

ANNEX IIIB

PACKAGE LEAFLET: INFORMATION FOR THE USER

Name of the medicinal product

ANDROGEL® 16.2 mg/g, gel

Testosterone

Text box

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.

What is in this leaflet

1. What ANDROGEL 16.2 mg/g, gel is and what it is used for
2. What you need to know before you use ANDROGEL 16.2 mg/g, gel
3. How to use ANDROGEL 16.2 mg/g, gel
4. Possible side effects
5. How to store ANDROGEL 16.2 mg/g, gel
6. Contents of the pack and other information

1. WHAT ANDROGEL 16.2 mg/g, gel IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group – ATC code: G03BA03 Testosterone

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

ANDROGEL 16.2 mg/g, gel is used in adult men to replace testosterone, in order to treat various health problems due to a lack of testosterone (male hypogonadism). This diagnosis must be confirmed by two separate measurements of testosterone in the blood, as well as by the presence of symptoms such as:

- impotence,
- infertility,
- reduced libido,
- fatigue,
- depressive mood,
- bone loss due to low hormone levels.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ANDROGEL 16.2 mg/g, gel

Do not use ANDROGEL 16.2 mg/g, gel:

- if you have prostate cancer or suspected prostate cancer
- if you have breast cancer or suspected breast cancer
- if you are allergic (hypersensitive) to testosterone or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Androgel 16.2 mg/g, gel.

Before starting any treatment with ANDROGEL 16.2 mg/g, gel, your testosterone deficiency must clearly be demonstrated by clinical signs (regression of male sexual characteristics, reduction in lean body mass, weakness or fatigue, reduced sex drive/libido, inability to get/maintain an erection, etc.) and confirmed by biological tests.

If you anticipate any tests on your blood samples while using ANDROGEL 16.2 mg/g, gel, you must ensure that all testosterone measurements are carried out at the same laboratory, as test values can vary depending on the diagnostic laboratory.

ANDROGEL 16.2 mg/g, gel is not indicated:

- in the treatment of male sterility or impotence,
- in children, as no clinical information is available in boys under 18 years of age

Androgens may increase the risk of prostate enlargement (benign prostatic hypertrophy) or prostate cancer. Regular tests will have to be performed on your prostate before the start and during treatment, as prescribed by your doctor.

If you have a serious heart, liver or kidney condition, treatment with ANDROGEL® 16.2 mg/g, gel may lead to severe complications characterised by water retention in the body, sometimes accompanied by congestive heart failure (fluid overload in the heart).

The following blood tests will have to be carried out by your doctor before and during treatment: blood testosterone levels and complete blood count.

Tell your doctor if you have high blood pressure or if you are being treated for high blood pressure, as testosterone can increase blood pressure.

Testosterone can cause a rise in blood pressure. ANDROGEL 16.2 mg/g, gel must therefore be used with caution if you have high blood pressure.

Worsening of breathing difficulties during sleep has been observed in some people during treatment with testosterone, especially in obese patients or those with pre-existing breathing disorders.

If you have bone cancer, calcium levels in your blood or urine may be increased. ANDROGEL 16.2 mg/g, gel can further affect these calcium levels. Your doctor may recommend regular monitoring of blood calcium levels during your treatment with ANDROGEL 16.2 mg/g, gel.

If you are on long-term testosterone replacement therapy, you are at risk of developing an abnormal rise in the number of red blood cells (polyglobulia). The number of red cells in your blood will have to be regularly monitored.

ANDROGEL 16.2 mg/g, gel must be used with caution if you suffer from epilepsy and/or migraine, as treatment may aggravate these conditions.

If you suffer from diabetes and use insulin to control your blood glucose, treatment with testosterone may affect your response to insulin and your antidiabetic treatment may need adjustment.

In the event of a severe skin reaction, treatment must be reviewed and stopped if necessary.

The following signs may indicate that the effect of the product is too strong: irritability, nervousness, weight gain, frequent or prolonged erections. Tell your doctor, who will adjust the daily dose of ANDROGEL 16.2 mg/g, gel.

A full medical examination is necessary before starting treatment, including, in particular, two separate measurements of testosterone in your blood. You will receive periodic medical surveillance during treatment (at least once a year and, if you are elderly or a patient at risk, twice a year).

