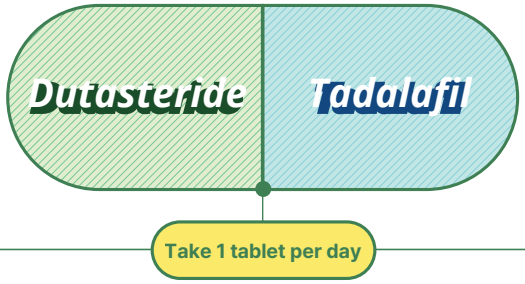
UROGUARD is a fixed-dose combination therapy (Dutasteride 0.5mg / Tadalafil 5mg) designed to synergistically treat LUTS associated with moderate to severe BPH.[1]

UROGUARD Tab.



5α-Reductase Inhibitor

Dutasteride 0.5mg

① Decreases DHT levels
② Reduces prostate volume
③ Improves LUTS and urinary flow
④ Lowers the risk of AUR and BPH-related surgeries

PDE5 Inhibitor

Tadalafil 5mg

① Increases cGMP levels in the corpus cavernosum
② Relaxes smooth muscles and promotes blood inflow into penile tissue
③ Selectively and reversibly inhibits PDE5 in the smooth muscles of blood vessels supplying the prostate and bladder

The 2025 European Association of Urology (EAU) guidelines recommend the use of 5α-reductase inhibitors and PDE5 inhibitors for treating LUTS.[2]

5α-Reductase Inhibitor

Recommendations	Grade
The use of 5α-reductase inhibitors is recommended for patients with moderate to severe LUTS who are at high risk of disease progression (e.g., prostate volume > 40 mL).	Strong
Counsel patients that the clinical effects of 5α-reductase inhibitors may appear gradually.	Strong

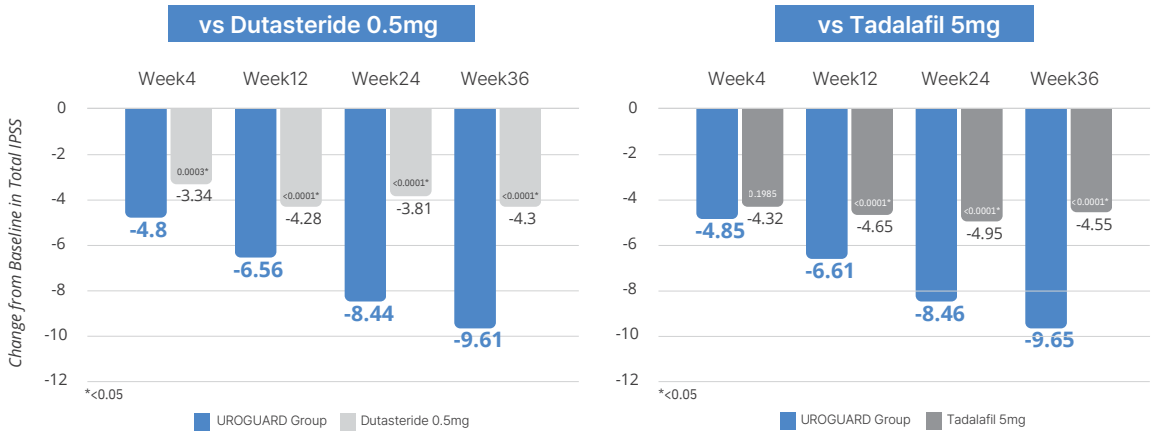
PDE5 Inhibitor

Recommendations	Grade
The use of PDE5 inhibitors is recommended for male patients with moderate to severe LUTS, regardless of the presence or absence of erectile dysfunction.	Strong

DHT, Dihydrotestosterone; AUR, Acute Urinary Retention; BPH, Benign Prostatic Hyperplasia; cGMP, cyclic Guanosine Monophosphate; PDE5, Phosphodiesterase type 5

In a domestic Phase 3 clinical trial, the fixed-dose combination of Dutasteride 0.5mg and Tadalafil 5mg demonstrated excellent efficacy in improving symptoms and reducing prostate volume in patients with BPH.

