

Dutasteride Cas No. : 164656-23-9

This medication is used to shrink an enlarged prostate in men with a condition called benign prostatic hyperplasia. It works by lowering amounts of the hormone responsible for prostate growth (dihydrotestosterone). Dutasteride reduces urinary blockage and improves urine flow.

Active Pharmaceuticals Ingredients Manufacturers



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Taj Pharmaceuticals Ltd.

Dutasteride

CAS No. : 164656-23-9

**Systematic (IUPAC) name**(5 α , 17 β)-N-{2,5 bis(trifluoromethyl) phenyl}-3-oxo-4- α androst-1-ene-17-carboxamide**Identifiers**

CAS number 164656-23-9

ATC code G04CB02

PubChem 152945

DrugBank APRD00385

Chemical dataFormula C₂₇H₃₀F₆N₂O₂

Mol. mass 528.53 g/mol

Pharmacokinetic data

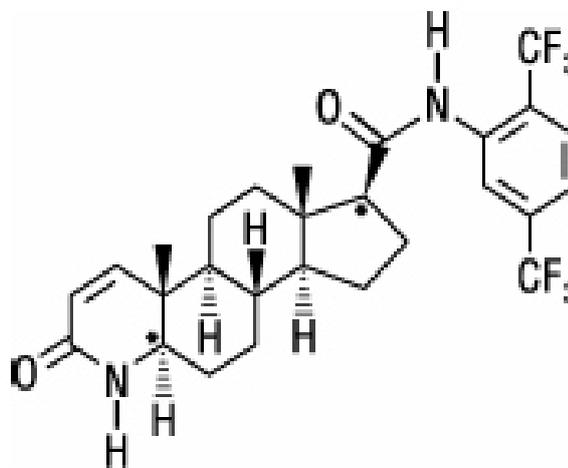
Bioavailability 60%

Protein binding 99%

Metabolism Hepatic (CYP3A4-mediated)

Half life 5 weeks

Excretion Fecal

**USES**

This medication is used to shrink an enlarged prostate in men with a condition called benign prostatic hyperplasia. It works by lowering amounts of the hormone responsible for prostate growth (dihydrotestosterone). Dutasteride reduces urinary blockage and improves urine flow.

HOW TO USE

Take this medication by mouth once daily, with or without food. Swallow the medication whole.

Use this medication regularly in order to get the most benefit from it. Remember to use it at the same time each day. It may take 3 to 6 months before you notice an improvement of your symptoms.

Read the Patient Information Leaflet available from your pharmacist.

SIDE EFFECTS

Sexual problems (e.g., impotence, decreased interest in sex, decrease in the amount of ejaculate/sperm) may infrequently occur, but then go away as your body adjusts to the drug. This medication may also cause breast enlargement and/or tenderness. If any of these effects persist or worsen, contact your doctor or pharmacist promptly.

Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

An allergic reaction to this drug is unlikely, but seek immediate

An allergic reaction to this drug is unlikely, but seek immediate medical attention if it occurs. Symptoms of an allergic reaction include: rash, itching, swelling, dizziness, trouble breathing.



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PRECAUTIONS

Before taking dutasteride, tell your doctor or pharmacist if you are allergic to it; or to finasteride; or if you have any other allergies.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: liver disease, urinary tract disease, prostate cancer.

Men taking this medication should not donate blood until at least 6 months after they have stopped taking it to prevent exposure through a blood transfusion to a pregnant female.

Since this drug can be absorbed through the skin, women who are pregnant or planning to become pregnant should not handle this medication. Any contact with this drug by a pregnant woman could result in abnormal external sex organs of a developing male unborn baby.

This medication should not be used in women or children.

MISSED DOSE

If you miss a dose, use it as soon as you remember. If it is near the time of the next dose, skip the missed dose and resume your usual dosing schedule. Do not double the dose to catch up.

STORAGE

Store at room temperature at 77 degrees F (25 degrees C) away from light and moisture. Brief storage between 59-86 degrees F (15-30 degrees C) is permitted. Do not store in the bathroom. Keep all medicines away from children and pets

DOSAGE

Take this medication by mouth once daily, with or without food. Swallow the medication whole. Use this medication regularly in order to get the most benefit from it. Remember to use it at the same time each day. It may take 3 to 6 months before you notice an improvement of your symptoms. Read the Patient Information Leaflet available from your pharmacist.

Dutasteride comes as a capsule to take by mouth. It is usually taken once a day with or without food. To help you remember to take dutasteride, take it 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 dutasteride exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

DRUG DESCRIPTION

Dutasteride

Dutasteride is a synthetic 4-azasteroid compound that is a selective inhibitor of both the type 1 and type 2 isoforms of steroid 5 α -reductase, an intracellular enzyme that converts testosterone to DHT.

Dutasteride is chemically designated as (5 α ,17 β -N-{2,5 bis(trifluoromethyl)phenyl}-3-oxo-4- α androst-1-ene-17-carboxamide. The empirical formula of dutasteride is C₂₇H₃₀F₆N₂O₂, representing a molecular weight of 528.5



Dutasteride is a white to pale yellow powder with a melting point of 242° to 250° C. It is soluble in ethanol (44 mg/mL), methanol (64 mg/mL), and polyethylene glycol 400 (3 mg/mL), but it is insoluble in water.

Each Dutasteride Soft Gelatin Capsule, administered orally, contains 0.5 mg of dutasteride dissolved in a mixture of mono-di-glycerides of caprylic/capric acid and butylated hydroxytoluene. The inactive excipients in the capsule shell are gelatin (from certified BSE-free bovine sources), glycerin, and ferric oxide (yellow). The soft gelatin capsules are printed with edible red ink.

Dutasteride is used to treat an enlarged prostate (benign prostatic hyperplasia, or BPH). Dutasteride is in a class of medications called 5- α reductase inhibitors. It works by blocking the production of a natural substance that enlarges the prostate. This shrinks the prostate, relieves symptoms of BPH, such as frequent and difficult urination, and decreases the chance that surgery will be needed to treat this condition.



Note /Government Notification: These chemicals are designated as those that are used in the manufacture of the controlled substances and are important to the manufacture of the substances. For any (Control Substance) products Import and Export *** subjected to your country government laws /control substance ACT.

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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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