

# Urinom® D

Tamsulosin Hydrochloride + Dutasteride

**Description:**

Tamsulosin is an antagonist of alpha1A-adrenoreceptors and Dutasteride, a 5 alpha-reductase inhibitor.

**Mode of action:**

Tamsulosin selectively inhibits alpha 1A-adrenoreceptor of the prostate and causes relaxation of prostate smooth muscle and decreases urethral resistance. Dutasteride is a selective inhibitor of both the type 1 and type 2 isoforms of steroid 5 alpha-reductase enzyme that converts testosterone to dihydrotestosterone (DHT). Dutasteride- inhibits hyperplasia of prostate gland.

**Pharmacokinetics:**

The bioavailability of Dutasteride is approximately 60% and Tamsulosin is >90%. Dutasteride is highly bound to plasma albumin (99.0%). Tamsulosin is extensively bound to human plasma proteins (94% to 99%). In vitro studies showed that dutasteride is metabolized by the CYP3A4 and CYP3A5 isoenzymes. Tamsulosin is extensively metabolized by cytochrome P450 enzymes in the liver and less than 10% of the dose is excreted in urine unchanged. Dutasteride and its metabolites is excreted mainly in feces. Tamsulosin is excreted mainly in urine (76%) and feces (21%).

**Composition:**

**Urinom® D Capsule:** Each capsule contains blended pellets of Tamsulosin Hydrochloride (0.2% w/w) modified release and Dutasteride (0.5% w/w) immediate release equivalent to Tamsulosin Hydrochloride USP 0.4 mg & Dutasteride BP 0.5 mg.

**Indications:**

- To reduce the symptoms of Benign Prostatic Hyperplasia (BPH)
- To improve urinary flow
- To reduce prostate size

**Dosage & administration:**

The recommended dosage is 1 capsule taken once daily approximately 30 minutes after the same meal each day.

**Contraindication:**

Hypersensitivity to any component of this product

**Side Effects:**

The most common adverse reactions, reported in 1% of patients are ejaculation disorders, impotence, decreased libido, dizziness, and breast disorders.

**Use in pregnancy and lactation:**

*Pregnancy:* pregnancy category X.

*Lactation:* It is not known whether dutasteride or tamsulosin is excreted in human milk.

**Precaution:**

Orthostatic hypotension.

**Drug Interaction:**

Ketoconazole, Paroxetine, Terbinafine, PDE-5 inhibitor and erythromycin.

**Overdose:**

No data are available with regard to over dosage with this preparation.

**Storage:**

Keep out of reach of children. Store in a dry place, below 25° C temperature & protected from light.

**Packaging:**

**Urinom® D Capsule:** Each carton contains 6x3 capsules in blister pack.