



# FINASTERIDE + TADALAFIL Tablets

Targeted for therapy  
of BPH

- **Indicated for** treatment of benign prostatic hyperplasia (BPH) in patients with enlarged prostate to:
  - Allow for early improvement of signs and symptoms of BPH during initial period needed to achieve beneficial response of Finasteride
  - Cause regression of the enlarged prostate, improve urinary flow, reduce the incidence of acute urinary retention and need for surgery
  - Treat erectile dysfunction in adult men with enlarged prostate who require concurrent treatment with 5-alpha reductase inhibitor Finasteride

Innovative Fixed-Dose- Combination (FDC) supported by guidelines\*

Less treatment discontinuation due to reduced erectile dysfunction compared to Finasteride alone

Available strengths: 5mg + 5mg

## Early onset of effect

- Improvement in IPSS (International Prostate Symptom Score) achieved earlier compared to Finasteride alone (which may be up to 6 months)

## Better erectile function with possible lasting effect

- While standard combination therapy of 5-alpha reductase inhibitors (such as Finasteride) with alpha-blockers (e.g. Tamsulosine) worsen erectile function, the combination with Tadalafil will not have this side effect

\*Ref : EAU Guidelines on Management of Non-Neurogenic Male Lower Urinary Tract Symptoms (LUTS), incl. Benign Prostatic Obstruction (BPO)

## Regulatory pathway

- Legal basis: Article 10b Fixed dose combination

## Development status

- Drug-drug interaction study and pivotal bio-equivalency study under fasting conditions successfully performed together with the food-effect study
- EU dossier submitted in 05/2022

## Partnership options

- Product is available for out-licensing in selected markets in Europe
- Dossier can be adjusted to markets outside Europe based on request

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