

AXIRON®

testosterone

Consumer Medicine Information

What is in this leaflet

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

For detailed instructions on the use of AXIRON, please read the Applicator Instructions for Use leaflet located inside the pack, prior to using AXIRON.

The information in this leaflet was last updated on the date shown on the final page. More recent information on this medicine may be available. Make sure you speak to your pharmacist, nurse or doctor to obtain the most up to date information on this medicine. You can also download the most up to date leaflet from www.lilly.com.au. The updated leaflet may contain important information about AXIRON and its use that you should be aware of.

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

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Axiron is used for

AXIRON is used to replace the body's natural hormone testosterone when not enough is made by the body.

Testosterone is a natural male hormone, known as an androgen, which controls normal sexual development in men.

Testosterone is essential for the development and maintenance of the male reproductive organs as well as other male characteristics, such as deep voice, increased muscle strength, hair growth etc.

AXIRON is a testosterone containing solution that is applied daily to the armpit(s). The testosterone passes through the skin and into the bloodstream.

The testosterone in AXIRON is identical to the naturally occurring testosterone present in the body.

A doctor's prescription is required to obtain this medicine.

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

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

Before you use Axiron

Before beginning therapy and each time you get a new pack, you should read the Applicator Instructions for Use leaflet located inside the pack,

When you must not use it

Do not use AXIRON if you have an allergy to:

- testosterone, the active ingredient in AXIRON
- any of the ingredients listed at the end of this leaflet.

Some of the 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 AXIRON if you have or are suspected to have:

- prostate cancer
- breast cancer (a rare condition in men)

Only men should use AXIRON.

AXIRON must not be used by children.

The safety of AXIRON in children under 18 years of age has not been established.

AXIRON must not be used by women, particularly if they are or anticipate becoming pregnant.

AXIRON may cause harm to the unborn child when administered to a pregnant woman. AXIRON may cause serious reactions in nursing infants. Pregnant women must avoid any contact with the AXIRON treated skin.

Do not use this medicine after the expiry date printed on the carton and bottle.

The expiry date is printed on the carton and bottle after "Exp" (e.g. 11 09 refers to November 2009). The expiry date refers to the last day of that month.

If it has expired return it to your pharmacist for disposal.

Do not take this medicine if the packaging is torn or if the seals over the carton ends are missing or broken. If the packaging is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking 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
- heart, liver or kidney disease
- epilepsy (fits)
- migraines
- diabetes
- bone cancer
- breathing problems during your sleep
- difficulty in passing water (urinating) due to an enlarged prostate gland

Before treatment with AXIRON your doctor will need to check that you do not have prostate or breast cancer.

AXIRON may increase the risk of benign prostatic hypertrophy (enlargement of the prostate gland) and/or prostate cancer. During treatment, your doctor may monitor the effects of this medicine.

Worsening of breathing problems during sleep (obstructive sleep apnoea) has been reported during treatment with testosterone replacement in predisposed people. This is especially true in overweight people or people with lung problems.

People using testosterone replacement over long periods of time may develop polycythaemia (an abnormal increase in the number of red blood cells in the blood). Your doctor may organise regular blood tests to check this is not happening.

Sportsmen

Athletes should note that the active substance, testosterone, may produce a positive reaction in anti-doping tests.

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

Taking other medicines

Tell your doctor 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 AXIRON may interfere with each other. These include:

- oral anticoagulants (blood thinning medications to treat or prevent blood clots)
- Medicines for diabetes (including insulin)
- corticosteroids

These medicines may be affected by AXIRON or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine. Your doctor will advise you.

How to use Axiron

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

Prior to using Axiron, you should read the Applicator Instructions for Use leaflet located inside the pack.

If you do not understand the instructions printed on the pharmacist label or in the Applicator Instructions for Use leaflet, ask your doctor or pharmacist for help.

How much to use

The usual starting dose is 60 mg every day, but your doctor may adjust the dose down to 30 mg per day or up to 120 mg per day.

How to use it

Use AXIRON exactly as your doctor tells you to use it. Your doctor will tell you the dose of AXIRON that is right for you. Apply your dose correctly by following the Applicator Instructions for Use leaflet inside the pack.

AXIRON is for use by adult men only.

AXIRON is to be applied to the armpits only.

Do not apply AXIRON to any other parts of your body such as your stomach area (abdomen), penis, scrotum, shoulders or upper arms.

Before applying AXIRON, make sure that your armpit is clean, dry and that there is no broken skin.

If you use a deodorant or antiperspirant apply it at least 2 minutes before applying AXIRON.

