

ANDROGEL 50MG, GEL OF TESTOSTERONE 1% ANDROGEL 25MG, GEL OF TESTOSTERONE 1%

Testosterone Gel 1%

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What is Androgel is used for

Androgel is a colourless gel containing Testosterone 1% in a 5 g sachet. Testosterone is a male hormone produced naturally in the body. (Pharmacotherapeutic group: urogenital system and sex hormones). Androgel is prescribed for problems relating to testosterone deficiency in men over 18 years as hormone replacement therapy.

How Androgel works

Androgel is a topical daily testosterone replacement therapy (TRT) that can help bring your testosterone levels back to normal with daily morning use. This clear, odorless, and concentrated quick-drying gel is used to treat adult males who have low or no testosterone due to certain medical conditions. The testosterone in AndroGel is the same as the testosterone your body makes naturally.

Before you use Androgel

When you must not use it

- Androgel is a transdermal product which is applied topically and should not be taken orally.
- If you are suffering from prostate cancer or breast cancer.
- If you are allergic to testosterone or to any of the ingredients of the gel

Pregnancy and lactation

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, 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.

Before you start to use it

Consult with your doctor or pharmacist before using Androgel.

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

-Androgel should not be used by children or women.

-Androgel may increase the risk of an enlarged prostate (benign prostatic hyperplasia, BPH) and the potential risk of prostate cancer. Regular examinations of the prostate gland should be performed in accordance with 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 (fluid overload in the heart).

-Testosterone may cause a rise in blood pressure. Androgel should therefore be used with caution if you are suffering from high blood pressure.

-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.

-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 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.

Taking other medicines

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

- Oral anticoagulants (used to thin the blood)
- Corticosteroids (used to reduce swelling)

How to use Androgel

How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

-The recommended dosage is 5 g of gel (i.e. 50 mg of testosterone) applied once daily

-The daily dose may be adjusted by your doctor or 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.

When to use it

Use as directed by your doctor or pharmacist. Commonly, to be used at approximately the same time, preferably in the morning.

How long to use it

Continue using Androgel for as long as your doctor recommends.

If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

-Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

If you use too much (overdose)

If you have taken more than the recommended dose of Androgel, contact your doctor immediately or go to the Emergency Department of your nearest hospital. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Taking more than the recommended dose of Androgel for a long period of time can cause serious health problems including

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effects on the heart, liver, and reproductive functions, as well as serious psychiatric problems.

While you are using Androgel

Things you must do

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 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.

Things you must not do

Do not take more than the recommended dose of Androgel, Individuals who have taken more than the recommended dose for

a long period of time may experience withdrawal symptoms lasting for weeks or months after abrupt discontinuation or a significant dose reduction of Androgel. These include: changes in mood and appetite, fatigue, insomnia, decreased sex drive as well as loss of function of the testes and ovaries.

Things you must be careful of **Flammability**

Androgel contains alcohol and is flammable until dry. Patients are advised to avoid fire, flame or smoking until Androgel has dried.

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 antidoping tests.

Driving and using machines

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

Side Effects

Like all medicines, Androgel can cause side effects, although not everybody gets them. Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

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, changes in laboratory test results (increase in the number of red blood cells in the blood lipids), 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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumer Reporting → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Androgel

Storage

Androgel 25mg & 50mg - Keep out of the reach and sight of children. Store below 30°C.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

Androgel is a transparent or slightly opalescent, colourless gel.

Ingredients

- Active ingredient: Testosterone
- Inactive ingredients: Carbomer 980, isopropyl myristate, ethanol 96%, sodium hydroxide, purified water.

MAL numbers

Androgel 25mg: MAL06100554ACZ
Androgel 50mg: MAL06100555ACZ

Manufacturer

Delpharm Drogenbos SA, Groot-Bijgaardenstraat 128, 1620 Drogenbos, Belgium

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Product Registration Holder

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Date of Revision: 10/03/2021

Serial Number: NPRA (R1/3)10032021/039