

ANDRODERM®

Testosterone (tes-TOS-te-rone)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some of the common questions about Androderm®. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the possible risks of you using Androderm® against the benefits they expect it will have for you.

If you have any concerns about using this medicine talk to your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Androderm® is used for

Androderm® is used to replace testosterone in males when the body is unable to produce enough of its own. Testosterone is a hormone that is necessary for the normal development and

maintenance of male reproductive tissues and other characteristic male traits.

Androderm[®] is a testosterone transdermal delivery patch. This means that when the patch is applied to the skin, the testosterone passes from the patch, through the skin and into the bloodstream.

The testosterone in Androderm[®] is identical to the naturally occurring testosterone present in the body.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

This medicine is not expected to affect your ability to drive a car or operate machinery.

There is not enough information to recommend the use of this medicine for children below the age of 15 years.

Before you use Androderm[®]

When you must not use it

Do not use Androderm[®] if you have an allergy to:

- any medicine containing testosterone

- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not use this medicine if you are female.

Do not use this medicine if you have any of the following medical conditions:

- known or suspected prostatic cancer (testosterone and other male hormones can speed up the growth of tumours of the prostate)
- cancer of the breast
- kidney disease (with protein in the urine)
- high levels of calcium in the blood.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- high blood pressure
- epilepsy
- migraines
- heart disease
- kidney or liver diseases
- an enlarged prostate gland (signs may include difficulty passing urine or frequent passing of urine)
- a tendency to retain fluid (signs may include swollen feet or ankles).

If you have not told your doctor about any of the above, tell him/her before you start using Androderm®.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Androderm[®] may interfere with each other. These include:

- medicines used to prevent blood clots, such as warfarin, or other anticoagulants
- medicines used to control blood sugar, such as insulin.

These medicines may be affected by Androderm[®] or may affect how well it works. You may need different amounts of your medicines, or you may need to use different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

How to use Androderm[®]

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to apply

The number of patches used may be different for different people. Usually one Androderm[®] 5 mg/day Transdermal Patch, or two Androderm[®] 2.5 mg/day Transdermal Patches, are applied to the skin once a day (if two Androderm[®] 2.5 mg/day Transdermal Patches are used, they should not overlap

one another). This will provide your body with approximately 5 milligrams of testosterone per day.

When to apply it

Apply Androderm® late in the evening (at approximately 10.00 pm).

It is important to apply Androderm® in the evening, as this will provide your body with testosterone levels similar to those normally produced in the body.

Where to apply it

Always apply Androderm® to clean dry flat areas of skin.

The best areas to use are the back, stomach, thighs and upper arms. The patch may not stick properly if applied to oily or hairy areas. If the skin is very hairy, the hair can be clipped (not shaved) so that the patch sticks well.

Never apply the patch to an area of skin that has sores, cuts or rashes.

Never apply the patch to the scrotum.

Avoid applying the patch to bony areas such as the point of the hip or shoulder.

Application here can cause skin blisters.

Avoid applying the patch to the chest or shins.

Application here may result in absorption of less testosterone.

Every day, remove the old patch and apply the new patch to a new area of skin. Avoid using the same skin site for at least seven days to reduce the risk of skin irritation.

How to apply it

Remove a pouch from the box and tear it open. Remove the patch from the pouch.

Hold the tabs on the patch and, whilst firmly holding the liner tab, gently peel the patch open.

Discard the liner.

Place the sticky side of the patch against the skin and press firmly around the edges so that the patch lies flat against the skin.

If a patch falls off before mid-day, replace it with a new patch on the same skin site. If the patch falls off later in the day do not replace it until the night time application (choose a new skin site). If a patch becomes loose, smooth it down and press your fingers around the edge of the patch.

When you take an old patch off, dispose of it by folding it in half with the sticky side inwards.

Dispose of it carefully in the household waste where children cannot reach it.

Even a used patch will still contain some medicine.

If you miss a dose

If you forget to apply Androderm[®] in the evening, apply it as soon as you remember, providing this is before 12 noon the following day. Otherwise do not apply it until your next evening application time. Then carry on as usual.

