

PART III: CONSUMER INFORMATION

 **ANDROGEL®**
Testosterone gel 1%

This leaflet is Part III of a three-part "Product Monograph" published when ANDROGEL was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ANDROGEL. Contact your doctor or pharmacist if you have any questions about the drug.

- One 5.0 g packet contains 50 mg of testosterone
- One full press of the pump delivers 1.25 g of gel which contains 12.5 mg of testosterone.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions
ANDROGEL can be transferred to another person when skin-to-skin contact with application site occurs.

- **Signs of puberty (unexpected sexual development) have been reported in children who were exposed to testosterone gel.**
- **Keep children away from unwashed or unclothed application sites of men using ANDROGEL and from unwashed clothing or other fabrics exposed to ANDROGEL.**
- **Men who use ANDROGEL must strictly follow the instructions for use to lower the risk of transferring ANDROGEL to another person.**

ABOUT THIS MEDICATION**What the medication is used for:**

Your doctor has prescribed ANDROGEL because your body is not making enough testosterone. The medical term for this condition is hypogonadism. This should be confirmed by two separate blood testosterone measurements.

What it does:

ANDROGEL delivers medicine into your bloodstream through your skin. ANDROGEL helps raise your testosterone to normal levels.

When it should not be used:

- If you have or it is suspected that you have prostate or breast cancer.
- If you have a known allergy to any of its components [the active ingredient is testosterone, which may be synthesized from soy; (see "**What the non-medicinal ingredients are**" in this section)].

ANDROGEL should **NOT** be used **by women**. Pregnant and breast feeding women are especially at risk and should avoid skin contact with application sites on men. Testosterone may cause harm to your unborn baby. Testosterone exposure during pregnancy has been reported to be associated with fetal abnormalities. If skin contact with unwashed or unclothed application sites of men using ANDROGEL and/or with clothing or other fabrics exposed to ANDROGEL occurs, pregnant or nursing women should immediately wash the area of contact with soap and water.

What the medicinal ingredient is:

Testosterone USP

What the non-medicinal ingredients are:

Alcohol, purified water, sodium hydroxide, Carbopol 980 and isopropyl myristate.

What dosage forms it comes in:

ANDROGEL is a gel containing 1% testosterone. It is supplied either in a pump or foil packets:

- One 2.5 g packet contains 25 mg of testosterone

You should prevent ANDROGEL from transferring to another person, especially **pregnant or breast feeding women**, or **children** by taking the following precautions:

- Children and women should avoid contact with the application sites on men using ANDROGEL.
- ANDROGEL should be applied only to the areas of the shoulders, upper arms, and/or abdomen that will be covered by a short sleeve T-shirt.
- Wash hands immediately with soap and water after application of ANDROGEL.
- Cover the application site(s) with clothing (such as a shirt) after ANDROGEL has dried.
- If direct skin-to-skin contact is anticipated, wash the application site(s) thoroughly with soap and water to remove any ANDROGEL left on the application site(s).
- In the event that an unwashed or uncovered ANDROGEL application site and/or unwashed clothing or other fabrics exposed to ANDROGEL does come in direct contact with the skin of another person, the general area of contact on the other person should be washed with soap and water as soon as possible.

In children, signs of testosterone exposure can include unexpected sexual development such as inappropriate enlargement of the penis or clitoris, development of pubic hair, increased erections, or aggressive behaviour. In women, signs of testosterone exposure include changes in body hair distribution, significant increase in acne, or other signs of the development of masculine traits. Any of these changes should be brought immediately to the attention of a doctor. The possibility of exposure to testosterone should be discussed with the doctor.

ANDROGEL must not be used by children under the age of 18. If you are suffering from severe heart, liver or kidney disease, treatment with testosterone may cause serious complications in the form of water retention in your body, sometimes accompanied by congestive heart failure (inadequate pumping of the heart with build-up of fluid in body tissues).

Testosterone may cause a rise in blood pressure. Therefore, ANDROGEL should be used with caution if you are suffering from high blood pressure.

In patients receiving long-term ANDROGEL therapy, the physician may prescribe regular blood tests, such as testosterone, complete blood count, liver function tests and lipid profile. Testosterone increases red blood cell count which theoretically could increase the risk of blood clots .

Your physician may also monitor your prostate gland for any negative effects of testosterone therapy by performing digital rectal examinations.

There is very little information from clinical trials with testosterone in the older male (>65 years of age) to support safe use for a long period of time.

You should not use testosterone in an attempt to reduce weight and increase muscle, or improve athletic performance as it may cause serious health problems.

You should not use testosterone to treat sexual dysfunction or male infertility.

Before using ANDROGEL, talk to your doctor if you:

- have difficulty urinating due to an enlarged prostate. Older patients may have a higher risk of developing an enlarged prostate or prostate cancer;
- have prostate cancer (confirmed or suspected);
- have liver, kidney or heart disease;
- have high blood pressure (hypertension);
- have diabetes;
- have breathing problems during sleep (sleep apnea).
- have heart or blood vessel problems or a history of these problems such as heart attacks, stroke, or blood clot in the lungs or legs.

