

Eziflo D

Tamsulosin Hydrochloride USP 0.4 mg and Dutasteride BP 0.5 mg

COMPOSITION

Eziflo D Capsule: Each modified release capsule contains Tamsulosin Hydrochloride USP 0.4 mg and Dutasteride BP 0.5 mg.

DESCRIPTION

Eziflo D capsule is a combination of 2 drugs with different mechanisms of action to improve symptoms in patients with BPH: Dutasteride, a 5 alpha-reductase inhibitor, and Tamsulosin, an antagonist of alpha1A-adrenoceptors. Tamsulosin: Smooth muscle tone is mediated by the sympathetic nervous stimulation of alpha1-adrenoceptors, which are abundant in the prostate, prostatic capsule, prostatic urethra, and bladder neck. Blockade of these adrenoceptors especially the alpha1-A receptor subtype can cause smooth muscles in the bladder neck and prostate to relax, resulting in an improvement in urine flow rate and a reduction in symptoms of BPH. Dutasteride: Dutasteride inhibits the conversion of testosterone to dihydrotestosterone. DHT is the androgen primarily responsible for the initial development and subsequent enlargement of the prostate gland. Testosterone is converted to DHT by the enzyme 5 alpha-reductase, which exists as 2 isoforms, type 1 and type 2. The type 2 isoenzyme is primarily active in the reproductive tissues, while the type 1 isoenzyme is also responsible for testosterone conversion in the skin and liver.

INDICATIONS

Eziflo D capsule (Tamsulosin Hydrochloride & Dutasteride) indicated for the treatment of symptomatic benign prostatic hyperplasia (BPH) in men with an enlarged prostate.

DOSAGE & ADMINISTRATION

One capsule daily approximately 30 minutes after the same meal each day.

CONTRAINDICATIONS

• Pregnancy and women of childbearing potential. • Pediatric patients. • Patients with previously demonstrated, clinically significant hypersensitivity (e.g., serious skin reactions, angioedema) to Dutasteride, other 5 alpha-reductase inhibitors, Tamsulosin, or any component of this product.

PRECAUTIONS

• Orthostatic hypotension and/or syncope can occur. Advise patients of symptoms related to postural hypotension and to avoid situations where injury could result if syncope occurs. • Eziflo D capsule (Tamsulosin Hydrochloride & Dutasteride) reduces serum prostatespecific antigen (PSA) concentration by approximately 50%. However, any confirmed increase in PSA while on this product may signal the presence of prostate cancer and to be evaluated, even if those values are still within the normal range for untreated men • Patients should not donate blood until 6 months after their last dose of this product. • Intraoperative Floppy Iris Syndrome has been observed during cataract surgery after alpha adrenergic antagonist exposure. Patients to be advised for considering cataract surgery to tell their ophthalmologist that they take or have taken this Capsule.

PREGNANCY AND LACTATION

Pregnancy Category X. There are no adequate and well-controlled studies in pregnant women with this product or its individual components. This combination product is contraindicated for use in women of childbearing potential, including nursing women. It is not known whether Dutasteride or Tamsulosin is excreted in human milk.

SIDE EFFECTS

The most common adverse reactions, reported in $\geq 1\%$ of subjects treated with co-administered Dutasteride and Tamsulosin are ejaculation disorders, impotence, decreased libido, dizziness, and gynaecomastia.

DRUG INTERACTIONS

Strong Inhibitors of CYP3A4: Tamsulosin-containing products, including this product, should not be co-administered with strong CYP3A4 inhibitors (e.g., Ketoconazole) as this can significantly increase Tamsulosin exposure. Inhibitors of CYP2D6 and Moderate Inhibitors of CYP3A4: Tamsulosin-containing products, including this product, should be used with caution when co-administered with moderate inhibitors of CYP3A4 (e.g., Erythromycin), strong (e.g., Paroxetine) or moderate (e.g., Terbinafine) inhibitors of CYP2D6, or in patients known to be poor metabolizers of CYP2D6, as there is a potential for significant increase in Tamsulosin exposure. Cimetidine: Caution is advised when Tamsulosin-containing products, including this product, are co-administered with Cimetidine.

PHARMACEUTICAL PRECAUTIONS

Store at 15°-30°C. Protect from light and moisture. Keep all medicines out of reach of children.

COMMERCIAL PACK

Eziflo D Capsule: Each box contains 3x10's capsules in blister pack.

Manufactured by



For further query on the use of this medicine, consult to a registered Doctor or Pharmacist.