Tamurin

Tamsulosin HCl USP

Presentation

Tamurin 0.4 capsule: Each modified release capsule contains Tamsulosin HCl USP 0.4 mg (as modified release pellets).

Description

Tamsulosin is a selective alpha-1A adrenoceptor blocking agent. It is pharmacologically related to other alpha-1A adrenergic receptor blockers Doxazosin, Prazosin, and Terazosin that play action in vascular smooth muscle but Tamsulosin exhibits selectivity with higher affinity to the alpha-1A adrenergic receptor that are mainly located in nonvascular smooth muscle (e.g., prostate). Blockade of these adrenoceptor can cause relaxation of smooth muscle in the bladder neck and prostate resulting in an improvement of urine flow rate and reduction of BPH symptoms.

Under fasting condition, 90% of absorption of Tamsulosin HCl capsule 0.4 mg is achieved & the time for maximum drug concentration (T_{max}) is 4-5 hours where T_{max} is 6-7 hours when administered with food. Tamsulosin HCl is extensively bind to plasma protein (94% to 99%). Less than 10% of the Tamsulosin dose is excreted in urine as unchanged form.

Indication

- **Tamurin** is used to-selectively relaxes prostatic smooth muscle in BPH & improve obstructive symptom (urgent need to urinate, difficulty urination, weak urinary stream and feeling of incomplete bladder emptying including during the middle of the night).
- Facilitate ureteral stone expulsion

Dosage and Administration

Tamurin 0.4 mg capsule once daily is recommended as the dose for the treatment of the signs and symptoms of BPH. It should be administered approximately one-half hour following the same meal each day.

For those patients who fail to respond to the 0.4 mg dose after 2 to 4 weeks of dosing, the dose of **Tamurin** capsule can be increased to 0.8 mg once daily. If capsules 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.

In Ureteral Stone 0.4 mg capsule once daily (average, 1-2 weeks); discontinued after successful stone expulsion.

Renal Impairment

Patients with renal impairment do not require an adjustment in Tamsulosin capsules dosing.

Hepatic Impairment

Mild to moderate hepatic impairment: Dosage adjustment is not necessary for moderate hepatic impaired patients.
Severe hepatic impairment: Not studied.

Side Effect

Dizziness, lightheadedness, drowsiness, runny nose, or ejaculation problems may occur. Allergic reaction including rash, itching especially of the face, tongue, throat, pruritus, urticaria and trouble breathing may occasionally appear. Postural hypotension, palpitations and gastrointestinal reactions (nausea, vomiting, diarrhea, and constipation) & with other alpha-blockers drowsiness, blurred vision, dry mouth or edema may occur. Rarely, males may have a painful or prolonged erection lasting 4 or more hours. If this occurs, stop using this drug and get medical help right away.

Precaution

As with other alpha-1 blockers, a reduction in blood pressure may happen in individual cases during treatment with Tamsulosin, as a result rarely syncope can occur. Orthostatic hypotension (dizziness, weakness) & syncope may cause at the first-dose effect. Tamsulosin HCl capsule should be used with caution in coronary artery disease, liver disease and general anesthesia. Prostatic cancer should be ruled out before therapy is initiated.

Use in Pregnancy & Lactation

Tamsulosin HCl capsule are not indicated for use in women.

Contraindication

Tamsulosin HCl capsule are is contraindicated in patients with known hypersensitivity to Tamsulosin or any component of the product. The capsule should be avoided in patients with a history of orthostatic hypotension (dizziness, weakness) and syncope.

Drug Interaction

Some alpha-blocker such as prazosin, terazosin or drugs used to treat erectile dysfunction or else pulmonary hypertension (e.g, sildenafil, tadalafil, vardenafil) may interact with Tamsulosin. Concomitant use of cimetidine with Tamsulosin and furosemide may rise the plasma level of Tamsulosin and may fall the plasma level of furosemide. Diclofenac and warfarin may increase the elimination rate of Tamsulosin. Simultaneous administration with ketoconazole resulted in an increase in AUC and C_{max} of Tamsulosin HCl.

Overdose

Overdose of Tamsulosin HCl may lead to hypotension. In that case, Blood pressure can be restored and heart rate brought back to normal by lying the patient down. Administration of intravenous fluid should be considered for restoration of blood pressure and normalization of heart rate.

Storage

Store at room temperature (below 30°C) and dry place, protected from direct light and moisture. Keep out of the reach of children.

Commercial Pack

Tamurin 0.4 Capsule: Each box contains modified release Tamsulosin HCl USP 0.4 mg capsules in 4 x 5's alu-alu blister strips.

Manufactured by
Globe
GLOBE PHARMACEUTICALS LTD.
Bangladesh