About AXIRON (testosterone) topical solution

Applying AXIRON

AXIRON should be applied to the underarm without rubbing into the skin with fingers or hands

AXIRON Application Video

Before you get started

- The first time you use a new bottle, prime it by pumping 3 times into the sink or toilet. Do not use any of the liquid that came out when you primed, and rinse or flush away to avoid exposure to others
- Apply deodorant or antiperspirant at least 2 minutes before applying AXIRON to keep it from getting on your deodorant
- Apply AXIRON at about the same time each morning

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 treated area for 24 hours after 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, 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 well or have someone wash it, starting a little above your underarm and ending a little below your underarm, swipe down and up. Your doctor will determine how many applications are right for you.**
- **Do not apply AXIRON with your fingers or hand, and do not rub in the solution with your fingers or hand once it has been applied.**
- **If AXIRON drips or runs, wipe it back up with the applicator cup**
- **Wash hands right away with soap and water. Store AXIRON safely out of the reach of children.**
- **Rinse the applicator cup with warm running water, pat it dry with a tissue, and discard the tissue safely. Clean up any spilled solution from sink or floor to prevent others from coming into contact with AXIRON.**
- **Cover your underarms with clothing and keep covered to avoid skin-to-skin contact with others until you've washed the application area or showered.**

**What should I tell my healthcare provider before using AXIRON?**

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

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

Tell your healthcare provider about all 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

**What are the possible side effects of AXIRON?**

Controlled substance

AXIRON is a controlled substance (CIII) because it contains testosterone, which can be a target for people who abuse prescription medicines. Keep your AXIRON in your sight and protect it from getting into the wrong hands. Use only the amount prescribed by your healthcare provider.

**Grooming considerations**

- Use deodorant or antiperspirant at least 2 minutes before applying AXIRON.
- **This is to help avoid the transfer of AXIRON onto the deodorant or antiperspirant.**
- **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.**
- **If you already have enlargement of your prostate gland, your signs and symptoms can get worse while using AXIRON.**
- **While this was not specifically studied in the AXIRON clinical trial, patients involved in the trial were not instructed to change their normal grooming routines or shave under their arms.**
- **You should apply AXIRON to clean, dry, and unbroken skin.**
- **Wait at least 2 hours after applying AXIRON before showering/bathing or swimming.**
- **Getting the area wet before this will remove most of the AXIRON you just applied.**

**Other important things to remember**

**What are the possible side effects of AXIRON?**

Controlled substance

AXIRON is a controlled substance (CIII) because it contains testosterone, which can be a target for people who abuse prescription medicines. Keep your AXIRON in your sight and protect it from getting into the wrong hands. Use only the amount prescribed by your healthcare provider.

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If they have the same symptoms you have. Selling or giving away this medicine may harm others and is against the law.

Contact with eyes
Throughout the application process, be careful to avoid splashing AXIRON in the eyes. In case of contact with eyes, flush thoroughly with water. If irritation persists, seek medical advice.

Flammability
Since AXIRON contains alcohol, it is flammable until dry. Always let it dry before smoking or going near an open flame.

In large doses AXIRON may lower your sperm count.

Know your testosterone (T) levels
• Enlarged or painful breasts
• Applying AXIRON daily can help keep your testosterone levels in the normal range

The most common adverse events include:
• Skin redness or irritation where AXIRON is applied, increased red blood cell count, headache, diarrhea, vomiting, and 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.
• Ask your doctor when to schedule a follow-up appointment to help monitor your results

AXIRON is available by prescription only

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Risk of Transfer

For more information, please see full Prescribing Information, including Boxed Warning regarding the risk of transfer to others, and Medication Guide.

Important Safety Information or considerations regarding the risk of transfer to others

AXIRON can transfer from your body to others. Women and children should avoid contact where AXIRON is applied as unexpected signs of puberty in children or changes in body hair or increased acne in women may occur. If contact is made, the contact area on the woman or child should be washed well with soap and water right away. To lower the risk of transfer, always follow these important instructions:

• Apply AXIRON only to your armpits
• Wash your hands right away with soap and water after applying AXIRON
About AXIRON (testosterone) topical solution

• After the solution has dried, cover the application area with clothing and keep 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 of puberty in a child, or changes in body hair or increased acne in a woman, that may have occurred through accidental exposure to AXIRON.

Dosing

Your doctor will prescribe the right dose for you

Use the chart below to make sure you’re properly applying your dose.

<table>
<thead>
<tr>
<th>DAILY DOSE</th>
<th>NUMBER OF PUMPS*</th>
<th>PUTTING IT ON</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 mg</td>
<td>1 each day</td>
<td>Swipe once on one underarm only (right OR left).</td>
</tr>
<tr>
<td>60 mg</td>
<td>2 each day</td>
<td>Swipe once on the left AND once on the right underarm.</td>
</tr>
<tr>
<td>90 mg</td>
<td>3 each day</td>
<td>Swipe once on the left AND once on the right underarm. Wait for AXIRON to dry. Then swipe again once on EITHER the right OR the left underarm.</td>
</tr>
<tr>
<td>120 mg</td>
<td>4 each day</td>
<td>Swipe once on the left AND once on the right underarm. Wait for AXIRON to dry. Then apply once again on the left AND once again on the right underarm.</td>
</tr>
</tbody>
</table>

*Pumps = applications.

Indication and Important Safety Information

Indication: AXIRON is used to treat adult males who have low or no testosterone due to certain medical conditions. It is not known if AXIRON is safe or effective to treat men who have low testosterone due to aging. AXIRON is not intended for use in women or anyone under 18 years of age. 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.

Important Safety Information for AXIRON (testosterone) topical solution

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, 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 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 and a large increase in acne.

Who should not use AXIRON?

Do not use AXIRON if you:
• have or might have prostate cancer
• have breast 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.

What should I tell my healthcare provider before using AXIRON?

Before you use AXIRON, tell your healthcare provider if you have:
• breast cancer
• or might have prostate cancer
• urinary problems due to an enlarged prostate
• heart problems
• kidney or liver problems
• problems breathing while you sleep (sleep apnea)
• any other medical conditions

Tell your healthcare provider about all 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

What are the possible side effects of AXIRON?

AXIRON can cause serious side effects. Call your healthcare provider right away if you have any of the following:
• 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 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).

The most common adverse events include: skin redness or irritation where AXIRON is applied, increased red blood cell count, headache, diarrhea, vomiting, and 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.

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

Axiron is available by prescription only

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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