

Finasteride Cas No. : 98319-26-7

Finasteride is used to shrink an enlarged prostate (benign prostatic hyperplasia or BPH) in adult men. It may be used alone or taken in combination with other medications to reduce symptoms of BPH and may also reduce the need for surgery.

Active Pharmaceuticals Ingredients Manufacturers

Taj Pharmaceuticals Ltd.**Finasteride****CAS No. : 98319-26-7****Systematic (IUPAC) name**N-(1,1-dimethylethyl)-3-oxo-(5 α ,17 β)-4- α androst-1-ene-17-carboxamide**Identifiers**

CAS number 98319-26-7

ATC code G04CB01 D11AX10

PubChem 194453

DrugBank APRD00632

ChemSpider 51714

Chemical dataFormula C₂₃H₃₆N₂O₂

Mol. mass 372.549 g/mol

Pharmacokinetic data

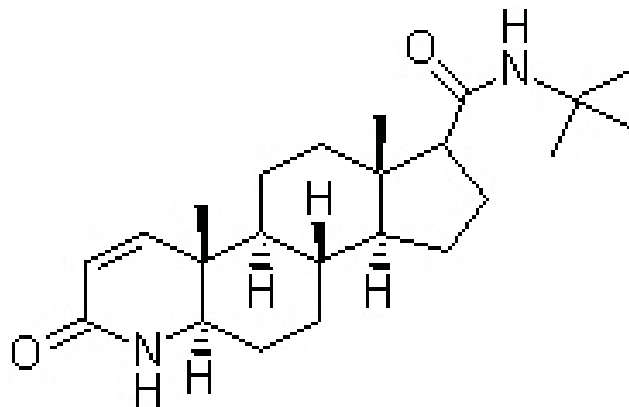
Bioavailability 63%

Metabolism Hepatic

Half life Elderly: 8 hours

Adults: 6 hours

Excretion Feces (57%) and urine (39%) as metabolites

**DOSAGE**

Finasteride comes as a tablet to take by mouth. It is usually taken once a day with or without food. Take finasteride at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take finasteride exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

If you are taking finasteride to treat BPH, you should know that finasteride controls your condition, but does not cure it. It may take at least 6 months before your symptoms improve. Continue to take finasteride even if you feel well. Do not stop taking finasteride without talking to your doctor.

If you are taking finasteride to treat male pattern hair loss, you should know that finasteride controls hair loss, but does not cure it. It may take at least 3 months before you see any benefit. Continue to take finasteride even if you have already seen an effect. Do not stop taking finasteride without talking to your doctor. If you stop taking finasteride, you will probably lose the hair you have regrown within 12 months of stopping your treatment.

If you are taking finasteride to treat male pattern hair loss and have not seen any improvement within 12 months, further treatment will probably not help. Talk to your doctor about whether you should continue your treatment.

SIDE EFFECTS

Unlikely to occur but the possible side effects include impotence, decreased sex drive or decrease in amount of ejaculate.

Finasteride may cause side effects.



Taj Pharmaceuticals Ltd.
Finasteride

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- * inability to have or maintain an erection
- * decreased sexual desire
- * decreased volume of ejaculate (amount of semen)
- * pain in the testicles

Some side effects can be serious. If you experience any of these symptoms, call your doctor immediately:

- * changes in the breasts such as increased size, lumps, pain, or nipple discharge
- * rash
- * itching
- * hives
- * swelling of the lips and face

PRECAUTIONS

Prior to initiating therapy with Finasteride, appropriate evaluation should be performed to identify other conditions such as infection, prostate cancer, stricture disease, hypotonic bladder or other neurogenic disorders that might mimic BPH.

Patients with large residual urinary volume and/or severely diminished urinary flow should be carefully monitored for obstructive uropathy. These patients may not be candidates for Finasteride therapy.

Caution should be used in the administration of Finasteride in those patients with liver function abnormalities, as Finasteride is metabolized extensively in the liver.

Effects on PSA and Prostate Cancer Detection

No clinical benefit has been demonstrated in patients with prostate cancer treated with Finasteride. Patients with BPH and elevated PSA were monitored in controlled clinical studies with serial PSAs and prostate biopsies. In these BPH studies, Finasteride did not appear to alter the rate of prostate cancer detection, and the overall incidence of prostate cancer was not significantly different in patients treated with Finasteride or placebo.

Finasteride causes a decrease in serum PSA levels by approximately 50% in patients with BPH, even in the presence of prostate cancer. This decrease is predictable over the entire range of PSA values, although it may vary in individual patients. Analysis of PSA data from over 3000 patients in a long-term efficacy and safety study confirmed that in typical patients treated with Finasteride for six months or more, PSA values should be doubled for comparison with normal ranges in untreated men. This adjustment preserves the sensitivity and specificity of the PSA assay and maintains its ability to detect prostate cancer.

Any sustained increases in PSA levels while on Finasteride should be carefully evaluated, including consideration of non-compliance to therapy with Finasteride.

Percent free PSA (free to total PSA ratio) is not significantly decreased by Finasteride. The ratio of free to total PSA remains constant even under the influence of Finasteride. If clinicians elect to use percent free PSA as an aid in the detection of prostate cancer in men undergoing Finasteride therapy, no adjustment to its value appears necessary.

DRUG DESCRIPTION

This medication is used to treat male pattern hair loss and is to be used only by adult men.



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Finasteride is a white crystalline powder with a melting point near 250°C. It is freely soluble in chloroform and in lower alcohol solvents, but is practically insoluble in water.

Finasteride tablets for oral administration are film-coated tablets that contain 5 mg of Finasteride and the following inactive ingredients: lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, pregelatinised starch, docusate sodium, magnesium stearate, hypromellose, hydroxypropyl cellulose, titanium dioxide, talc, iron oxide yellow,

Finasteride is used alone or in combination with another medication to treat benign prostatic hypertrophy (BPH, enlargement of the prostate gland). Finasteride improves symptoms of BPH such as frequent and difficult urination and may reduce the chance of acute urinary retention (suddenly being unable to pass urine). It also may decrease the chance of needing prostate surgery. Finasteride is also used to treat male pattern hair loss (a common condition in which men have gradual thinning of the hair on the scalp, leading to a receding hairline or balding on the top of the head.) Finasteride has not been shown to treat thinning hair at the temples and is not used to treat hair loss in women or children. Finasteride is in a class of medications called 5-alpha reductase inhibitors. Finasteride treats BPH by blocking the body's production of a male hormone that causes the prostate to enlarge. Finasteride treats male pattern hair loss by blocking the body's production of a male hormone in the scalp that stops hair growth.



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The Controlled Substances Act (CSA) was enacted into law by the Congress of the United States as Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970.[1] The CSA is the federal U.S. drug policy under which the manufacture, importation, possession, use and distribution of certain substances is regulated. The Act also served as the national implementing legislation for the Single Convention on Narcotic Drugs

This document plus the full buyer/ prescribing information, prepared for health professionals can be found at:

<http://www.tajapi.com>

or by contacting the sponsor, Taj Pharmaceuticals Limited., at:
91 022 30601000.

This leaflet was prepared by
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