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Dutasteride

Updated: January 9, 2018.

OVERVIEW

Introduction

Dutasteride is a 5-alpha reductase inhibitor used in the therapy of symptomatic benign prostatic hypertrophy. Dutasteride is associated with a low rate of transient serum aminotransferase elevations, but has yet to be linked to instances of clinically apparent acute liver injury.

Background

Dutasteride (doo tas' ter ide) was the second 5-alpha reductase inhibitor to be approved in the United States for the treatment of symptomatic benign prostatic hypertrophy. Dutasteride inhibits the conversion of testosterone to dihydrotestosterone, which is important in the development and maintenance of prostatic hyperplasia. Dihydrotesterone levels decrease during dutasteride therapy, but serum testosterone levels do not. Dutasteride usually takes several months to have an effect on prostate size and the symptoms of prostatic hypertrophy (urinary hesitancy and poor stream), unlike the alpha-1 adrenergic receptor blockers (alpha blockers) which have a more immediate effect. Dutasteride was approved for use in the United States in 2001 and is available in 0.5 mg capsules generically and under the trade name Avodart. A fixed dose combination of dutasteride (0.5 mg) with tamsulosin (0.4 mg: an alpha blocker) is available under the trade name Jalyn. The recommended dose of dutasteride is 0.5 mg once daily. Dutasteride is usually given long term and an effect is usually not seen until 3 to 6 months of therapy. Side effects are uncommon, but include impotence and decreased libido, ejaculation disorders, gynecomastia, dizziness and fatigue. Dutasteride also decreases serum PSA levels which should be monitored during therapy.

Hepatotoxicity

Dutasteride has been associated with a low rate of serum aminotransferase elevations that, in controlled trials, was no higher than with placebo therapy. These elevations were transient and rarely required dose modification. There have been no published reports of clinically apparent liver injury due to dutasteride therapy.

Likelihood score: E (unlikely cause of clinically apparent liver injury).

Mechanism of Injury

The cause of the minor serum aminotransferase elevations associated with dutasteride is not known. Dutasteride is an azosteroid and is extensively metabolized in the liver by the cytochrome P450 system (predominantly CYP 3A4 and 3A5).

References on the safety and potential hepatotoxicity of dutasteride are given in the Overview section on the 5-Alpha Reductase Inhibitors.

Drug Class: Benign Prostatic Hypertrophy Agents, 5-Alpha Reductase Inhibitors

PRODUCT INFORMATION

REPRESENTATIVE TRADE NAMES

Dutasteride – Avodart®

DRUG CLASS

Benign Prostatic Hypertrophy Agents

COMPLETE LABELING

Product labeling at DailyMed, National Library of Medicine, NIH

CHEMICAL FORMULA AND STRUCTURE

DRUG	CAS REGISTRY NUMBER	MOLECULAR FORMULA	STRUCTURE
Dutasteride	164656-23-9	C27-H30-F6-N2-O2