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Finasteride

Updated: January 9, 2018.

OVERVIEW

Introduction

Finasteride is a 5-alpha reductase inhibitor used to treat symptoms of benign prostatic hypertrophy and male pattern baldness. Finasteride 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

Finasteride (fin as' ter ide) was the first 5-alpha reductase inhibitor to be approved for use as therapy of symptomatic benign prostatic hypertrophy in the United States. Finasteride inhibits the steroid 5-alpha reductase, which blocks the conversion of testosterone to dihydrotestosterone, a form of the androgenic hormone that is important in the development and maintenance of prostatic hyperplasia. Serum dihydrotesterone levels are decreased by 70% to 90% by finasteride therapy with little effect on testosterone levels. Finasteride takes several months to have an effect on prostate size and symptoms of prostatic hypertrophy (urinary hesitancy and poor stream), unlike the alpha-1 adrenergic receptor blockers which have a more immediate effect. Finasteride also inhibits the steroid 5-alpha reductase present in skin, which led to its use in the therapy or prevention of male pattern baldness. Finasteride was approved for use in the United States in 1992 and is available in 5 mg tablets generically and under the trade name Proscar for prostatic hypertrophy, and as 1 mg tablets under the name Propecia for male pattern baldness. The recommended dose for therapy of prostatic hypertrophy is 5 mg once daily, and it generally requires 3 to 6 months before an effect is obtained and thereafter requires long term therapy. The dose of finasteride for male pattern baldness is 1 mg daily. It is not recommended as therapy for baldness in women. Side effects are uncommon, but include a low rate of impotence and decreased libido, gynecomastia, dizziness and weakness. Finasteride also decreases serum PSA levels (~50%), which should be monitored during therapy.

Hepatotoxicity

Finasteride 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, and have occurred with both the 5 mg dose for prostatic hypertrophy and the 1 mg dose for hair growth. There have been published reports of transient serum enzyme elevations occurring during finasteride therapy, but none of clinically apparent liver injury.

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

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Mechanism of Injury

The cause of liver injury associated with finasteride is not known. Finasteride is an azosteroid and is extensively metabolized in the liver via the cytochrome P450 system (CYP 3A4) and a relatively toxic intermediate might cause the mild serum enzyme elevations that can occur with therapy.

References on the safety and potential hepatotoxicity of finasteride 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

Finasteride – Generic, Proscar®

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 |
|-------------|---------------------|-------------------|-----------|
| Finasteride | 98319-26-7 | C23-H36-N2-O2 | O N H H H |