

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

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Source

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Abstract

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.