

**PART III: CONSUMER INFORMATION  
ANDRODERM®**

**Testosterone Transdermal Delivery System**

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

What dosage forms it comes in:

Androderm® (testosterone transdermal system) **2.5 mg/day**

Each patch contains 12.2 mg testosterone for delivery of 2.5 mg of testosterone per day. Available in cartons of 60 patches.

Androderm® (testosterone transdermal system)

**5 mg/day**

Each patch contains 24.3 mg testosterone for delivery of 5 mg of testosterone per day. Available in cartons of 30 patches.

**ABOUT THIS MEDICATION**

What the medication is used for:

Your doctor has prescribed this medicine because your body is not making enough testosterone. The medical term for this condition is hypogonadism.

What it does:

Androderm® delivers medicine into your bloodstream through your skin. Androderm® 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 difficulty in urinating due to an enlarged prostate
- Known allergy to any of its components [the active ingredient is testosterone, which may be synthesized from soy; (see "What the nonmedicinal ingredients are" in this section)]

Androderm® 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.

What the medicinal ingredient is:

Testosterone USP.

What the nonmedicinal ingredients are:

Alcohol, carbomer, glycerin, glycerol monooleate, methyl laurate, purified water and sodium hydroxide.

**WARNINGS AND PRECAUTIONS**

Androderm is not indicated for use in children < 18 years of age

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 Androderm®, talk to your doctor if you:

- Have heart or blood vessel problems or a history of these problems such as heart attacks, stroke, or blood clot in the lungs or the legs
- 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).

Skin burns have been reported at the patch site in patients wearing an aluminised transdermal system during a magnetic

resonance image scan (MRI). Because Androderm contains aluminium it is recommended to remove the system before undergoing an MRI.

Drug Abuse and Dependence:

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

Precautions while using Androderm®

Androderm® can be transferred to another person, including children, when skin-to-skin contact is made with the application sites.

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

- Wash hands immediately with soap and water after application of Androderm®.

In the event that an unwashed or uncovered Androderm® application site 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.

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.

**INTERACTIONS WITH THIS MEDICATION**

Tell your doctor or pharmacist if you are taking or have recently taken any other drugs or herbal products, even those without a prescription.

Drugs that may interact with Androderm® include:

- Insulin
- Corticosteroids
- Propranolol
- Warfarin

**PROPER USE OF THIS MEDICATION**

*It is essential that you take Androderm exactly as your doctor has prescribed, and follow the following recommendations regarding use of the patches.*

**Recommendations on When and Where to Apply Androderm®**

1. Apply one 5 mg or two 2.5 mg patches which will deliver 5 mg of testosterone per day into the body.
2. Apply the patch at night ( around 10:00 PM). Nightly application results in a daily variation of circulating testosterone levels similar to the pattern in healthy young men.
3. Apply the patch to clean dry areas of the body, such as back, abdomen, thighs, and upper arms (see figure 4). Only apply the patch to healthy, normal skin.
4. Never apply the patch to the scrotum, mucosal surface (i.e. inside of mouth or nose), or damaged skin (open sores, wound, irritation, sun burn ).
5. Avoid application of the patch to bony areas, such as the point of shoulder and the upper hip or on a part of the body that could be subjected to prolonged pressure during sleep or sitting. Application to these sites has been associated with burn-like blisters. Skin areas which are oily, perspire intensely or are covered with hair may interfere with adhesion of the patches and should be avoided.
6. Change the patch every 24 hours. The new patch should never be applied to the places just used.
7. Rotate application sites regularly: to prevent irritation, do not reapply patches to a previously used area for at least 7 days. If you experience skin irritation talk to

your pharmacist or doctor.

8. **Maintain normal activities:** When applied to clean dry skin, the patch will remain in place during normal activities. Currently it is unknown how long showering or swimming should be delayed after application of Androderm. Androderm® does not have to be removed during sexual intercourse. Androderm® does not have to be removed while bathing.
9. **What to do if the patches falls off:** If a patch falls off, do not replace it until the night time application (when a new site should be chosen). If a patch becomes loose, smooth it down again by rubbing over the perimeter of the patch.
10. **What to do if Androderm gets in the eye:** if you get Androderm in your eyes, rinse your eyes right away with warm, clean water to flush out any Androderm. Call your doctor if discomfort persists.
11. **What to do if you miss a dose of Androderm®:** if you miss a dose, do not double your next dose the next day to catch up. Resume your normal dosing the next day.

Androderm® should be used with caution by men with previous history of photosensitivity or hypersensitivity to topically applied medications, and by those individuals who have been sun burnt in the area of the proposed application site within three weeks prior to the initiation of treatment.