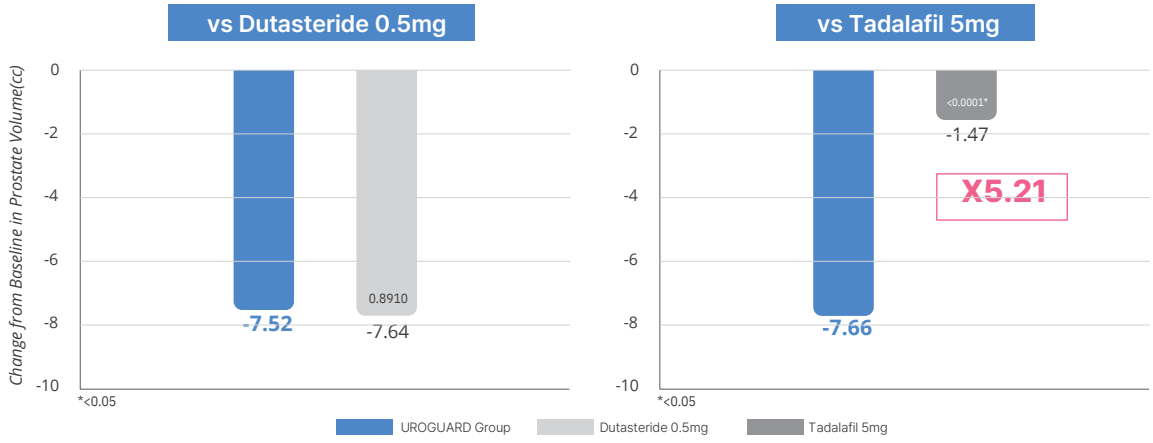
Changes in Total IPSS Over Time



→ The UROGUARD group **maintained a statistically significant improvement in IPSS** from Week 4 compared to the dutasteride 0.5mg group, and from Week 12 compared to the tadalafil 5mg group.

→ The UROGUARD group showed a **continuous and progressive reduction in IPSS from Week 4 onwards.**

Changes in Prostate Volume at Week 48



→ After 48 weeks of treatment, the UROGUARD treatment group showed an approximately 5-fold greater reduction in prostate volume compared to the tadalafil 5mg group.

I Study Design : A multicenter, randomized, double-blind, double-dummy, 3-arm parallel, 48-week, Phase 3 clinical trial.
I Subjects : 655 male patients aged 45 to 79 years, diagnosed with benign prostatic hyperplasia (BPH) (IPSS ≥ 13).
I Administration : Orally administered once daily at approximately the same time every day, with or without food, for 48 weeks. Patients were divided into three groups: the UROGUARD group (Dutasteride 0.5mg/Tadalafil 5mg), the Dutasteride 0.5mg group, and the Tadalafil 5mg group.
I Assessments : Changes from baseline in total IPSS, IPSS subscores (voiding symptoms, storage symptoms, quality of life), maximum urinary flow rate, post-void residual volume, prostate volume, PSA, and IIEF-EF. Monitoring of adverse events including subjective and objective symptoms.

IPSS, International Prostate Symptom Score; PSA, Prostate-Specific Antigen; IIEF-EF, International Index of Erectile Function – Erectile Function

Safety Profile [1,3]

In a domestic double-blind, double-dummy, 3-arm parallel study of 655 BPH patients, **the most common adverse events were COVID-19 (5.48%), headache (3.65%), and dyspepsia (2.28%).**[1]

There were no statistically significant differences between the UROGUARD arm and the control arm concerning adverse drug reactions (ADRs), serious adverse events (SAEs), serious ADRs, AEs leading to treatment discontinuation, or fatal AEs. Notably, **no cases of erectile dysfunction or ejaculation disorders were reported in the UROGUARD group.**[3]

[Precautions for Use]

· Do not administer to the following patients (Contraindications):

1. Women
2. Pediatric patients under 18 years of age
3. Patients with hypersensitivity to tadalafil, dutasteride (including other 5α-reductase inhibitors), or any of the excipients in this product.
4. Coadministration of tadalafil with any form of organic nitrate, either regularly and/or intermittently, is contraindicated. In clinical trials, tadalafil was shown to potentiate the hypotensive effect of nitrates. As tadalafil has vasodilatory properties, it causes a transient, mild decrease in blood pressure, thereby increasing the blood pressure-lowering effect of nitrates. This is considered a result of the combined effects of nitrates and tadalafil on the nitric oxide/cGMP pathway.
5. Tadalafil should not be used in men with cardiac disease for whom sexual activity is inadvisable. Physicians should consider the potential cardiac risk of sexual activity in patients with pre-existing cardiovascular disease.
6. Tadalafil is contraindicated in the following groups of patients with cardiovascular diseases, as they were not included in clinical trials:
   - Patients who have had a myocardial infarction within the last 90 days
   - Patients with unstable angina or angina occurring during sexual intercourse
   - Patients with New York Heart Association (NYHA) Class 2 or greater heart failure within the last 6 months
   - Patients with uncontrolled arrhythmias, hypotension (< 90/50 mmHg), or uncontrolled hypertension (> 170/100 mmHg)
   - Patients who have had a stroke within the last 6 months
7. The use of tadalafil is not recommended in patients with known hereditary degenerative retinal disorders, including retinitis pigmentosa, as they were not included in clinical trials.
8. The safety and efficacy of combinations of tadalafil and other treatments for erectile dysfunction have not been studied. Therefore, the use of such combinations is not recommended.
9. Tadalafil is contraindicated in patients who have loss of vision in one eye because of non-arteritic anterior ischemic optic neuropathy (NAION), regardless of whether this episode was in connection with previous PDE5 inhibitor exposure or not.
10. Coadministration of PDE5 inhibitors, including tadalafil, with guanylate cyclase (GC) stimulators (e.g., riociguat) is contraindicated, as it may potentiate the hypotensive effects of GC stimulators.
11. Since this product contains lactose, it should not be administered to patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency, or glucose-galactose malabsorption.