

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, 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.

ANDROGEL 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 ANDROGEL

- 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 ANDROGEL

Before starting any treatment with ANDROGEL, 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.

ANDROGEL is not recommended for:

- The treatment of male sterility or impotence,
- 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 ANDROGEL 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.

Thrombophilia (an abnormality of blood coagulation that increases the risk of thrombosis – blood clots in blood vessels).

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. ANDROGEL may further affect these calcium levels. Your doctor may wish to check these calcium levels using blood tests during your treatment with ANDROGEL.

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.

ANDROGEL 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 ANDROGEL.

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. 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. It may cause changes in the menstrual cycle of women. Wearing clothes covering the application area or showering before contact protects against such transfer.

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.

If you believe testosterone has been transferred to another person (woman or child)

- * wash the area of skin onto which may have been affected 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.

To make sure no-one else is accidentally put at risk you should leave a long period of time between applying ANDROGEL and making contact. You should also either wear a T-shirt during times of close contact to cover the area where ANDROGEL has been applied or bathe or shower before making contact.

You should preferably wait at least 6 hours between applying the gel and taking a bath or shower. If you occasionally need to bathe or shower between 1 and 6 hours after applying the gel it should not significantly change the effects of your treatment.

Other medicines and ANDROGEL

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 ANDROGEL being adjusted.

Pregnancy and breast-feeding

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

Pregnant women must avoid **any** contact with the ANDROGEL 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

ANDROGEL 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.

3. How to use ANDROGEL

This medicine is for 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.

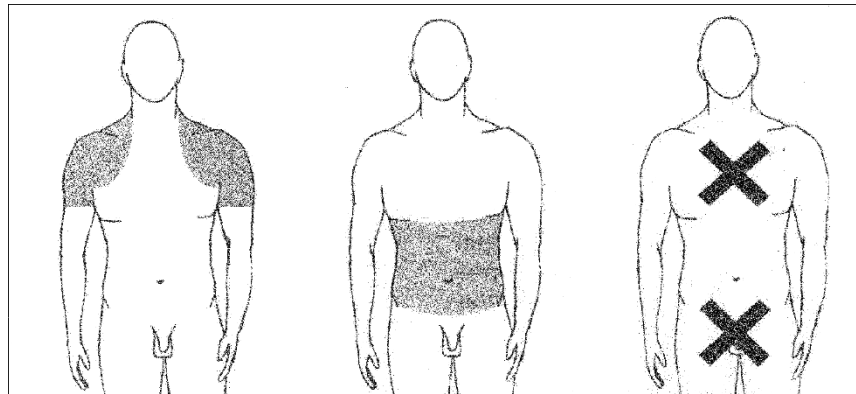
The recommended dose is 5g of gel (i.e.50 mg of testosterone) applied once daily at approximately the same time, preferably in the morning.

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 ANDROGEL than you should

Seek advice from your doctor.

If you forget to use ANDROGEL

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

If you stop using ANDROGEL

You should not stop therapy with ANDROGEL 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, ANDROGEL 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)

ANDROGEL 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 HPRA Pharmacovigilance, 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 ANDROGEL 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 ANDROGEL 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 Manufacturer

Marketing 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		Groot Bijgaardenstraat, 128
92120 Montrouge		1620 Drogenbos
France		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 : **ANDROTOP GEL**
Poland, Slovenia : **ANDROTOP**

This leaflet was last revised in 12/2016