For a stick or roll-on product, this will help avoid contamination.

Apply AXIRON to the skin of the armpit using the applicator provided.

Do not apply AXIRON with your hands. The applicator is provided so you avoid getting AXIRON on your fingers or hands.

Hands should be washed well with soap and water after AXIRON has been applied.

AXIRON is flammable until dry. Let AXIRON dry before smoking or going near an open flame.

As soon as AXIRON has dried you should cover the armpit area with a shirt or similar.

Avoid swimming or bathing for at least two (2) hours after applying AXIRON.

When to use it

Apply AXIRON once per day at approximately the same time each day as part of your normal daily routine.

Using it at the same time each day helps maintain a steady level of testosterone in the blood. It will also help you remember when to apply it.

How long to use it

AXIRON helps control the symptoms of your condition, but does not cure it. Therefore you must use AXIRON every day. Continue using AXIRON for as long as your doctor tells you to.

If you forget to use it

Do not apply a double dose to make up for a missed dose.

If your next dose is less than 12 hours away, do not apply the missed dose, but continue with your next dose as normal.

If it is more than 12 hours until your next dose, apply the dose that you have missed.

Continue as normal the following day.

If you use too much (overdose)

Wash the skin with soap and water. Immediately telephone your doctor or the Poisons Information Centre on 13 11 26 for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have used too much AXIRON. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using Axiron

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using AXIRON.

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

Things you must not do

Do not use AXIRON to treat any other complaints unless your doctor tells you to.

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

Do not stop using AXIRON, or change the dosage, without checking first with your doctor.

Things to be careful of

AXIRON can transfer from your body to others. This can happen if other people come into contact with the area where AXIRON was applied.

If you expect another person to have direct skin-to-skin contact with your armpits, first wash the application area well with soap and water.

Unwanted transfer of testosterone to another person can be substantially reduced by wearing a shirt or similar.

Women and children should avoid contact with the unwashed or unclothed area where AXIRON has been applied. If your partner is pregnant, it is extra important that you take care to protect her from testosterone. If a woman or child makes contact with the application area, the contact area on the woman or child should be washed well with soap and water right away.

Call your doctor right away if you see any signs in a child or a woman that may have occurred through accidental exposure to AXIRON.

Signs of increased testosterone in children include enlarged penis or clitoris, early development of pubic hair, increased erections or sex drive, aggressive behaviour. In women, this may include changes in body hair and a large increase in acne.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using AXIRON. Ask your doctor or pharmacist to answer any questions you may have.

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.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

Very common side effects

- Mild forms of skin irritation at the application site (these often disappear over time by themselves)

Common side effects

- Headache
- Migraine
- Dizziness
- Acne and other skin conditions
- Nausea and vomiting
- Diarrhoea
- Increased blood pressure
- Difficulty sleeping
- Mood swings
- Anger
- Anxiety
- Increased blood cholesterol

- Increased haematocrit (percentage of red blood cells in the blood), haemoglobin and red blood cell count
- Changes in the levels of blood glucose
- Increased Prostate Specific Antigen (PSA). PSA is a protein produced by the prostate, which can be used to detect prostate disease

You should also tell your doctor if you have severe skin reactions when using AXIRON.

Sperm production may be reduced when using testosterone replacement.

The following side effects that have been observed during treatment with testosterone products can sometimes be serious. These may also occur with AXIRON. You may need urgent medical attention.

- Prostatic and urinary disorders
- Painful long-lasting erections
- Fluid retention and swelling
- Shortness of breath or problems breathing during sleep
- Blood clots
- Increased risk of prostate cancer

Other side effects not listed above may also occur in some patients.

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

After using Axiron

Storage

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

Do not store it or any other medicine in the bathroom, near a sink, or on a window-sill. Do not leave it in the car.

Heat and damp 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 taking this medicine or the expiry date has passed, return any unused medicine to your pharmacist

Product description

What it looks like

AXIRON is the brand name for a 2% w/v testosterone solution presented in a 110 mL pump bottle.

Ingredients

Active ingredient:

- 2% w/v testosterone

Inactive ingredients:

- isopropyl alcohol
- ethanol
- octyl salicylate
- povidone

Supplier

Eli Lilly Australia Pty Limited
112 Wharf Road
West Ryde, NSW, 2114
AUSTRALIA

AXIRON is distributed in New Zealand by:

Eli Lilly and Company (NZ) Limited
Level 3, Axon House
414-422 Khyber Pass Road,
Newmarket
PO Box 109 197, Newmarket
Auckland
NEW ZEALAND

® = Registered Trademark

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