

# Uriviga D Tablet

**Tamsulosin (0.4mg) + Dutasteride (0.5mg)  
Tablet**

- **Tamsulosin (0.4mg)**
- **Dutasteride (0.5mg)**

**Category: Alpha-1 Blocker + 5-Alpha  
Reductase Inhibitor  
Dosage Form: Oral Tablet**

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## Indications:

**This combination tablet is indicated for:**

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## Description:

The combination tablet of Tamsulosin (0.4mg) and Dutasteride (0.5mg) is used to treat benign prostatic hyperplasia (BPH), commonly known as an enlarged prostate. This combination therapy helps to manage the symptoms associated with BPH, including difficulty urinating, frequent urination, and the feeling of incomplete bladder emptying.

- 1. Benign Prostatic Hyperplasia (BPH):**
  - Treatment of moderate to severe BPH symptoms, such as urinary frequency, urgency, weak stream, and incomplete emptying of the bladder.
  - To improve urinary flow and reduce the size of the prostate, thus improving quality of life for patients with enlarged prostate.
- 2. Prevention of BPH progression:**
  - Dutasteride helps to reduce the risk of progression to more severe BPH symptoms or complications like acute urinary retention or the need for surgical intervention (e.g., prostatectomy).

- Tamsulosin is an alpha-1 adrenergic blocker that works by relaxing the muscles in the prostate and the bladder neck, making it easier to urinate.
- Dutasteride is a 5-alpha reductase inhibitor that works by inhibiting the enzyme responsible for converting testosterone into dihydrotestosterone (DHT). DHT is a hormone that causes prostate enlargement, and by reducing its levels, dutasteride helps shrink the prostate and improve symptoms over time.

Together, these two medications address the problem from different mechanisms, providing relief from BPH symptoms and reducing the risk of prostate-related complications.

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## Dosage and Administration:

- **Recommended Dosage:**
  - One tablet per day, taken orally, usually with food to reduce the risk of stomach upset.
  - The tablet should be swallowed whole and not crushed or chewed.
- **Duration of Treatment:**
  - Treatment is typically long-term. While Tamsulosin provides rapid symptomatic relief within 2 weeks, the effect of Dutasteride in reducing prostate size may take 6

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## Composition (Per Tablet):

months or longer to become noticeable.

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- **Severe renal impairment:** Use with caution in patients with severe kidney dysfunction.
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### **Mechanism of Action:**

- **Tamsulosin (Alpha-1 Blocker):**
    - Tamsulosin selectively blocks alpha-1 adrenergic receptors in the smooth muscles of the prostate and bladder neck. This results in the relaxation of these muscles, which reduces the resistance to urinary flow and improves urinary symptoms.
  - **Dutasteride (5-Alpha Reductase Inhibitor):**
    - Dutasteride inhibits both type I and type II forms of the enzyme 5-alpha reductase, which converts testosterone to dihydrotestosterone (DHT). Lower DHT levels reduce the size of the prostate over time and help improve urinary symptoms associated with BPH.
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### **Contraindications:**

- **Hypersensitivity to Tamsulosin, Dutasteride, or any of the tablet's ingredients.**
- **Women (especially during pregnancy or breastfeeding):** Dutasteride can cause birth defects in male fetuses. Women who are pregnant or may become pregnant should avoid handling this medication.
- **Severe hepatic impairment:** Due to the potential for increased systemic exposure to the drug, this combination should not be used in patients with severe liver disease.

### **Warnings and Precautions:**

1. **Prostate Cancer:**
  - The medication should be used cautiously in patients with undiagnosed prostate cancer. Dutasteride may lower the levels of prostate-specific antigen (PSA), which could mask the presence of prostate cancer. Screening for prostate cancer should be performed before and during treatment.
2. **Orthostatic Hypotension:**
  - Tamsulosin can cause orthostatic hypotension (a drop in blood pressure when standing), especially during the initial dose. Patients should be cautioned about the risk of dizziness or fainting, particularly when standing up quickly.
3. **Impaired Liver Function:**
  - Patients with moderate liver impairment should be monitored closely, as Dutasteride may increase in concentration in the bloodstream.
4. **Pregnancy and Women of Childbearing Age:**
  - Dutasteride is contraindicated in women who are pregnant or may become pregnant due to the risk of fetal harm, especially in male fetuses (i.e., birth defects). Women should avoid handling crushed or broken tablets to prevent accidental absorption of the drug.
5. **Allergic Reactions:**
  - Rare allergic reactions (e.g., rash, itching, or swelling) may occur.

**Discontinue use and consult a healthcare provider if signs of a serious allergic reaction appear.**

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#### **Adverse Effects:**

#### **Common Side Effects:**

- **Erectile dysfunction or decreased libido.**
- **Dizziness or headache.**
- **Decreased semen volume.**
- **Retrograde ejaculation (semen may flow backward into the bladder instead of out of the urethra).**
- **Fatigue.**
- **Breast tenderness or enlargement (due to Dutasteride).**

#### **Serious Side Effects:**

- **Severe allergic reactions, such as difficulty breathing, swelling of the face, lips, or tongue.**
  - **Chest pain or palpitations.**
  - **Breast lumps, nipple discharge, or other breast abnormalities. Although rare, these symptoms should be evaluated to rule out any serious conditions.**
  - **Changes in mood or depression.**
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#### **Drug Interactions:**

- **CYP3A4 Inhibitors (e.g., ketoconazole, ritonavir, clarithromycin): These can increase Dutasteride concentrations, leading to potential side effects. Monitor closely or adjust dosage.**
- **Alpha-blockers (e.g., alfuzosin, terazosin): Concomitant use with Tamsulosin may increase the risk of low blood pressure (orthostatic hypotension). Monitoring of blood pressure is recommended.**

- **Beta-blockers, calcium channel blockers, and other antihypertensive agents: May increase the risk of orthostatic hypotension when combined with Tamsulosin.**
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#### **Storage Instructions:**

- **Store at room temperature (15°C - 30°C).**
  - **Protect from moisture and light.**
  - **Keep out of reach of children.**
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#### **Key Points for Use:**

- **Tamsulosin (0.4mg) + Dutasteride (0.5mg) combination is an effective long-term treatment for BPH.**
  - **Tamsulosin provides quick symptom relief, while Dutasteride works to reduce the size of the prostate over time.**
  - **Treatment may take several months to show full benefits, especially for prostate size reduction.**
  - **Women who are pregnant or may become pregnant should not handle this medication due to the potential for birth defects in male fetuses.**
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**Please consult a healthcare provider for personalized advice and to ensure this medication is right for you.**

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