ANDROGEL 16.2 mg/g, gel must not be used in women due to its potentially virilising effects (such as the development of facial or body hair, deepening of the voice or changes in the menstrual cycle).

Children and adolescents

ANDROGEL 16.2 mg/g, gel is not indicated in children, as no clinical information is available in boys under 18 years of age.

Other medicines and ANDROGEL 16.2 mg/g, gel

Tell your doctor or pharmacist if you are taking, have recently taken used or might take any other medicines, especially:

- oral anticoagulants (used to thin the blood)
- corticosteroids

These medicines may require an adjustment in the doses of ANDROGEL 16.2 mg/g, gel.

ANDROGEL 16.2 mg/g, gel with food and food

Not applicable.

Pregnancy, breast-feeding

ANDROGEL 16.2 mg/g, gel is not indicated in pregnant or breast-feeding women.

Pregnant women must avoid all contact with sites where ANDROGEL® 16.2 mg/g, gel has been applied. This medicine may have adverse virilising effects on the foetus. In case of contact, as recommended above, wash the contact area as soon as possible with soap and water.

In the event of pregnancy in your partner, you must pay particular attention to the precautions for use and avoid all transfer of the testosterone gel.

The production of sperm may be reversibly suppressed by ANDROGEL 16.2 mg/g, gel.

Athletes

Athletes should note that this medicine contains an active substance (testosterone) which may induce a positive reaction in tests conducted during anti-doping controls.

Possible transfer of testosterone

Direct and relatively prolonged skin contact may result in the transfer of testosterone to others, unless the gel application site is covered. This may cause signs of androgenisation in your partner, such as increased facial and body hair, and deepening of the voice. It may lead to changes in the menstrual cycle, premature puberty and enlargement of the genital organs in

children. This transfer can be avoided by wearing an item of clothing that covers the application site or by taking a shower before contact.

The following precautions are recommended:

- wash your hands with soap and water after applying the gel,
- cover the application site with an item of clothing after the gel has dried,
- take a shower before any intimate contact or, if this is not possible, wear an item of clothing such as a shirt or T-shirt covering the application site during the contact period,
- wear an item of clothing (such as a sleeved shirt) covering the application site during periods of contact with your children.

If you think that testosterone may have been transferred to anyone else (woman or child):

- wash the skin surface concerned immediately with soap and water,
- tell your doctor about any signs that occur, such as acne or changes in facial or body hair.

You should preferably observe an interval of at least 2 hours between applying the gel and taking a bath or shower. However, occasional baths or showers taken between 2 and 6 hours after applying the gel should not significantly affect the course of your treatment.

To improve your partner's safety, you must wash the application site with soap, while taking a shower for instance, before having sex, or, if this is not possible, you must wear a T-shirt covering the application site at the time of contact.

You must also wear a T-shirt covering the application site during contact with children, so as to avoid the risk of transferring the gel to the child's skin.

Driving and using machines

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

ANDROGEL 16.2 mg/g, gel contains

Not applicable.

3. HOW TO USE ANDROGEL 16.2 mg/g, gel

This medicine is for 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 the pump for the first time, you need to prepare it for use as follows:

- Remove the cap from the canister to reveal the plunger,
- Remove the stopper from the spout,
- Press the plunger down three times,
- **Do not use** the gel from these three depressions of the plunger. This dose must be safely discarded.
- Your pump is now ready to use. You will not need to prime it again.

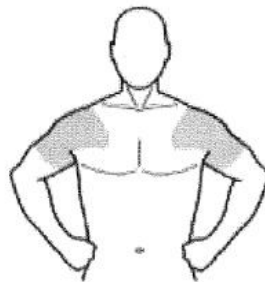
Each time you depress the plunger, the pump will deliver 1.25 g gel.

The recommended dose is 2.5 g gel (i.e. 40.5 mg testosterone) applied once daily at about the same time, preferably in the morning. To obtain 2.5 g gel, you must depress the plunger twice. The dose may be adjusted by your doctor, but without exceeding 5 g gel per day (four depressions of the plunger).

Your doctor will tell you how many depressions of the plunger to make, so as to get the right dose of gel in your case. The table below gives you more information on this.

