

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet See section 4.

ANDROGEL 50 mg transdermal gel in sachet will be referred to as “this medicine” throughout this leaflet.

ANDROGEL 50 mg transdermal gel in sachet Testosterone

What is in this leaflet:

1. What ANDROGEL is and what it is used for
2. What you need to know before you use ANDROGEL
3. How to use ANDROGEL
4. Possible side effects
5. How to store ANDROGEL
6. Content of the pack and other information

1. What ANDROGEL is and what it is used for

This medicine contains testosterone, a male hormone produced naturally in the body.

This medicine is used in adult men for testosterone replacement to treat various health problems caused by a lack of testosterone (male hypogonadism). This should be confirmed by two separate blood testosterone measurements and also include clinical symptoms such as:

- impotence,
- infertility,
- low sex drive,
- tiredness,
- depressive moods,
- bone loss caused by low hormone levels,
- regression of masculine characteristics,
- reduced lean body mass,
- inability to have/maintain an erection.

2. What you need to know before you use ANDROGEL

Do not use this medicine

- If you are allergic to testosterone or any of the ingredients of this medicine (listed in section 6),
- If you are suffering from prostate cancer,
- If you are suffering from breast cancer.

Warning and precautions

Take special care with this medicine

Before starting any treatment with this medicine, your testosterone deficiency must be clearly demonstrated by clinical signs (regression of masculine characteristics, reduced lean body mass, weakness or fatigue, reduced sexual desire/drive, inability to have/maintain an erection, etc.) and confirmed by laboratory tests carried out in the same laboratory.

This medicine is not recommended for:

- Children as no clinical information is available for boys under 18 years,
- By women because of possibly developing male characteristics.

Androgens may increase the risk of an enlarged prostate gland (benign prostatic hypertrophy) or prostate cancer. Regular examinations of the prostate gland before the beginning and during therapy should be performed to follow your doctor's recommendations.

If you are suffering from severe heart, liver or kidney disease, treatment with this medicine may cause severe complications in the form of water retention in your body sometimes accompanied by congestive heart failure.

The following blood checks should be carried out by your doctor before and during the treatment: testosterone blood level, full blood count.

Blood clotting problems:

- Thrombophilia (an abnormality of blood coagulation that increases the risk of thrombosis – blood clots in blood vessels).
- factors that increase your risk for blood clots in a vein: previous blood clots in a vein; smoking; obesity; cancer; immobility; if one of your immediate family has had a blood clot in the leg, lung or other organ at a young age (e.g. below the age of about 50); or as you get older.

How to recognise a blood clot: painful swelling of one leg or sudden change in colour of the skin e.g. turning pale, red or blue, sudden breathlessness, sudden unexplained cough which may bring up blood; or sudden chest pain, severe light headedness or dizziness, severe pain in your stomach, sudden loss of vision. Seek urgent medical attention if you experience one of these symptoms.

Tell your doctor if you have high blood pressure or if you are treated for high blood pressure, as testosterone may cause a rise in blood pressure.

Worsening of breathing problems during sleep have been reported during treatment with testosterone in some people, particularly those who are very overweight or are already suffering from breathing difficulties.

If you have cancer that affects your bones, you may develop increased levels of calcium in your blood or urine. This medicine may further affect these calcium levels. Your doctor may wish to

check these calcium levels using blood tests during your treatment with this medicine.

If you receive testosterone replacement treatment over long periods of time you may develop an abnormal increase in the number of red blood cells in your blood (polycythaemia). You will need regular blood tests to check that this is not happening.

This medicine must be used with caution if you are suffering from epilepsy and/or from migraine as these conditions may be made worse.

In case of severe skin reactions, treatment should be reviewed and stopped if necessary.

The following may indicate you are taking too much of the product: irritability, nervousness, weight gain, frequent or prolonged erections. Report any of these to your doctor who will adjust the daily dose of this medicine.

Before starting treatment your doctor will perform a full examination. He/she 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 and twice a year if you are elderly or an at-risk patient) during treatment.

Possible transfer of testosterone

During close and relatively long periods of skin contact testosterone may be transferred to another person unless you cover the treated area and could result in the other person showing signs of increased testosterone such as more hair on the face and body and a deepened voice. It may cause changes in the menstrual cycle of women. Wearing clothes covering the application area or washing the application area before contact protects against such transfer.

The following precautions are recommended:

For the patient:

- wash your hands with soap and water after applying the gel,
- cover the application area with clothing once the gel has dried,
- wash the application area before making close contact with another person.

If you believe testosterone has been transferred to another person (man, woman or child), this person should:

- wash the affected area of skin immediately with soap and water,
- report any signs such as acne or changes in the growth or pattern of hair on your body or face to your doctor.

