

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.