If you use too much (overdose)

Remove the patches and immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26 in Australia, or call 0800 764 766 in New Zealand) for advice, or go to Accident and Emergency at your nearest hospital, If you think that you or anyone else may have used too much Androderm[®]. Do this even if there are no signs of discomfort or poisoning.

While you are using Androderm[®]

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist you are using Androderm[®].

If you are undergoing an MRI scan, tell your doctor you are using Androderm[®].

Skin burns have been reported at the patch site in several patients wearing aluminised transdermal patches during a magnetic resonance imaging scan (MRI). Because Androderm[®] contains aluminium, it is recommended that you remove the patch before undergoing MRI.

Tell any other doctors, dentists and pharmacists who treat you that you are using this medicine.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor will conduct regular examinations of your prostate gland during treatment with this medicine to detect unwanted side effects. Your doctor may also measure the level of testosterone in your blood to make sure the medicine is working.

Things you must not do

Do not use Androderm[®] to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not use the patch if it is damaged.

Things to be careful of

When applied to clean dry skin, the patch is expected to remain in place during normal activities. Contact with water such as showering or swimming, should not affect the patch. Strenuous exercise or excessive perspiration may loosen the patch or cause it to fall off.

Do not heat the patch or press the reservoir too hard.

The patch may burst if it is handled incorrectly.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Androderm®.

This medicine helps most males with low testosterone levels, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- skin irritation, for example rash or slight redness and itching of the skin where the patch has been. Mild skin irritation usually disappears within 3 to 4 days after removal of the patch. If skin irritation persists, your doctor or pharmacist may be able to help
- acne where the patch has been
- loss of head hair (male pattern baldness)

- headache, confusion, tiredness, body pain
- nausea, increased appetite
- numbness, tingling or pins and needles
- frequent or persistent erections, increased or decreased sex drive.

These side effects are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- more severe skin reactions such as blistering or contact dermatitis. This is a sign of allergy and your doctor may decide not to continue the use of Androderm®
- swollen feet or ankles due to fluid retention
- difficulty in passing urine, frequent passing of urine, loss of bladder control or blood in the urine
- depressed mood, thinking abnormalities, anxiety.

The above list includes serious side effects which may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- blood in the bowel motions (black tarry stools).

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people. Some of these side effects (for example a reduction in the number of sperm produced or high blood pressure) can only be found when your doctor does tests from time to time to check your progress.

After using Androderm®

Storage

Keep the patches in the original pack until it is time to use them.

If you take the patches out of the pouch they will not keep well.

Keep the pack in a cool dry place where the temperature stays below 25°C.

Do not store Androderm® or any other medicine in the bathroom or near a sink.

Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any patches that are left over.

Dispose of used or damaged patches in the household garbage in a way that stops any pet, child, or other person from accidentally applying or swallowing them.

Product description

What it looks like

Androderm[®] 2.5 mg/day Transdermal Patches are round, skin-toned patches with distinct concentric heat sealed rings.

Androderm[®] 5 mg/day Transdermal Patches are elliptical ("egg-shaped") skin-toned patches with distinct heat sealed rings. (Available in Australia only)

Each Androderm[®] patch is packaged in a heat sealed pouch.

Ingredients

Each Androderm[®] 2.5 mg/day Transdermal Patch contains 12.2 milligrams of testosterone and delivers 2.5 milligrams of testosterone over 24 hours.

It is available in packs of 60 patches.

Each Androderm® 5 mg/day Transdermal Patch contains 24.3 milligrams of testosterone and delivers approximately 5 milligrams of testosterone over 24 hours.

It is available in packs of 30 patches.

Other ingredients in the gel reservoir include:

- ethanol,
- purified water,
- glycerol,
- glycerol monooleate,
- methyl laurate,
- carbomer copolymer (type B), and sodium hydroxide.

The adhesive substance is laminate AR-7584.

Sponsor

Australian Sponsor:

Teva Pharma Australia Pty Limited

Level 1, 37 Epping Rd

Macquarie Park, NSW, 2113

New Zealand Sponsor:

Teva Pharma New Zealand Limited

Auckland, 1024

Australian Registration Numbers:

2.5 mg - AUST R 61818

5 mg - AUST R 82398

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