present in the body. This medicine is not addictive. This medicine is not expected to affect your ability to drive a car or operate machinery.

Before you use TESTOSTERONE

When you must not use it

Do not use TESTOSTERONE if you have an allergy to testosterone, the active ingredient in TESTOSTERONE

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 TESTOSTERONE if you have or are suspected to have:

- prostate cancer
- breast cancer (a rare condition in men)

The safety of TESTOSTERONE in children under 18 years of age has not been established.

TESTOSTERONE may cause harm to the unborn child when administered to a pregnant woman. TESTOSTERONE may cause serious reactions in nursing infants. Pregnant women must avoid any contact with the TESTOSTERONE treated skin.

Do not use this medicine after the expiry date printed on the carton and bottle.

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

If you are not sure whether you should start taking 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. Tell your doctor if you have, or have had, any of the following medical conditions:

- high blood pressure
- heart, liver or kidney disease
- epilepsy (fits)

- migraines
- diabetes
- bone cancer
- breathing problems during your sleep
- difficulty in passing water (urinating) due to an enlarged prostate gland

Before treatment with TESTOSTERONE your doctor will need to check that you do not have prostate or breast cancer.

TESTOSTERONE may increase the risk of benign prostatic hypertrophy (enlargement of the prostate gland) and/or prostate cancer. During treatment, your doctor may monitor the effects of this medicine.

Worsening of breathing problems during sleep (obstructive sleep apnoea) has been reported during treatment with testosterone replacement in predisposed people. This is especially true in overweight people or people with lung problems.

People using testosterone replacement over long periods of time may develop polycythaemia (an abnormal increase in the number of red blood cells in the blood). Your doctor may organise regular blood tests to check this is not happening.

If you have not told your doctor about any of the above, tell him/her before you start using TESTOSTERONE.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and TESTOSTERONE may interfere with each other. These include:

- oral anticoagulants (blood thinning medications to treat or prevent blood clots)
- Medicines for diabetes (including insulin)
- corticosteroids

These medicines may be affected by TESTOSTERONE 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 taking this medicine. Your doctor will advise you.

How long to use it

TESTOSTERONE helps control the symptoms of your condition, but does not cure it. Therefore you must use TESTOSTERONE every day. Continue using TESTOSTERONE for as long as your doctor tells you to.

If you use too much (overdose)

Immediately telephone your doctor or 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 used too much TESTOSTERONE. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using TESTOSTERONE

Things you must do

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

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

Things you must not do

Do not use TESTOSTERONE to treat any other complaints unless your doctor tells you to.

Do not give TESTOSTERONE to anyone else, even if they have the same condition as you.

Do not stop using TESTOSTERONE, or change the dosage, without checking first with your doctor.

Call your doctor right away if you see any signs in a child or a woman that may have occurred through accidental exposure to TESTOSTERONE.

Signs of increased testosterone in children include enlarged penis or clitoris, early development of pubic hair, increased erections or sex drive, aggressive behaviour. In women, this may include changes in body hair and a large increase in acne.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using TESTOSTERONE. Ask your doctor or pharmacist to answer any questions you may have.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

Very common side effects

- Mild forms of skin irritation at the application site (these often disappear over time by themselves)

Common side effects

- Headache
- Migraine
- Dizziness
- Acne and other skin conditions
- Nausea and vomiting
- Diarrhoea
- Increased blood pressure
- Difficulty sleeping
- Mood swings
- Anger
- Anxiety

- Increased blood cholesterol
- Increased haematocrit (percentage of red blood cells in the blood), haemoglobin and red blood cell count
- Changes in the levels of blood glucose
- Increased Prostate Specific Antigen (PSA). PSA is a protein produced by the prostate, which can be used to detect prostate disease

You should also tell your doctor if you have severe skin reactions when using TESTOSTERONE.

Sperm production may be reduced when using testosterone replacement.

The following side effects that have been observed during treatment with testosterone products can sometimes be serious. These may also occur with TESTOSTERONE. You may need urgent medical attention.

- Prostatic and urinary disorders
- Painful long-lasting erections
- Fluid retention and swelling
- Shortness of breath or problems breathing during sleep
- Blood clots
- Increased risk of prostate cancer

Other side effects not listed above may also occur in some patients.

Tell your doctor if you notice anything else that is making you feel unwell.

After using TESTOSTERONE

Storage

Keep TESTOSTERONE in a cool dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a window-sill. Do not leave it in the car.

Heat and damp 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 taking this medicine or the expiry date has passed, return any unused medicine to your pharmacist