

PACKAGE LEAFLET

Read this entire leaflet carefully before you start using this medicine. It contains important information about your treatment.

If you have further questions, please ask your doctor or your pharmacist.

This medicine has been prescribed for your personal use and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

Keep this leaflet. You may need to read it again.

TESTOGEL® 50 mg, gel in sachet

– Each sachet contains 50 mg of the active ingredient testosterone in 5 g of gel.

– The other ingredients are:

Carbomer 980, isopropyl myristate, ethanol 96%, sodium hydroxide, purified water.

1. WHAT IS TESTOGEL 50 mg, gel in sachet AND WHAT IS IT USED FOR?

Testogel 50 mg is a colourless gel presented in a 5 g sachet. It contains testosterone, a male hormone produced naturally in the body.

This medicine is a hormone treatment. It is used for problems related to testosterone deficiency.

2. BEFORE YOU TAKE TESTOGEL 50 mg, gel in sachet

TESTOGEL 50 mg, gel in sachet MUST NEVER BE USED:

- If you are allergic to testosterone or to any of the ingredients of the gel,
- If you are suffering from prostate cancer,
- If you are suffering from breast cancer.

What you should know before using TESTOGEL 50 mg:

Before starting treatment your doctor will perform a full examination. Your doctor will need to take blood samples on 2 visits to measure your levels of testosterone before you are given this medicine. You will have regular check-ups (at least once a year) during treatment.

Special warnings:

Testogel is not used for the treatment of male sterility or impotence.

Testogel is not to be used by children or women.

Testogel may increase the risk of benign prostatic hypertrophy (enlarged prostate gland) or prostate cancer and regular examinations of the prostate gland should be performed in accordance with your doctor's recommendations.

In people suffering from severe heart, liver or kidney disease treatment with Testogel may cause severe complications in the form of oedema (water retention in the body) either accompanied or not accompanied by congestive heart failure (fluid overload in the heart).

Worsening of breathing problems during sleep has been reported during treatment with testosterone in predisposed individuals, particularly people who are very overweight (obese) or are suffering from respiratory disease.

If you are suffering from cancer affecting your bones, you may develop increased levels of calcium in your blood or urine. Testogel may further affect these calcium levels. Your doctor may wish to check these calcium levels using blood tests during your treatment with Testogel.

People receiving testosterone replacement treatment over long periods of time may develop polycythaemia (an abnormal

increase in the number of red blood cells in the blood). You will have regular blood tests to check that this is not happening.

It may be necessary to adjust treatment doses in people who are receiving oral anticoagulants (used to thin the blood), insulin or corticosteroids.

When you should take special care:

Testosterone may be transferred to another person during close and relatively prolonged skin contact with the gel application area if no precaution is taken. This could cause your partner to show the signs of increased testosterone such as more hair on the face and body and a deepened voice, if contact is made a number of times or for long periods of time. This may also cause changes in the menstrual cycle of women. Wearing clothes covering the application area or showering before contact allows such transfer to be avoided.

As a result, the following precautions are recommended:

- * wash your hands with soap and water after applying the gel,
- * cover the application area with clothing once the gel has dried,
- * take a shower before intimate contact.

For people not being treated with Testogel 50 mg:

- * in the event of contact with the application area, wash the area of skin onto which the testosterone may have been transferred immediately with soap and water
- * report the development of signs such as acne or changes in the growth or pattern of hair on your body or face to your general practitioner.

You should preferably wait at least 6 hours between applying the gel and taking a bath or shower. A bath or shower may occasionally be taken between 1 and 6 hours after applying the gel and should not significantly change the effects of your treatment.

To make sure your partner is not put at risk of receiving testosterone by accident you should leave a long period of time between applying Testogel and having sex. You should also either wear a T-shirt during the time when you are in close contact with your partner to cover the area where Testogel has been applied, or have a shower or bath before starting having sex.

You should also wear a T-shirt covering where Testogel has been applied when you are going to be in close contact with children. This is to avoid any of the medicine being passed onto the children's skin.



Pregnancy and breast-feeding:

Testogel is not to be used by pregnant or breast-feeding women.

