

Medication Guide

AXIRON[®] (AXE-e-RON) CIII (testosterone) topical solution

Read this Medication Guide before you start using AXIRON and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your medical condition or treatment.

What is the most important information I should know about AXIRON?

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

Signs of puberty that are not expected (for example, pubic hair) have happened in young children who were accidentally exposed to testosterone through skin to skin contact with men using topical testosterone products like AXIRON.

- **Women and children should avoid contact with the unwashed or unclothed area where AXIRON has been applied. 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.**
- To lower the risk of transfer of AXIRON from your body to others, you should follow these important instructions:
 - Apply AXIRON **only** to your armpits.
 - Wash your hands **right away** with soap and water after applying AXIRON.
 - After the solution has dried, **cover the application area with clothing**. Keep the area covered until you have washed the application area well or have showered.
 - **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.**

Stop using AXIRON and call your healthcare provider right away if you see any signs and symptoms in a child or a woman that may have occurred through accidental exposure to AXIRON:

Signs and symptoms in **children** may include:

- enlarged penis or clitoris
- early development of pubic hair
- increased erections or sex drive
- aggressive behavior

Signs and symptoms in **women** may include:

- changes in body hair
- a large increase in acne

What is AXIRON?

AXIRON is a prescription medicine that contains testosterone. AXIRON is used to treat adult males who have low or no testosterone due to certain medical conditions.

Your healthcare provider will test your blood before you start and while you are taking AXIRON.

It is not known if AXIRON is safe or effective to treat men who have low testosterone due to aging.

It is not known if AXIRON is safe and effective in children younger than 18 years old. Improper use of AXIRON may affect bone growth in children.

AXIRON is a controlled substance (CIII) because it contains testosterone that can be a target for people who abuse prescription medicines. Keep your AXIRON in a safe place to protect it. Never give AXIRON to anyone else, even if they have the same symptoms you have. Selling or giving away this medicine may harm others and it is against the law.

AXIRON is not meant for use in women.

Who should not use AXIRON?

Do not use AXIRON if you:

- have breast cancer
- have or might have prostate cancer
- are pregnant or may become pregnant or are breast-feeding. AXIRON may harm your unborn or breast-feeding baby.

Women who are pregnant or who may become pregnant should avoid contact with the area of skin where AXIRON has been applied.

Talk to your healthcare provider before taking this medicine if you have any of the above conditions.

What should I tell my healthcare provider before using AXIRON?

Before you use AXIRON, tell your healthcare provider if you:

- have breast cancer
- have or might have prostate cancer
- have urinary problems due to an enlarged prostate
- have heart problems
- have kidney or liver problems
- have problems breathing while you sleep (sleep apnea)
- have any other medical conditions

Tell your healthcare provider about all of the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Using AXIRON with other medicines can affect each other.

Especially tell your healthcare provider if you take:

- insulin
- medicines that decrease blood clotting
- corticosteroids

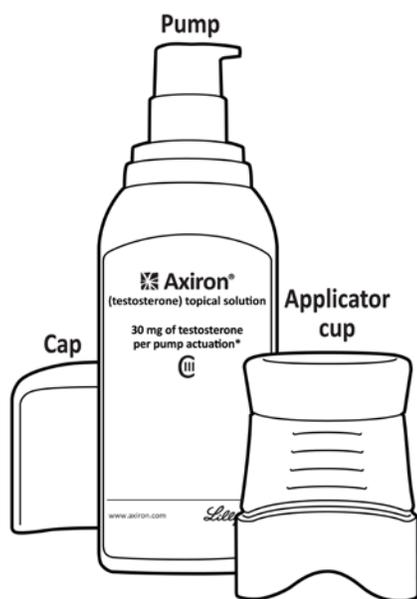
Know the medicines you take. Ask your healthcare provider or pharmacist for a list of all of your medicines if you are not sure. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

How should I use AXIRON?

- It is important that you apply AXIRON exactly as your healthcare provider tells you to.

