Eziflo

Tamsulosin Hydrochloride Capsule

Composition

Eziflo 0.4 mg Capsule: Each modified release capsule contains Tamsulosin Hydrochloride USP 0.4 mg.

Pharmacodynamic Properties

Tamsulosin, an alpha-1 adrenoceptor blocking agent, exhibits selectivity for alpha-1 receptors in the prostate gland. Tamsulosin is used to treat the symptoms of an enlarged prostate- a condition technically known as benign prostatic hyperplasia or BPH. The prostate gland surrounds the urethra. If the gland becomes enlarged, then it can squeeze the urethra and interfering with the flow of urine. Tamsulosin relaxes the muscle around urethra as a result freeing the flow of urine and decreasing symptoms of BPH.

Pharmacokinetic Properties

Tamsulosin hydrochloride is extensively bound to plasma proteins (94% to 99%). The time to maximum concentration (Tmax) is reached by 4 to 5 hours under fasting condition. Tamsulosin hydrochloride is extensively metabolized by cytochrome P_{450} enzymes in the liver and less than 10% of the dose is excreted in urine unchanged.

Indications

Eziflo is indicated for the treatment of the signs and symptoms of Benign Prostatic Hyperplasia (BPH).

Dosage & Administration

0.4 mg once daily is recommended as the dose for the treatment of the signs and symptoms of BPH. It should be administered approximately 30 minutes following the same meal each day. For those patients who fail to respond to the 0.4 mg dose after two to four weeks of dosing, the dose can be increased to 0.8 mg once daily. If the administration is discontinued or interrupted for several days at either the 0.4 mg or 0.8 mg dose, therapy should be started again with the 0.4 mg once daily dose. Missed dose should be taken as soon as possible. If it is almost time for the next dose, missed dose should be skipped and the next regularly scheduled dose have to be taken. A double dose of the medicine should not be taken.

Contra-indications

Contraindicated in patients known to be hypersensitive to Tamsulosin HCl or any other component of the products, a history of postural hypotension and Micturition syncope.

Side Effects

Side effects include drowsiness, hypotension (notably postural hypotension), syncope, asthenia, depression, headache, dry mouth, gastrointestinal disturbances (including nausea, vomiting, diarrhea, and constipation), oedema, blurred vision, rhinitis, erectile disorders (including priapism), tachycardia and palpitations. Hypersensitivity reactions including rash, pruritus and angioedema have also been reported.

Precautions

Tamsulosin reduces blood pressure; patients receiving antihypertensive treatment may require reduced dosage and specialist supervision. Caution may be required in the elderly and in patients with hepatic impairment and severe renal impairment.

Drug Interactions

The pharmacokinetic and pharmacodynamic interactions between Tamsulosin and other alpha- adrenergic blocking agents have not been determined. However, interactions may be expected and Tamsulosin should not be used in combination with other apha- adrenergic blocking agents. The pharmacokinetic interaction between Cimetidine and Tamsulosin was investigated. The results indincate significant changes in Tamsulosin clearance (26% decreases) and AUC. Therefore, Tamsulosin should be used with caution in combination with cimetidine, particularly at doses higher than 0.4 mg. Caution should be exercised with concomitant administration of Warfarin and Tamsulosin.

Use in Pregnancy and Lactation

Not applicable for female. Tamsulosin is intended for male patients only.

Storage Condition

Store in a cool and dry place. Keep away from light and out reach of children.

Commercial Pack

Eziflo Capsule: Each box contains 3 alu-alu blister packs of 10 Capsule.

Manufactured by

BIOPHARMA LIMITED
A-116, BSCIC, Industrial Estate
TONGI, GAZIPUR, BANGLADESH

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