

For consumer information only

# UTPASS<sup>TM</sup>-D

(Tamsulosin hydrochloride 0.4mg (As modified release) +Dutasteride 0.5mg)

**Each film coated tablets contains:**

Tamsulosin hydrochloride..... 0.4mg  
(As modified release)  
Dutasteride.....0.5mg  
Excipients.....q.s.

**Clinical pharmacology:**

**Tamsulosin & Dutasteride;** treats the symptoms of an enlarged prostate (benign prostatic hyperplasia). It works by decreasing the size of the prostate. It also relaxes the muscles in the prostate and bladder, which makes it easier to urinate.

**Tamsulosin hydrochloride**, an antagonist of  $\alpha_{1a}$  and  $\alpha_{1d}$  adrenoreceptors & **Dutasteride**, a dual 5  $\alpha$ -reductase inhibitor (5 ARI) and These drugs have complementary mechanisms of action that rapidly improve symptoms, urinary flow and reduce the risk of acute urinary retention (AUR) and the need for BPH related surgery.

**Tamsulosin** inhibits  $\alpha_{1a}$  and  $\alpha_{1d}$  adrenergic receptors in the stromal prostatic smooth muscle and bladder neck. Approximately 75% of the  $\alpha_1$ -receptors in the prostate are of the  $\alpha_{1a}$  subtype.

**Dutasteride** inhibits both type 1 and type 2, 5 alpha-reductase isoenzymes, which are responsible for the conversion of testosterone to dihydrotestosterone (DHT). DHT is the androgen primarily responsible for prostate growth and BPH development.

**Indications:**

- Benign prostatic hyperplasia.
- Benign prostatic enlargement.
- Terminal dripping.
- Incomplete voiding.
- Acute urinary retention.

**Use in Specific Population:**

- Renal Impairment: Has not been studied in patients with end-stage renal disease.
- Hepatic Impairment: Has not been studied in patients with severe hepatic impairment.

**Contraindications: Patients with a history of hypersensitivity to tamsulosine & dutasteride**

**Drug Interaction:** CYP Inhibitors: UTPASS-D is metabolized by both CYP3A4 and CYP2D6. Concomitant use with known inhibitors can cause a marked increase in plasma levels resulting in an increased rate of side effects. Use of UTPASS-D with ketoconazole and paroxetine is not recommended. Caution should be exercised when used with less potent inhibitors, such as, but not limited to terbinafine and erythromycin.

**Adverse Side effects:**

- Blistering, flaking, or peeling of the skin.
- Difficulty with breathing.
- Fast, irregular, pounding, or racing heartbeat or pulse.

**Overdosage:** Taking too much tamsulosin can decrease your blood pressure and increase your heart rate.

**Route of Administration:** Oral.

**Type of Tablet:** Film coated tablet.

**Dosage:** As directed by physician

**Storage:** Store in cool dry and dark place.

**SCHEDULE H PRESCRIPTION DRUG-CAUTION** Not to be sold retail without the Prescription of a Registered Medical Practitioner.

**Presentation:** UTPASS-D tablet is available as 1×10 Tablet/ Strip.

**Marketed by:**



804, Suyog Center, Gultekadi, Pune-411037 (MH), India.  
[www.epionepharma.com](http://www.epionepharma.com)