Pregnant women must avoid **any** contact with the Testogel application sites. This medicine may cause the development of unwanted male characteristics in the developing baby. In the event of contact, wash the area of contact as soon as possible with soap and water.

If your partner becomes pregnant you **must** follow the advice regarding avoiding transfer of the testosterone gel.

Ask your doctor or pharmacist for advice before taking any medicines.

Driving or using machines:

Not applicable.

Sportsmen and women:

The attention of sportsmen and women is drawn to the fact that this proprietary medicine contains an active substance (testosterone) which may produce a positive reaction in anti-doping tests.

Taking or using other medicines:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed, but particularly oral anticoagulants (used to thin the blood).

3. HOW TO TAKE TESTOGEL 50 mg, gel in sachet

THIS MEDICINE IS FOR USE BY ADULT MEN ONLY

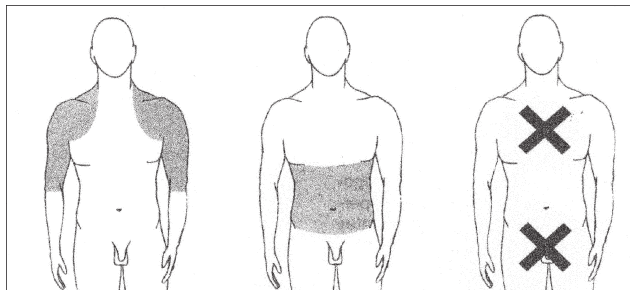
The recommended dosage is 5 g of gel (i.e. 50 mg of testosterone) applied once daily at approximately the same time, preferably in the morning.

The daily dose may be adjusted by your doctor, on an individual patient basis, not exceeding 10 g of gel per day.

The gel must be gently spread onto clean, dry, healthy skin as a thin layer on the shoulders, arms or stomach.

After opening the sachet, the entire contents should be taken out of the sachet and applied immediately onto the skin. Allow the gel to dry for at least 3-5 minutes before dressing. Wash your hands with soap and water after applying.

Do not apply to the genital areas (penis and testes) as the high alcohol content may cause local irritation.



ALWAYS TAKE TESTOGEL 50 mg EXACTLY AS YOUR DOCTOR HAS INSTRUCTED YOU.

If you have taken more TESTOGEL 50 mg, gel in sachet than you should have:

Seek advice from your doctor.

If you have forgotten to take TESTOGEL 50 mg, gel in sachet:

Do not take a double dose to make up for a forgotten individual dose.

You should not stop therapy with Testogel unless told to do so by your doctor.

4. POSSIBLE SIDE EFFECTS OF TESTOGEL 50 mg, gel in sachet

Like all medicines, TESTOGEL 50 mg, gel in sachet may have side effects:

Skin reactions such as irritation, acne, and dry skin may occasionally occur at the application site.

Testogel may cause headaches, hair loss, development of painful, tender or enlarged breasts, changes to your prostate gland, diarrhoea, dizziness, pins and needles, an increase in blood pressure, changes to your mood, changes in laboratory tests (increase in the number of red blood cells in the blood, lipids), skin hypersensitivity and stinging and loss of memory.

Other side effects have been observed during treatment with oral or injectable testosterone: enlarged prostate gland and prostate cancer, itching over the entire body, redness of the face and neck, nausea, yellowing of the skin (jaundice), increased sex drive, depression, nervousness, muscular pain, electrolyte changes (changes of the salts in the blood), oligospermia (reduction in the number of sperm), frequent or prolonged erections, changes in the results of tests that check how the liver is working and blockages that may make it difficult to pass urine.

Certain clinical signs: irritability, nervousness, weight gain, frequent or prolonged erections, may indicate an excessive effect due to the product. Report these to your doctor who will adjust the daily dose of Testogel.

Because of the alcohol this substance contains, frequent applications to the skin may cause irritation and skin dryness.

Tell your doctor or pharmacist if you experience side effects not listed in this leaflet.

5. STORING TESTOGEL 50 mg, gel in sachet

There are no special precautions for storage.

Keep out of the reach and sight of children.

Do not use after the expiry date stated on the box.

Do not use TESTOGEL 50 mg if you notice signs that the substance has deteriorated.

The last date on which this leaflet was approved was 3 March 2003.