You should preferably wait at least 1 hour before showering or bathing after applying this medicine.

Other medicines and this medicine

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, even those not prescribed, but particularly oral anticoagulants (used to thin the blood), insulin or corticosteroids. These particular medicines may lead to your dose of this medicine being adjusted.

Pregnancy and breast-feeding

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

Pregnant women must avoid **any** contact with this medicine's application sites. This medicine may cause the development of unwanted male characteristics in the developing baby. In the event of contact, as recommended above, 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.

Driving and using machines

This medicine has no influence on the ability to drive or use machines.

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.

This medicine contains alcohol (ethanol)

This medicine contains 3.6 g alcohol (ethanol) in each sachet.

It may cause burning sensation on damaged skin.

This product is flammable until dry.

3. How to use ANDROGEL

This medicine is for transdermal use by adult men only.

Always use this medicine exactly as your doctor has told you. you should check with your doctor if you are not sure.

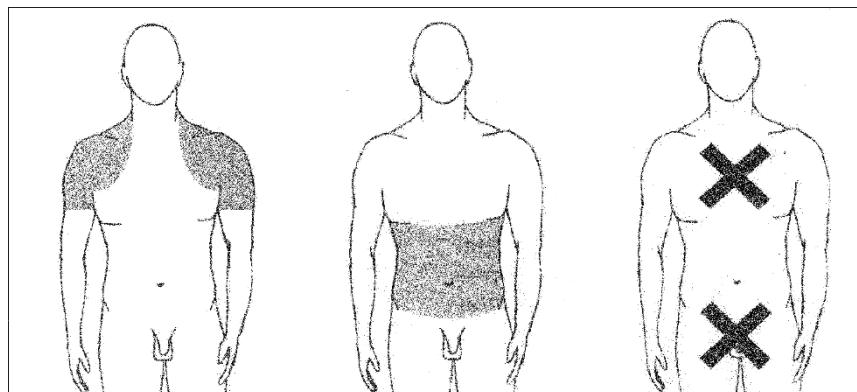
The recommended dose is 5g of gel (i.e.50 mg of testosterone) applied once daily at approximately the same time, preferably in the morning.

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.



If you use more this medicine than you should

Seek advice from your doctor.

If you forget to use this medicine

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

If you stop using this medicine

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

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them:

Very common side effects may be experienced by 10 people in every 100

Because of the alcohol this medicine contains, frequent applications to the skin may cause irritation and skin dryness. Moreover, acne may occur.

Common side effects (between 1 and 10 people in every 100)

this medicine may cause headaches, hair loss, development of painful, tender or enlarged breasts, changes to your prostate gland, diarrhoea, dizziness, an increase in blood pressure, changes to your mood, increase in red blood cell count haematocrit (percentage of red blood cells in blood) and haemoglobin (the component of red blood cells that carries oxygen) identified by periodic blood tests, changes in lipid levels), skin hypersensitivity, stinging and loss of memory.

Other side effects have been observed during treatment with oral or injectable testosterone: weight gain, changes of the salt in the blood, muscular pain, nervousness, depression, hostility, breathing problem during sleep, yellowing of the skin (jaundice), changes in the results of tests that check how the liver is working seborrhoea, sex drive changes, reduction in the number of sperm, frequent or prolonged erections, blockages that may make it difficult to pass urine, water retention, hypersensitivity reactions.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAPharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store ANDROGEL

This medicinal product does not require any special storage conditions.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the box.

6. Content of the pack and other information**What this medicine contains**

- The active substance is testosterone. Each 5 g sachet contains 50 mg testosterone.
- The other ingredients are Carbomer 980, isopropyl myristate, ethanol 96%, sodium hydroxide, purified water.

What this medicine looks like and contents of the pack

ANDROGEL 50 mg is a colourless gel presented in a 5 g sachet.

ANDROGEL is available in boxes of 1, 2, 7, 10, 14, 28, 30, 50, 60, 90 or 100 sachets (not all pack sizes may be marketed).

Marketing Authorisation Holder and ManufacturerMarketing Authorisation Holder

Laboratoires Besins International

3, rue du Bourg l'Abbé

75003 Paris

France

Manufacturers

Laboratoires Besins International or Besins Manufacturing Belgium

13, rue Périer

92120 Montrouge

France

Groot Bijgaardenstraat, 128

1620 Drogenbos

Belgium

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria, Belgium, Czech Republic, Denmark, France, Hungary, Ireland, Italy, Latvia,

Lithuania, Luxemburg, Portugal, The Netherlands: **ANDROGEL**

Germany, Poland, Slovenia : **ANDROTOP**

This leaflet was last revised in 06/2022