

Axiron® (testosterone) – First-time generic

- Perrigo and Prasco have received FDA approval for their generic versions of Eli Lilly's <u>Axiron</u> (testosterone) topical solution.
 - Perrigo's generic is AT-rated to brand Axiron. Prasco's product is an authorized generic.
- Axiron is indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone:
 - Primary hypogonadism (congenital or acquired): testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals.
 - Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation.
- U.S. annual <u>sales</u> for Axiron were approximately \$254 million for the 12 months ending in January 2017.
- The launch plans for Perrigo's and Prasco's generic Axiron are pending.



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