UROLOSIN-D

Tamsulosin Hydrochloride 0.4 mg & Dutasteride 0.5 mg Capsule

Composition
UROLOSIN-D Capsule: Each Capsule Contains Tamsulosin Hydrochloride USP 0.4 mg Sustained Release & Dutasteride INN 0.5 mg Immediate Release (As blended pellets).

Pharmacology
Pharmacodynamic Properties
Tamsulosin
Smooth muscle tone is mediated by the sympathetic nervous stimulation of alpha-1-adrenoceptors, which are abundant in the prostate, prostatic capsule, prostatic urethra, and bladder neck. Blockade of these adrenoceptors especially the alpha1-A receptor subtype can cause smooth muscles in the bladder neck and prostate to relux, resulting in an improvement in urine flow rate and a reduction in symptoms of BPH.
Dutasteride
Dutasteride inhibits the conversion of testosterone to dihydrotestosterone. DHT is the androgen primarily responsible for the initial development and subsequent enlargement of the prostate gland. Testosterone is converted to DHT by the enzymes 5 alpha-reductase, which exists as 2 isoforms, type-1 and type-2. The type-2 isoenzyme is primarily active in the reproductive tissues, while the type-1 isoenzyme is also responsible for testosterone conversion in the skin and liver.

Pharmacokinetic Properties
Absorption
Dutasteride
Following administration of a single 0.5-mg dose capsule, time to peak absolute bioavailability is approximately 60% (range: 40% to 94%).
Tamsulosin
Absorption of tamsulosin is essentially complete (>90%) following oral administration of 0.4-mg tamsulosin hydrochloride capsules under fasting conditions. Tamsulosin exhibits linear kinetics following single and multiple dosing.
Effect of Food
Food does not affect the pharmacokinetics of dutasteride following administration of Dutasteride and Tamsulosin. However, a mean 30% decrease in tamsulosin Cmax was observed when Dutasteride and Tamsulosin was administered with food.
Distribution
Dutasteride
Dutasteride is highly bound to plasma albumin (99.0%) and alpha-1 acid glycoprotein (96.6%).
Tamsulosin
Tamsulosin is extensively bound to human plasma proteins (94% to 99%).
Metabolism
Dutasteride
Dutasteride is extensively metabolized in humans. In vitro studies showed that dutasteride is metabolized by the CYP3A4 and CYP3A5 isoenzymes.
Tamsulosin
Tamsulosin is extensively metabolized by cytochrome P450 enzymes in the liver and less than 10% of the dose is excreted in urine unchanged. Tamsulosin undergo extensive conjugation to glucuronide or sulfate prior to renal excretion.
Excretion
Dutasteride
Dutasteride and its metabolites were excreted mainly in feces.
Tamsulosin
Urine (76%) representing the primary route of excretion compared to feces (21%) over 168 hours. The elimination half-life of tamsulosin in plasma ranges from 5 to 7 hours.

Indications
It is indicated for the treatment of symptomatic benign prostatic hyperplasia (BPH) in men with an enlarged prostate.

Dosage and Administration
Take one capsule daily approximately 30 minutes after the same meal each day.

Contraindications
- Pregnancy and women of childbearing potential.
- Pediatric patients.
- Patients with previously demonstrated, clinically significant hypersensitivity (e.g., serious skin reactions, angioedema, urticaria, pruritus, respiratory symptoms) to dutasteride, other 5 alphareductase inhibitors, tamsulosin, or any component of Dutasteride & Tamsulosin.

Precautions
- Orthostatic hypotension and/or syncope can occur. Advise patients of symptoms related to postural hypotension and to avoid situations where injury could result if syncope occurs.
- Do not use with other alpha adrenergic antagonists & PDE-5 inhibitors, as this may increase the risk of hypotension.
- Do not use with strong inhibitors of cytochrome P450 (CYP) 3A4 (e.g., ketoconazole). Use caution in combination with moderate CYP3A4 inhibitors (e.g., erythromycin) or strong (e.g., paroxetine) or moderate CYP2D6 inhibitors, or known poor metabolizers of CYP2D6. Concomitant use with known inhibitors can cause a marked increase in drug exposure.
- May increase the risk of high-grade prostate cancer.
- Women who are pregnant or could become pregnant should not handle Dutasteride & Tamsulosin Capsules due to potential risk to a male fetus.
- Advise patients about the possibility and seriousness of priapism.
- Patients should not donate blood until 6 months after their last dose of Dutasteride & Tamsulosin.
- Intraoperative Floppy Iris Syndrome has been observed during cataract surgery after alpha adrenergic antagonist exposure. Advise patients considering cataract surgery to tell their ophthalmologist that they take or have taken Dutasteride & Tamsulosin Capsules.

Side Effects
The most common side effects of Dutasteride and Tamsulosin include:
- Ejaculation problems
- A decrease in sex drive (libido)
- Dizziness
- Enlarged or painful breasts.
- Runny nose
- Depressed mood

Pregnancy and lactation
Pregnancy Category X. There are no adequate and well-controlled studies in pregnant women with Dutasteride and Tamsulosin or its individual components.

Storage Conditions
Store in a cool and dry place, away from light. Keep out of reach of children.

Commercial Pack
UROLOSIN-D Capsule: Each box contains 4 blister packs of 4 Capsules.

Manufactured by:
general GENERAL
Pharmaceuticals Ltd.
Kaliakair, Gazipur, Bangladesh

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