Drug Abuse and Dependence:

ANDROGEL contains testosterone, which is a controlled substance under Schedule G of the Food and Drugs Act.

Precautions while using ANDROGEL:

Following application of ANDROGEL, allow gel to dry completely before smoking or going near an open flame.

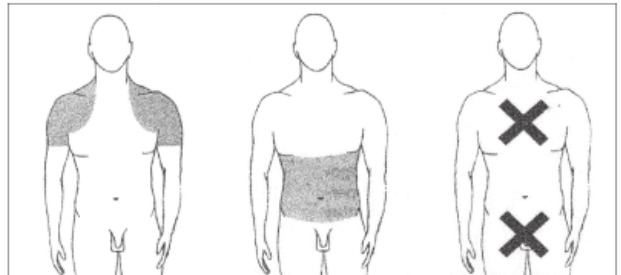
INTERACTIONS WITH THIS MEDICATION

Be sure to tell your doctor about all other prescription and non-prescription medicines you are taking, if any. Drugs that may interact with ANDROGEL include:

- insulin
- corticosteroids
- propranolol
- anti-clotting medications (e.g., warfarin)

PROPER USE OF THIS MEDICATION

1. **Apply ANDROGEL at the same time each day, (preferably in the morning).** Apply the proper amount of gel every morning as instructed by your doctor. The amount of testosterone you need may be adjusted by your doctor. Always follow your doctor's recommendations.
2. **Be sure your skin is completely dry before applying ANDROGEL.** For example, if you take a bath or shower in the morning, apply ANDROGEL *after* your bath or shower once your skin is completely dry.
3. **Apply ANDROGEL *only* to your abdomen (stomach area), shoulders, and/or upper arms, as shown in the following diagram.**



- Use a circular motion to rub in the gel for several seconds. Applying ANDROGEL only to the areas shown helps ensure that your body will absorb the right amount of testosterone. ANDROGEL may be applied to the same areas of the body each day. It is not necessary to alternate application sites.
 - **Never apply ANDROGEL to your genitals (penis and scrotum) or to damaged skin.**
 - Apply ANDROGEL only to healthy, normal skin. Avoid skin with open sores, wounds, sunburn, or irritation.
4. **Following application of ANDROGEL, allow gel to dry completely before smoking or going near an open flame.**

5. **Wash your hands immediately following application.**
 - It is important to wash your hands with soap and water right away to reduce the chance that any ANDROGEL will spread from your hands to other people.
 - If, however, you expect direct skin contact with someone else, you should wash your application site(s) with soap and water before that encounter. This will reduce the chance that any ANDROGEL will transfer to the other person.

6. **Let ANDROGEL dry for a few minutes before you dress.**
 - This prevents your clothing from absorbing or wiping the gel off your skin, ensuring that your body will absorb the correct amount of testosterone.
 - **Wait 5 to 6 hours before showering or swimming.** To ensure that ANDROGEL is fully absorbed into your system, you should generally wait five to six hours after application before showering or swimming. However, once in a while you may shower or swim as soon as one hour after applying ANDROGEL. Although this is not recommended, if done infrequently, it will have little effect on the overall amount of ANDROGEL that is absorbed by your body.
 - Transference of ANDROGEL to another person can be completely prevented when the application site is covered with a long-sleeved shirt (cotton-polyester blend).

7. **It is important that you read and follow the directions below on how to use ANDROGEL properly:**
 - See Section A if you are using the ANDROGEL pump
 - See Section B if you are using the ANDROGEL packets

Section A: Using the ANDROGEL pump

- i) **Priming the pump:**
Before using a new pump for the first time, you must prime the pump to remove the air. Up to five depressions may be needed before all of the air is removed and gel is discharged. The first two depressions that deliver any amount of gel are to be discarded by thoroughly rinsing down the sink or discarding in the household trash in a manner that prevents accidental application or ingestion by household members, especially nursing/pregnant women and children.

- ii) **Determining the number of full depressions (presses of the pump) needed for each dose:**
Each full press of the pump delivers 1.25 g of ANDROGEL. Please refer to the chart below to determine the number of full depressions required for the daily dose prescribed by your doctor:

Prescribed Daily Dose	Number of Full Pump Depressions
5.0 g	4
7.5 g	6
10.0 g	8

iii) Number of days of treatment per pump (after priming):

The ANDROGEL pump contains enough gel to allow for priming and a set number of precise doses. Please refer to the chart below to determine the number of days of treatment each pump will provide based on your individual dose. Discard the pump afterwards.

Prescribed Daily Dose	Number of Days of Treatment per Pump (after priming)
5.0 g	15
7.5 g	10
10.0 g	7.5

iv) Applying ANDROGEL to your skin:

Fully press the pump the appropriate number of times to deliver the daily dose prescribed by your doctor. The gel should be delivered directly into the palm of your hand and then applied to the desired application sites, either one pump depression at a time or upon completion of all pump depressions required for the daily dose. Alternatively, the product can be applied directly to the application sites. Application directly to the sites may prevent loss of product that may occur during transfer from the palm of the hand onto the application sites.