Number of depressions	Amount of gel (g)	Amount of testosterone applied to the skin (mg)
1	1.25	20.25
2	2.5	40.5
3	3.75	60.75
4	5.0	81.0

The gel must be gently spread onto clean, dry and healthy skin as a thin layer, on both shoulders and arms. Do not allow it to penetrate the skin by rubbing. Leave the gel to dry for at least 3 to 5 minutes before getting dressed. Wash your hands with soap and water after application. Do not apply the gel to the genital organs (penis and testicles), as the large amount of alcohol in the gel may cause local irritation.



If you use more ANDROGEL 16.2 mg/g, gel than you should:

Consult your doctor or pharmacist immediately. Treatment of an overdose consists of stopping ANDROGEL 16.2 mg/g, gel, combined with appropriate symptomatic care.

If you forget to use ANDROGEL 16.2 mg/g, gel:

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

If you stop using ANDROGEL 16.2 mg/g, gel:

Do not stop your treatment with ANDROGEL 16.2 mg/g, gel without talking to your doctor first.

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

4. POSSIBLE SIDE EFFECTS

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

Common side effects (up to 1 in 10 people)

ANDROGEL 16.2 mg/g, gel may cause mood disorders (mood swings, anger or aggressiveness, impatience, insomnia, abnormal dreams and increased libido) and skin reactions (acne, hair loss, dry skin, skin irritation, changes in hair colour, rash and skin sensitivity), an increase in the number of red blood cells, increased haematocrit (percentage of red blood cells) and haemoglobin (the component of red blood cells that transports oxygen), revealed by regular blood samples, as well as changes in the prostate gland (including an increase in blood concentrations of a protein called prostate-specific antigen produced by the prostate).

Rare side effects (up to 1 in 100 people)

ANDROGEL 16.2 mg/g, gel may cause an increase in blood pressure, vasomotor flushes, inflammation of the veins, diarrhoea, bloating, sore mouth, breast development, nipple sensitivity, testicular pain and fluid retention.

Other side effects observed during treatment with ANDROGEL 16.2 mg/g, gel: fatigue, depression, anxiety, headache, dizziness, pins and needles, blood clots, difficulty in breathing, feeling sick, sweating, abnormal development of body hair, muscle or bone pain, difficulty in passing urine, reduced sperm count, muscle weakness, malaise, weight gain.

Due to the presence of alcohol in this medicine, frequent applications to the skin may cause irritation and dry skin.

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 the national reporting system: *Agence nationale de sécurité du médicament et des produits de santé (ANSM) et réseau des Centres Régionaux de Pharmacovigilance* (National Agency for the Safety of Medicines and Health Products and Network of Regional Pharmacovigilance Centres) - Website: www.ansm.sante.fr.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ANDROGEL 16.2 mg/g, gel

This medicine 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 stated on the packaging after EXP.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What ANDROGEL 16.2 mg/g, gel contains

- The active substance is testosterone
- The other ingredients are: carbomer 980, isopropyl myristate, 96% ethanol, sodium hydroxide and purified water.

What ANDROGEN 16.2 mg/g, gel looks like and contents of the pack

ANDROGEL 16.2 mg/g, gel is a colourless gel in a multidose, metered-dose container, containing 88 g gel and delivering a minimum of 60 doses.

ANDROGEL 16.2 mg/g, gel is available in boxes of 1, 2, 3 or 6 containers.

Marketing Authorisation Holder

BESINS HEALTHCARE

AVENUE LOUISE 287

1050 BRUSSELS

BELGIUM

Marketing Authorisation Distributor

LABORATOIRES BESINS INTERNATIONAL

3 RUE DU BOURG L'ABBE

75003 PARIS

FRANCE

Manufacturer

LABORATOIRES BESINS INTERNATIONAL

13, RUE PERIER

92120 MONTROUGE

FRANCE

BESINS MANUFACTURING BELGIUM

GROOT-BIJGAARDENSTRAAT 128

1620 DROGENBOS

BELGIUM

Names of the medicinal product in the Member States of the European Economic Area

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

In accordance with prevailing regulations.

This leaflet was last revised in:

[to be subsequently completed by the holder]

< {MM/YYYY}>< {month YYYY}.>

Other

Detailed information on this medicine is available on the ANSM (France) web site.