**How to apply the patch**

After choosing an application site according to the above recommendations, apply Androderm® patch as follows:

1. **Open the Pouch:** Open the pouch containing the Androderm® patch by tearing along the edge (Figure 1). Remove the patch from the pouch.

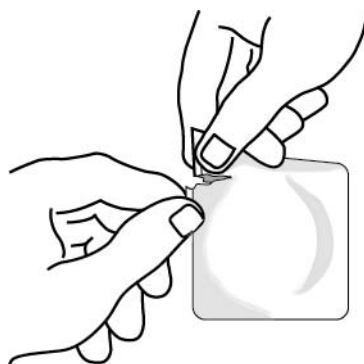


Figure 1

2. **Prepare the Patch for Application:** Grasp the tabs on the patch and protective plastic liner (Figure 2). While firmly holding the clear plastic liner, gently pull open, exposing the adhesive and central reservoir area (Figure 3). Discard the liner.

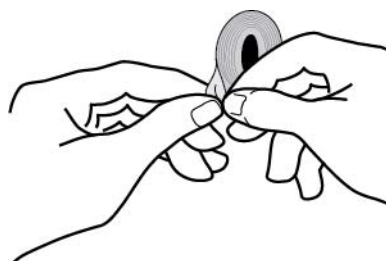


Figure 2

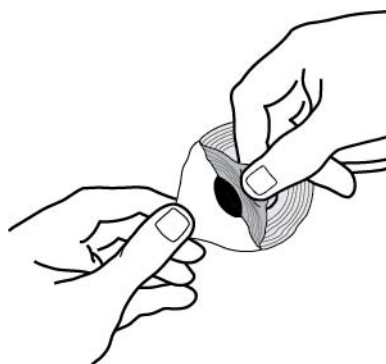
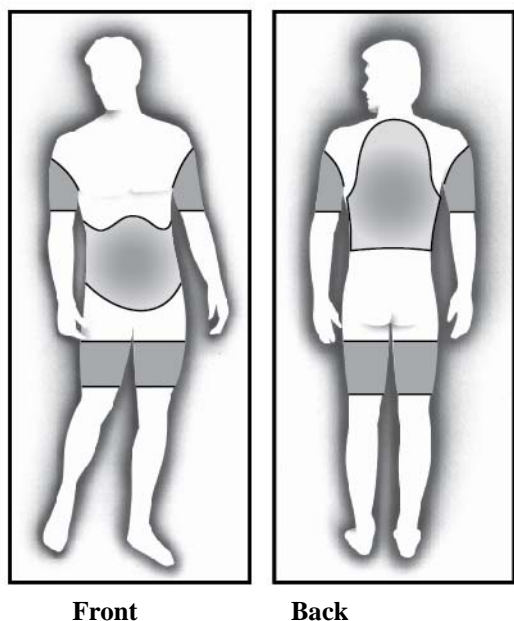


Figure 3

3. **Apply the Patch:** Place the patch on the skin and firmly press around the edges to insure that the patch adheres to the skin. The patch must lie flat against the skin to insure proper testosterone absorption. The best areas to apply patches are: the back, abdomen, thighs and upper arms (see Figure 4).

Figure 4



- loss of hair and baldness;
- high blood pressure
- weight gain;
- headache, dizziness.

Please talk to your doctor if your female partner develops changes in hair distribution, increases in acne, or signs of masculinity.

**Overdose:**

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

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

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

- Increased or irregular heart rate, blood clot in the lungs or the legs
- 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;

**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) |                                     | √            |   |
| Uncommon (after prolonged use) | Breast enlargement or breast pain   |                                     | √            |   |
| Uncommon                       | Heart attack and stroke   |                                     |              | √   |
| Uncommon                       | Swelling of ankles and legs (in patients with heart, kidney or liver damage)  |                                     |              | √   |
| Uncommon                       | Erections that are too frequent or continue for too long, or are painful.   |                                     | √            |   |
| Uncommon                       | Liver problems, with symptoms such as nausea, vomiting, along with yellowed or darkened skin                            |                                     |              | √   |

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

**HOW TO STORE IT**

Store Androderm® at room temperature (15°C-30°C).

Keep in a safe place out of reach of children and pets.

**REPORTING SUSPECTED SIDE EFFECTS**

**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](http://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, Ontario  
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](http://www.healthcanada.gc.ca/medeffect).**

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

**MORE INFORMATION**

This document plus the full product monograph, prepared for health professionals can be found at [www.allergan.ca](http://www.allergan.ca) or by contacting Allergan Inc. at 1-800-668-6424.

This leaflet was prepared by:  
Allergan Inc.  
Markham, Ontario L6G 0B5  
CANADA

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