



Axiron® (Testosterone) Topical Solution CIII Now Available in Pharmacies

Axiron is the first and only FDA-approved testosterone therapy applied to the underarm

INDIANAPOLIS, April 1, 2011 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that Axiron® (testosterone) topical solution is available in pharmacies throughout the United States. Axiron is a prescription medicine used to treat adult males that have low or no testosterone. Safety and efficacy of Axiron in males younger than 18 years of age have not been established.

The U.S. Food and Drug Administration (FDA) approved Axiron on November 23, 2010, making it the first and only testosterone replacement therapy applied to the underarm. Other forms of testosterone replacement therapies include: buccal tablets, subcutaneous pellets, transdermal patches, injections and topical gels.

"Currently, healthcare professionals and patients have access to topical testosterone treatment options that are applied to various areas of the skin. Axiron offers a new application method for patients to apply testosterone to the underarm using an applicator," said Dr. Ronald Swerdloff, clinical trial investigator, Los Angeles Biomedical Research Institute, and professor of medicine, University of California, Los Angeles, CA. "It is important to have different options available for treating low testosterone to help a patient select an option that's best for him."

Testosterone deficiency is a clinical condition in which the testicles, hypothalamus or pituitary gland is affected by disease or damage that results in inhibiting hormone secretion and testosterone production.(1) Testosterone deficiency also may be known as hypogonadism or low testosterone.

Axiron has been shown to restore testosterone levels to within the normal range in most men.(2) The most common side effects of Axiron are skin redness or irritation where Axiron is applied, increased red blood cell count, headache, diarrhea, vomiting and an increase in blood level of Prostate Specific Antigen (a test used to screen for prostate cancer).2

"Lilly has built a strong reputation in men's health by providing innovative treatment options to patients and physicians," said David Ricks, president, Lilly USA. "The addition of Axiron to our product portfolio allows us to build on that momentum and provide an innovative solution to patients who have a testosterone deficiency."

About Axiron (testosterone) topical solution CIII

Axiron is a prescription medication used to treat adult males who have low or no testosterone. 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 may affect bone growth in children.

Axiron contains testosterone, a Schedule III controlled substance as defined by the Anabolic Steroid Control Act of 2004 and can be a target for people who abuse prescription medicines. Patients should keep Axiron in a safe place to protect it. Never give it to anyone else, even if they have the same symptoms you have. Selling or giving away this medicine may harm others and is against the law.

Important Safety Information for AXIRON

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.
- 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).
- Blood clots in the legs. This can include pain, swelling or redness of your legs.

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.

You are encouraged to report negative side effects of Prescription drugs to the FDA. Visit <http://www.fda.gov/medwatch> or call 1-800-FDA-1088. For additional safety information, please see the medication guide, <http://pi.lilly.com/us/axiron-medguide.pdf>, for full Prescribing Information including Boxed Warning, <http://pi.lilly.com/us/axiron-pi.pdf>, or visit www.axiron.com for additional information.

About Eli Lilly and Company

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers — through medicines and information — for some of the world's most urgent medical needs. Additional information about Lilly is available at www.lilly.com.

This press release contains forward-looking statements about the potential of Axiron for replacement therapy in men for certain conditions associated with a deficiency or absence of testosterone, and reflects Lilly's current beliefs. Safety and efficacy of Axiron in males younger than 18 years of age have not been established. Axiron is not intended for use in women. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. There is no guarantee that the product will prove to be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's most recent Forms filed with the U.S. Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.

Axiron® is a registered trademark of Eli Lilly and Company.

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(1) Winters, S. Current Status of Testosterone Replacement in Men. Archives of Family Medicine. 1999;8:257-263. Available at <http://archfami.ama-assn.org/cgi/content/full/8/3/257>. Last accessed March 30, 2011.

(2) Axiron Prescribing Information. Last accessed March 30, 2011.

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