

ANDROGEL 16.2MG/G GEL, TESTOSTERONE

Testosterone (16.2mg/g)

What is in this leaflet

1. What ANDROGEL 16.2 mg/g is used for
2. How ANDROGEL 16.2 mg/g works
3. Before you use ANDROGEL 16.2 mg/g
4. How to use ANDROGEL 16.2 mg/g
5. While you are using it
6. Side effects
7. Storage and Disposal of ANDROGEL 16.2 mg/g
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial Number

What ANDROGEL 16.2 mg/g is used for

ANDROGEL 16.2 mg/g 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

How ANDROGEL 16.2 mg/g works

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

Before you use ANDROGEL 16.2 mg/g

- When you must not use it
- if you have or are suspected of having prostate cancer
- if you have or are suspected of having breast cancer
- if you are allergic to testosterone or any of the other ingredients of this medicine

Pregnancy and lactation

ANDROGEL 16.2 mg/g is not to be used by pregnant or breast-feeding women.

Pregnant women must avoid any contact with the ANDROGEL 16.2 mg/g application sites. This medicine may cause the development of unwanted male characteristics in the developing baby. In 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. Spermatozoid production may be reversibly suppressed with ANDROGEL 16.2 mg/g.

- Before you start to use it
Talk to your doctor or pharmacist before using ANDROGEL 16.2 mg/g.

Before starting any treatment with ANDROGEL 16.2 mg/g, 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.

Your doctor will need to take blood samples on two 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. The following blood checks should be carried out by your doctor before and during the treatment: testosterone blood level, full blood count.

If you are arranging for testing of blood samples while using ANDROGEL 16.2 mg/g you must ensure that all testosterone measurements are performed in the same laboratory, because of the variability in analytical values among diagnostic laboratories.

ANDROGEL 16.2 mg/g is not recommended for:

- the treatment of male sterility or impotence
- children, as no clinical information

is available for boys under 18 years
- women due to possible virilising effects (such as growth of facial or body hair, deepening of the voice or changes in the menstrual cycle).

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 have cancer that affects your bones, you may develop increased levels of calcium in your blood or urine. ANDROGEL 16.2 mg/g may further affect these calcium levels. Your doctor may wish to check these calcium levels using blood tests during your treatment with ANDROGEL 16.2 mg/g.

If you are suffering from severe heart, liver or kidney disease, treatment with ANDROGEL 16.2 mg/g 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 16.2 mg/g should therefore be used with caution if you are suffering from high blood pressure.

Testosterone may cause blood clotting disorders:

- o thrombophilia (a blood clotting abnormality that increases the risk of thrombosis [formation of blood clots in the blood vessels]),
- o factors that increase the risk of blood clots in a vein: history of blood clots in a vein, smoking, obesity, cancer, immobility, if a member of your immediate family has had a blood clot in a leg, lung, or other organ at a young age (for example, before about 50 years old), or as you grow older.

How to recognize a blood clot: painful swelling of a leg or sudden change in skin colour that, for example, becomes pale, red, or blue, sudden shortness of breath, sudden and unexplained cough that may spit up blood, or sudden chest pain, severe feeling of dizziness or vertigo, intense

ANDROGEL 16.2MG/G GEL, TESTOSTERONE

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stomach pain, sudden loss of vision. See a doctor immediately if you have any of these symptoms.

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 16.2 mg/g must be used with caution if you are suffering from epilepsy and/or from migraine as these conditions may worsen.

If have diabetes and use insulin to control your blood sugar levels, testosterone treatment may affect your response to insulin and your antidiabetics' medication might need adjustment.

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

The following signs 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 16.2 mg/g.

- 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. This is because ANDROGEL 16.2 mg/g can affect the way some other medicines work. Also, some other medicines can affect the way ANDROGEL 16.2 mg/g works. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, particularly the following:

- oral anticoagulants (used to thin the

blood)
- corticosteroids

These particular medicines may lead to your dose of ANDROGEL 16.2 mg/g being adjusted.

How to use ANDROGEL 16.2 mg/g

- How much to use

This medicine is for use by adult men only.

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Using the pump for the first time. Before using your new pump for the first time, you need to prepare it for use as follows:

- Remove the cap from the canister to reveal the plunger
- Press the plunger down three times
- Do not use the gel from these three depressions of the plunger. This dose should be safely discarded.
- Your pump is now ready to use. You will not need to prime it again
- Each time the plunger is depressed it delivers 1.25 g of gel

The recommended dose is 2.5 g of gel (i.e. 40.5 mg of testosterone) applied once daily at approximately the same time each day, preferably in the morning. To obtain 2.5 g of gel the plunger should be depressed twice. The dose may be adjusted by your doctor, and the maximum dose is 5 g of gel per day (no more than four depressions of the plunger).

