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## JOURNAL ARTICLE

# A ten-year safety study of the oral androgen testosterone undecanoate

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Testosterone undecanoate (Andriol) is an oral androgen that provides the hypogonadal patient with the unmodified testosterone molecule. It was introduced in the mid-1970s. This is a report on the safety of this oral androgen. Of 35 men originally included in the study, 33 could be followed up for a minimum of 10 years. In them no alteration in the biochemical parameters of liver function could be detected.

Upon annual measurements (7-9 hours after ingestion of testosterone undecanoate), serum levels of testosterone ranged between 5.4 +/- 1.9 and 6.5 +/- 1.9 nmol/L (normal range 8-24) and of 5 alpha-dihydrotestosterone between 3.2 +/- 1.8 and 3.5 +/- 1.7 nmol/L (normal range 0.8-2.5). These levels remained constant during the study period, indicating that there is no increased hepatic enzymatic breakdown of the androgen over time. Eight men were older than 50 years at the start of the study. Over the 10-year period in two of them a mild reduction in urine flow was measured, whereas in the other six this could not be demonstrated. Digital examination of the prostate did not reveal signs of prostate tumors. Testosterone undecanoate appears to be a safe oral androgen. A yearly checkup of the patient on therapy with this androgen seems adequate.

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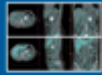
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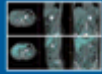
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New Testosterone Buccal System (Striant) Delivers Physiological Testosterone Levels: Pharmacokinetics Study in Hypogonadal Men  
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M. Korbonits, M. Slawik, D. Cullen, R. J. Ross, G. Stalla, H. Schneider, M. Reincke, P. M. Bouloux, and A. B. Grossman  
A Comparison of a Novel Testosterone Bioadhesive Buccal System, Striant, with a Testosterone Adhesive Patch in Hypogonadal Males  
*J. Clin. Endocrinol. Metab.*, May 1, 2004; 89(5): 2039 - 2043.

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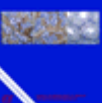
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Contribution of Lymphatically Transported Testosterone Undecanoate to the Systemic Exposure of Testosterone after Oral Administration of Two Andriol Formulations in Conscious Lymph Duct-Cannulated Dogs

*J. Pharmacol. Exp. Ther.*, September 1, 2003; 306(3): 925 - 933.

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Androgens and Women at the Menopause and Beyond  
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R. E. Gerstenbluth, P. N. Maniam, E. W. Corty, and A. D. Seftel  
Prostate-Specific Antigen Changes in Hypogonadal Men Treated With Testosterone Replacement  
*J Androl*, November 1, 2002; 23(6): 922 - 926.

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S. von Eckardstein and E. Nieschlag  
Treatment of Male Hypogonadism With Testosterone Undecanoate  
Injected at Extended Intervals of 12 Weeks: A Phase II Study  
J Androl, May 1, 2002; 23(3): 419 - 425.  
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A. M. Matsumoto  
Andropause: Clinical Implications of the Decline in Serum  
Testosterone Levels With Aging in Men  
J. Gerontol. A Biol. Sci. Med. Sci., February 1, 2002; 57(2): M76 - 99.  
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A. Vermeulen  
Androgen Replacement Therapy in the Aging Male--A Critical  
Evaluation  
J. Clin. Endocrinol. Metab., June 1, 2001; 86(6): 2380 - 2390.  
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G.-y. Zhang, Y.-q. Gu, X.-h. Wang, Y.-g. Cui, and W. J. Bremner  
A Clinical Trial of Injectable Testosterone Undecanoate as a  
Potential Male Contraceptive in Normal Chinese Men  
J. Clin. Endocrinol. Metab., October 1, 1999; 84(10): 3642 - 3647.  
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S. J. Winters  
Current Status of Testosterone Replacement Therapy in Men  
Arch Fam Med, May 1, 1999; 8(3): 257 - 263.  
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Sex Steroid Treatment of Constitutionally Tall Stature  
Endocr. Rev., October 1, 1998; 19(5): 540 - 558.  
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S. Bhasin and W. J. Bremner  
Emerging Issues in Androgen Replacement Therapy  
J. Clin. Endocrinol. Metab., January 1, 1997; 82(1): 3 - 8.  
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