

DUTASTERIDE

DUTRIDE

500 mcg Softgel Capsule

TESTOSTERONE-5-ALPHA REDUCTASE INHIBITOR



FORMULATION:

Each soft-gelatin capsule contains:
Dutasteride 500 mcg

INDICATION:

Dutasteride is indicated in the treatment of symptomatic prostatic hyperplasia (BPH) in men with enlarged prostate to improve symptoms, reduce the risk of acute urinary retention, and reduce the risk of need for BPH-related surgery.

PHARMACOLOGY:

Inhibits the conversion of testosterone to 5-alpha-dihydrotestosterone, a potent androgen.

PHARMACOKINETICS:

Absorption

Tmax is 2 to 3h; bioavailability is approximately 60%; administration with food decreased Cmax 10% to 15%.

Distribution

Vd is 300 to 500 L; highly protein bound (99%).

Metabolism

Metabolized by CYP3A4 and CYP3A5.

Elimination

Mainly excreted in feces (approximately 5% as unchanged dutasteride and approximately 40% as metabolites).

The half life is approximately 5 wk.

ADVERSE REACTIONS:

Central Nervous System (CNS)

Decreased libido (3%).

Genitourinary

Impotence (5%); breast disorder including breast enlargement and breast tenderness, ejaculation disorder (1%).

Hypersensitivity

Allergic reactions including angioedema, localized edema, pruritus, rash, serious skin reactions, and urticaria (postmarketing).

If you think you are allergic to Dutasteride, consult a doctor before discontinuing its usage.

PRECAUTIONS:

Monitor

Perform digital rectal exams, as well as other evaluations for prostatic cancer prior to starting therapy and periodically thereafter. Assess patient to rule out other urologic diseases prior to treatment. Carefully monitor patients with larger residual urine volume or severely diminished urinary flow for obstructive uropathy.

Pregnancy

Category X

Lactation

Undetermined

Children

Contraindicated for use in children. Safety and efficacy not established.

Hepatic function

Use with caution

Blood donation

Men should not donate blood until at least 6 months after the last dose of dutasteride.

Handling capsules

Women who are pregnant or may be pregnant should not handle the capsules. Dutasteride is absorbed through the skin and could result in unintended fetal exposure. Women who are not pregnant should use caution whenever handling the capsules. If contact is made with leaking capsules, wash the contacted area immediately with soap and water.

Obstructive uropathy

Patients with large residual urine volume or severely diminished urinary flow may not be good candidate for therapy.

Prostate effects

Total serum Prostate-Specific Antigen (PSA) concentrations are decreased. Establish a new baseline PSA concentration after 3 to 6 months of treatment and use this new value to assess potentially cancer-related changes

PSA. To interpret an isolated PSA value in a man treated with dutasteride for 6 months or more double the PSA value for comparison with normal values in untreated men.

Reproductive effects

Sperm control may be reduced in some patients.

DOSAGE AND ADMINISTRATION:

Adults

Dutasteride 500 mcg once daily.

Take one capsule daily, at the same time each day, with or without food. Swallow the medication whole, and bear in mind that it may take from three to six months to notice any improvement of symptoms.

General Advice

Administer with or without food.

Swallow capsules whole. Do not crush, cut or chew.

Do not use capsules that are cracked or leaking.

DRUG INTERACTIONS:

CYP3A4 inhibitors (eg, cimetidine, ciprofloxacin, diltiazem, ketoconazole, ritonavir, troleandomycin, verapamil).

Plasma concentrations of dutasteride may be elevated, increasing the risk of adverse reactions. Use with caution.

However, the change in dutasteride exposure with co administration of diltiazem or verapamil is not considered clinically important and no dosage adjustment is recommended.

Food

When dutasteride is taken with food, the dutasteride Cmax is reduced 10% to 15%. This reduction is not considered to be clinically important. Dutasteride may be taken with or without food.

CONTRAINDICATIONS:

Pregnancy; women of childbearing potential; children; hypersensitivity to 5-alpha-reductase inhibitors or any component of the product.

WARNINGS:

Using Dutasteride may affect the results of the blood test used to detect prostate cancer. Inform your doctor before taking this test if you are using dutasteride.

OVERDOSE:

Symptoms of Dutasteride overdose are not known. If you suspect overdose, contact your local poison control center or emergency room immediately.

STORAGE CONDITION:

Store at temperatures not exceeding 30°C.

CAUTION:

Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

AVAILABILITY:

Alu/Clear PVC Blister Pack x 10's (Box of 30's).

Manufactured by:

STERIL-GENE LIFE SCIENCES (P) LTD.

No. 45, Mangalam Main Road, Mangalam Village,
Villianur Commune, Puducherry - 605 110, India

Manufactured for:

SWATI SPENTOSE PVT. LTD.

114, Marine Chambers, 11, New Marine Lines,
Mumbai - 400 020, India

Imported by:

AMBICA INTERNATIONAL CORPORATION

#9 Amsterdam Extn., Merville Park Subd.,
Parañaque City, Philippines

Distributed by:
SCRIPTMED INC.

104-A Residencia 8888 Condominium
Bldg., Pearl Drive cor. Amethyst St.,
Ortigas Center, Pasig City, Metro Manila, Philippines.