Your doctor will tell you how many depressions of the plunger to make to get the correct dose of gel for you.

The gel must be gently spread onto clean, dry, healthy skin as a thin layer on both shoulders and upper arms. Do not rub it into 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 preferably in the morning or as directed by your doctor or pharmacist.

- How long to use it

You should not stop therapy with ANDROGEL 16.2 mg/g unless told to do so by your doctor.

- If you forget to use it

Do not use a double dose to make up for a forgotten individual dose. Apply the next dose at the usual time.

- If you use too much (overdose)

If you have taken more than the recommended dose of ANDROGEL 16.2 mg/g, 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 16.2 mg/g for a long period of time can cause serious health problems including effects on the heart, liver, and reproductive functions, as well as serious psychiatric problems

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give ANDROGEL 16.2 mg/g to anyone else, even if they have the same symptoms or condition as you.

Do not take more than the recommended dose of ANDROGEL 16.2 mg/g. Individuals who have taken more than the

ANDROGEL 16.2MG/G GEL, TESTOSTERONE

Testosterone (16.2mg/g)

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 16.2 mg/g. These include: changes in mood and appetite, fatigue, insomnia, decreased sex drive as well as loss of function of the testes and ovaries.

- Things to be careful of *Sportsmen and women*

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

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, premature puberty and genital enlargement in children. 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 or if not possible wear clothing such as a shirt or a T- shirt covering the application site during the contact period
- wear clothing (such as a sleeved shirt) covering the application site during contact periods with children

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

- wash the area of skin that 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

You should preferably wait at least 2 hours between applying the gel and taking a bath or shower. If you occasionally need to bath or shower between 2 and 6 hours after applying the gel it should not significantly change the effects of your treatment.

In order to improve the safety of your partner you should wash the area with soap for instance during a shower before having sexual intercourse or, if not possible, wear a T-shirt that covers the application site at the time of contact.

You should wear a T-shirt that covers the application site when in contact with children in order to avoid the risk of transferring the gel to the child's skin.

Driving and using machines

ANDROGEL 16.2 mg/g has no influence on the ability to drive or use machines.

Side effects

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

Common side effects (may affect up to 1 in 10 people)

ANDROGEL 16.2 mg/g may cause changes to your mood (including mood swings, anger or aggression, impatience, sleeplessness, abnormal dreams and increased sex drive) and skin reactions (including acne, hair loss, dry skin, skin irritation, hair colour changes, rash and sensitive skin), 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 and changes to the prostate gland (including increased blood levels of a protein called prostate specific antigen that is produced by the prostate).

Uncommon side effects (may affect up to 1 in 100 people)

ANDROGEL 16.2 mg/g may cause an increase in blood pressure, flushing, inflammation of the veins, diarrhoea, bloated stomach, pain in the mouth,

development of breasts, tender nipples, pain in the testicles, fluid retention.

Other side effects have been observed during treatment with ANDROGEL 16.2 mg/g :

Tiredness, depression, anxiety, headache, dizziness, tingling skin, blood clots, difficulty breathing, feeling sick, sweating, abnormal body hair growth, muscle or bone pain, difficulty passing urine, reduced number of sperm, muscle weakness, feeling unwell, weight gain.

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

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

Storage and Disposal of ANDROGEL

- Storage

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date stated on the label. Do not store above 30°C. Store in original pack.

- 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. Any unused medicinal product or waste material should be disposed of in accordance with local requirements. Unused medicinal product should be returned to the pharmacist at the end of treatment.

Product Description

- What it looks like

Transparent or slightly opalescent colourless gel.

Packaging

88gm Gel is packaged in Low Density Polyethylene lined pouch. The pouch is held in a multi dose polypropylene 100mL canister with a metered-dose pump and polypropylene cap. Each actuation of the pump delivers a unit dose of 1.25g of minimum of 60 doses.

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- *Ingredients*

- Active ingredient: Testosterone

- Inactive ingredients: Isopropyl
Myristate, Ethanol 96%, Carbomer,
Sodium Hydroxide, Purified Water

- *MAL number(s)*: xxxxx

Manufacturer

LABORATOIRES BESINS
INTERNATIONAL,
13 Rue Perier, Montrouge, 92120, France

Product Registration Holder

BREGO LIFE SCIENCES SDN. BHD,
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