

200248-09

How to Use ANDRODERM® Testosterone Transdermal System



Revised: November 2005

Rx only





The **Androderm** patch delivers testosterone to your body through your skin. Androderm is prescribed for men whose bodies do not produce enough testosterone, a condition known as testosterone deficiency. The center of each Androderm patch contains a testosterone gel. The edges of the patch are coated with adhesive to hold the patch in place on your skin. The round patch contains 12.2 mg of testosterone which delivers approximately 2.5 mg of testosterone over a 24-hour period. The oval patch contains 24.3 mg of testosterone which delivers approximately 5 mg of testosterone over a 24-hour period. The testosterone in the patch is delivered through the skin into your bloodstream. The testosterone delivered by Androderm is the same as the testosterone produced by the male genital organs (the testes). The patches should be applied to healthy, normal skin (see recommendations below).

If you have any questions about using **Androderm**, talk with your doctor. Make sure you understand why you are using it; discuss precautions or warnings regarding treatment and side effects that may occur during treatment. For additional information you may call the **Androderm** Information Line at (800) 454-2436.

PRECAUTIONS

Androderm must not be used by women, or by those with known hypersensitivity to any of the patch components.

Be sure to tell your doctor if you have had any of the following:

- Carcinoma of the breast (breast cancer)
- · Carcinoma of the prostate (prostate cancer)
- · Suspected prostate cancer
- · Heart disease
- · Kidney disease
- · Liver disease

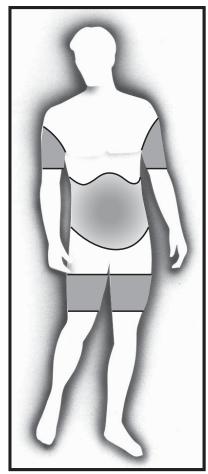
After using **Androderm**, be sure to tell your doctor if you experience:

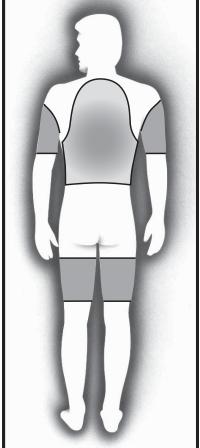
- · Too frequent or persistent erections
- · Nausea, vomiting, jaundice or ankle swelling

Mild redness of the skin under the patches when they are removed is common. However, you should tell your doctor about excessive irritation at the sites of application and about any other side effects you may have. Read the package insert for more information.

Skin burns have been reported at the patch site in several patients wearing an aluminized transdermal system during a magnetic resonance imaging scan (MRI). Because *Androderm* contains aluminum, it is recommended to remove the system before undergoing an MRI.

Apply Androderm patches only within shaded areas





FRONT

BACK

The usual starting dose is one *Androderm* 5 mg/day (oval) or two *Androderm* 2.5 mg/day (round) patches applied each evening.

It is important that you read and follow these directions on how to use *Androderm* properly.

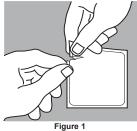
How to Use Androderm (Testosterone Transdermal System)

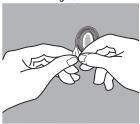
- Apply Androderm at the Same Time Every Evening:
 Unless your doctor tells you to use fewer or more patches, you should apply one (1) new Androderm 5 mg patch or two (2) new Androderm 2.5 mg patches every evening.
 This delivers approximately 5 milligrams of testosterone per day into the body, about the same amount of testosterone normally produced in men.
- 2. Apply Androderm Each Evening, Between 8:00 p.m. and Midnight: This results in a daily cycle of testosterone levels similar to the pattern in healthy young men with normal levels of testosterone.
- Replace Every 24 Hours: Remove the Androderm
 patch(es) after 24 hours and apply new patch(es).
 Although gel remains in the patch, new patch(es) are
 required each day to maintain normal testosterone levels.
- Only Apply Androderm to Your Back, Abdomen, Thighs or Upper Arms: This way your body will absorb the correct amount of testosterone (see diagram).
- 5. Apply Androderm to Clean and Dry Areas: Choose areas of the body where the patch will remain flat against the skin without excessive stretching or folding as you go about your normal activities. Avoid areas of skin that are oily, perspire heavily, or are covered with hair, since the patch may not stick tightly to these areas.
- Never Apply a Patch to Your Genitals (Scrotum), or to Damaged Skin: Apply Androderm only to healthy, normal skin. Never apply a patch to your genitals (scrotum), or onto skin areas with open sores, wounds or irritation.
- 7. Avoid Application over Bony Areas: Applying Androderm to bony areas, such as the upper shoulder and the upper hip, or on a part of the body that could be subject to prolonged pressure during sleep or sitting may cause burn-like blisters to form under the patch.
- 8. To Help Prevent Skin Irritation, Change Application Sites Regularly: When you remove a patch, do not put another patch back on that same spot for at least a week. If you experience mild skin irritation, it may be relieved with over-the-counter topical hydrocortisone cream, which your pharmacist can recommend. If you experience persistent irritation, please consult your doctor regarding additional treatment options.
- 9. Maintain Normal Activities: A patch applied to clean, dry skin will remain in place during normal activities. Androderm may be worn during sex. Also, contact with water, such as showering or swimming, will not affect the patch. Strenuous exercise or excessive perspiration may loosen a patch or cause it to fall off.
- 10. What to Do if a Patch Becomes Loose, or Falls Off: If the patch becomes loose, smooth it down again by rubbing your finger firmly around the edges. If a patch falls off before noon, replace it with a fresh patch and wear it until you apply fresh patch(es) that evening. If it falls off later in the day, do not replace it until you apply fresh patches that evening.

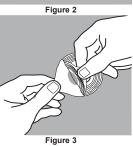
How to Apply Androderm

Choose a skin location following the directions above, and then apply the number of *Androderm* patches your doctor prescribed, following these directions.

- Open the pouch. Open the foil pouch containing the Androderm patch by tearing along the edge (Figure 1). Remove the patch from the pouch.
- 2. Remove the protective liner and silver disc from the patch. Grasp the tabs on the patch and on the protective plastic liner (Figure 2). While firmly holding the tabs, gently pull the two apart, to remove the liner and silver disc from the patch. This will expose the adhesive and central reservoir area on the patch (Figure 3). Discard the clear plastic liner and silver disc.
- 3. Apply the patch. Place the patch on the skin and firmly press around the edges to ensure that the patch sticks to the skin. The patch must lie flat against the skin, with sticky side down, to ensure proper absorption of the testosterone.







Storage and Disposal of Androderm

Store **Androderm** (Testosterone Transdermal System) patches at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) in their sealed pouches until use. Apply each patch immediately after removing it from the protective pouch. The reservoir containing the gel may be burst under excessive pressure or heat. Do not use damaged patches. Discard used or damaged patches in household trash in a manner that prevents accidental application to or ingestion by any pet, child, or other person.

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U.S. Patent Nos. 4,849,224, 4,855,294, 4,863,970, 4,983,395, 5,152,997, and 5,164,190



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