- Your healthcare provider will tell you how much AXIRON to apply and when to apply it.
- Your healthcare provider may change your AXIRON dose. Do not change your AXIRON dose without talking to your healthcare provider.
- **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.
- Do not apply AXIRON with your fingers or hands.
- Apply AXIRON at about the same time each morning. AXIRON should be applied after showering or bathing.
- Avoid swimming or bathing for at least 2 hours after you apply AXIRON.
- You can use an antiperspirant or deodorant before applying AXIRON. If you use antiperspirant or deodorant, then it should be applied at least 2 minutes before you apply AXIRON.
- **AXIRON is flammable until dry. Let AXIRON dry before smoking or going near an open flame.**
- **Avoid splashing in the eyes. In case of contact with eyes, flush thoroughly with water. If irritation persists, seek medical advice.**

Applying Axiron



AXIRON
Figure 1

- Before using a new bottle of AXIRON for the first time, you will need to prime the pump. To prime the AXIRON pump gently push down on the pump 3 times. Do not use any AXIRON that came out while priming. Wash it down the sink to avoid accidental exposure to others. Your AXIRON pump is now ready to use.
- **Use AXIRON exactly as your healthcare provider tells you to use it.** Your healthcare provider will tell you the dose of AXIRON that is right for you. Apply your dose correctly by following the application instructions in the table below.

Find Your Dose as Prescribed by Your Doctor	Each application equals 1 depression of the pump.
30 mg	Apply 1 application once to one armpit only (left OR right).
60 mg	Apply 2 applications: one to the left armpit and then one to the right armpit.
90 mg	Apply 3 applications: one to the left and one to the right armpit, wait for the product to dry, and then apply again one to the left OR right armpit.

120 mg	Apply 4 applications: one to the left and one to the right armpit, wait for the product to dry, and then apply again one to the left AND one to the right armpit.
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- Before applying AXIRON, make sure that your armpit is clean, dry and that there is no broken skin.



Figure 2

- Remove the cap and the applicator cup from the pump. Then, position the nozzle over the applicator cup and depress the pump gently (see Figure 2).



Figure 3

- To apply the AXIRON solution, keep the applicator upright, place it up into the armpit application site and wipe steadily down and up (see Figure 3).
- If AXIRON drips or runs, wipe it back up with the applicator cup. Do not rub in the solution with your fingers or hand once it has been applied.

- Let the application site dry completely before putting on a shirt.
- After you have finished applying AXIRON, rinse the applicator cup with room temperature running water, and then pat it dry with a tissue. Carefully replace the applicator cup and cap back onto the bottle and make sure you store the bottle safely.
- Clean up any spilled solution from surfaces such as the sink or floor to make sure others do not come into contact with it.
- **Wash your hands with soap and water right away.**

What are the possible side effects of AXIRON?

See also “What is the most important information I should know about AXIRON?”

AXIRON can cause serious side effects including:

- If you already have enlargement of your prostate gland your signs and symptoms can get worse while using AXIRON. This can include:
 - increased urination at night
 - trouble starting your urine stream
 - having to pass urine many times during the day
 - having an urge that you have to go to the bathroom right away
 - having a urine accident

- being unable to pass urine or weak urine flow
- **Possible increased risk of prostate cancer.** Your healthcare provider should check you for prostate cancer or any other prostate problems before you start and while you use AXIRON.
- **Blood clots in the legs or lungs.** Signs and symptoms of a blood clot in your leg can include leg pain, swelling or redness. Signs and symptoms of a blood clot in your lungs can include difficulty breathing or chest pain.
- **Possible increased risk of heart attack or stroke.**
- **In large doses AXIRON may lower your sperm count.**
- **Swelling of your ankles, feet, or body.**
- **Enlarged or painful breasts.**
- **Problems breathing while you sleep (sleep apnea).**

Call your healthcare provider right away if you have any of the serious side effects listed above.

The most common side effects of AXIRON include:

- skin redness or irritation where AXIRON is applied
- increased red blood cell count
- headache
- diarrhea
- vomiting
- increase in blood level of Prostate Specific Antigen (a test used to screen for prostate cancer)

Other side effects include more erections than are normal for you or erections that last a long time.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of AXIRON. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store AXIRON?

Store AXIRON at 15°C to 30°C (59°F to 86°F)

When it is time to throw away the bottle, safely throw away all parts of the AXIRON dispenser including bottle applicator cup and cap. Be careful to prevent accidental exposure of children or pets.

Keep AXIRON away from fire.

General information about AXIRON

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use AXIRON for a condition for which it was not prescribed. Do not give AXIRON to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about AXIRON. If you would like more information, talk to your healthcare provider. You can ask your pharmacist or healthcare provider for information about AXIRON that is written for health professionals.

For more information, go to www.axiron.com or call 1-800-545-5979.

What are the ingredients in AXIRON?

Active ingredient: testosterone.

Inactive ingredients: ethanol, isopropyl alcohol, octisalate, and povidone.

The bottle and the applicator cup are not made with natural rubber latex.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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