Section B: Using the ANDROGEL packet

- i) **Opening the packet:**
Open one ANDROGEL aluminum foil packet by folding it along the top edge and carefully tearing it open.

- ii) **Applying ANDROGEL to your skin:**
 - Gently squeeze the gel from the bottom of the packet toward the top.
 - Squeeze out half (1/2) of the contents of the packet and apply it to the areas of your body *shown in the diagram*. Use a circular motion to rub in the gel for several seconds. Once you have applied this first half to your skin, squeeze out the second half and apply it in the same manner. Discard the empty packet in the household trash in a manner that prevents accidental application or ingestion by household members, especially nursing/pregnant women and children.

What should I do if I get ANDROGEL in my eyes?

If you get ANDROGEL in your eyes, rinse your eyes right away with warm clean water to flush out any ANDROGEL. Seek medical attention if discomfort persists.

Missed Dose

If you miss a dose, **do not double your next dose** the next day to catch up. If your next dose is less than 12 hours away, it is best to wait. Do not take the skipped dose. If it is more than 12 hours until your next dose, take the dose that you missed. Resume your normal dosing the next day.

Overdose

Contact your doctor or pharmacist or poison control centre immediately if you suspect an overdose.

If you use more ANDROGEL than the recommended dose (an overdose), wash the skin with soap and water where ANDROGEL was applied and contact your doctor or pharmacist .

What to do if someone is exposed to the medication:

If someone else is exposed to ANDROGEL either by direct contact with the gel itself or indirectly because of contact with your treated skin, that person should wash his or her area of contact thoroughly with soap and water as soon as possible. The longer the gel is in contact with the skin before washing, the greater is the chance that the other person will absorb some testosterone.

This is particularly important for women, especially pregnant or nursing women, and children. Children have naturally low levels of testosterone and could be harmed by higher levels. Pregnant women are at an even higher risk because increased testosterone levels may cause harm or abnormalities in the unborn baby.

Never share your ANDROGEL with anyone.

- increased or irregular heart rate, blood clot in the lungs or the legs.

Signs of puberty (unexpected sexual development) have been reported in children who were exposed to testosterone gel. See **WARNINGS AND PRECAUTIONS**.

Changes in body hair distribution, significant increase in acne, or other signs of the development of masculine traits in the female partner or in any person (including children) exposed to skin-to-skin contact, should be brought to the attention of a doctor.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	Urinary symptoms (i.e. change in frequency/color, dribbling, pain on urination straining, weak stream, small amounts)		√	
Common (after prolonged use)	Breast enlargement or breast pain		√	
Uncommon	Swelling of ankles and legs (in patients with heart, kidney or liver damage)			√
	Erections that are too frequent or continue for too long		√	
	Liver problems, with symptoms such as nausea, vomiting, along with yellowed or darkened skin-			√

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, ANDROGEL can have side effects. The following side effects have been reported for products containing testosterone:

- Skin irritation or redness or rash at the application site;
- increased prostatic specific antigen (PSA);
- enlarged prostate (benign prostatic hyperplasia);
- an increase in red blood cell count (hematocrit and hemoglobin);
- acne;
- change in mood, depression;
- prolonged or painful erection;
- sleep disturbances caused by breathing problems;
- aggression or aggressive behaviour;
- breast enlargement and breast pain;
- loss of hair and baldness;
- high blood pressure;
- weight gain;
- headache, dizziness;

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	
Heart attack (symptoms include sharp or crushing chest pain or heaviness, coughing blood, or sudden shortness of breath)			√
Stroke (symptoms include sudden severe headache or worsening of headache, vomiting, dizziness, fainting, disturbance of vision or speech, or weakness or numbness in the face, arm or leg)			√

This is not a complete list of side effects. For any unexpected effects while taking ANDROGEL, contact your doctor or pharmacist.

HOW TO STORE IT

Store ANDROGEL (testosterone gel) at room temperature (15 -30°C).

Keep out of reach of children and pets.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected side effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

Report online at www.healthcanada.gc.ca/medeffect

Call toll-free at 1-866-234-2345

Complete a Canada Vigilance Reporting Form and:

-Fax toll-free to 1-866-678-6789, or

-Mail to: Canada Vigilance Program

Health Canada

Postal Locator 0701E

Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of the side effect, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

The most recent version of this document plus the full Product Monograph, prepared for health professionals can be found at:

www.mylan.ca

or by contacting the sponsor, BGP Pharma ULC, Etobicoke, Ontario, M8Z 2S6 at:
1-844-596-9526

This leaflet was prepared by BGP Pharma ULC

®Registered Trademark Abbott Laboratories (USA) Licensed use by BGP Pharma ULC, Etobicoke, Ontario, M8Z 2S6

Last revised: January 8, 2016