# TAMSULOSIN HYDROCHLORIDE

# TAMSIA 0.4

400 mcg Prolonged-Release Capsule
ALPHA-ADRENOCEPTOR ANTAGONIST

Rx

**FORMULATION:**
Each capsule contains
Tamsulosin Hydrochloride BP ..... 400 mcg
(as prolonged-release pellets)
Excipients ..... q.s.

**PRODUCT DESCRIPTION:**
Hard gelatin capsule of size "2" with blue cap and clear transparent body containing spherical white to off-white coloured modified release pellets.

**DESCRIPTION:**
Tamsulosin, a selective alpha 1-adrenoceptor blocking agent, exhibits selectivity for alpha-1A receptors in the human prostate. At least, three discrete alpha 1-adrenoceptor subtypes have been identified: alpha-1A, alpha-1B and alpha-1D; their distribution differs between human organs and tissues. Approximately 70% of the alpha 1-adrenoreceptors in human prostate are of the alpha-1A subtype.

**PHARMACOLOGICAL ACTION:**
**Mechanism of Action**
Tamsulosin binds selectively and competitively to postsynaptic alpha 1-receptors, in particular to the subtype alpha-1A, which bring about relaxation of the smooth muscle of the prostate, whereby tension is reduced.

**PHARMACODYNAMICS**
Tamsulosin Hydrochloride increases maximum urinary flow rate by reducing smooth muscle tension in prostate and urethra and thereby relieving obstruction.
It also improves the complex of irritative and obstructive symptoms in which bladder instability and tension of the smooth muscles of the lower urinary tract play an important role. Alpha 1-adrenoceptor blockers can reduce blood pressure by lowering peripheral resistance.

**PHARMACOKINETICS:**
**Absorption**
Tamsulosin Hydrochloride is absorbed from the intestine and is almost completely bioavailable.
Absorption of Tamsulosin Hydrochloride is reduced by a recent meal.
Uniformity of absorption can be promoted by the patient always taking Tamsulosin Hydrochloride after the same meal each day.
Tamsulosin shows linear kinetics.
After a single dose of Tamsulosin Hydrochloride in the fed state, plasma levels of Tamsulosin peak at around 6 hours and, in the steady state, which is reached by day 5 of multiple dosing, $C_{max}$ in patients is about two-thirds higher than that reached after a single dose. Although this was seen in elderly patients, the same finding would also be expected in young ones.
There is a considerable interpatient variation in plasma levels both after single and multiple dosing.

**Distribution**
In man, Tamsulosin is about 99% bound to plasma proteins and volume of distribution is small (about 0.2 L/kg).

**Biotransformation**
Tamsulosin has a low first pass effect, being metabolized slowly. Most Tamsulosin is present in plasma in the form of unchanged drug. It is metabolized in the liver.
No dose adjustment is warranted in hepatic insufficiency.
None of the metabolites are more active than the original compound.

**Elimination**
Tamsulosin and its metabolites are mainly excreted in the urine with about 9% of a dose being present in the form of unchanged drug.
After a single dose of Tamsulosin Hydrochloride in the fed state and in the steady state in patients, elimination half-lives of about 10 and 13 hours, respectively, have been measured.
The presence of renal impairment does not warrant lowering the dose.

**INDICATIONS:**
Tamsulosin Hydrochloride capsules are indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH). Tamsulosin Hydrochloride capsules are not intended for use as an antihypertensive drug.

**DOSAGE AND ADMINISTRATION**
- 400 mcg once daily, approximately one-half hour following the same meal every day. The capsule should be swallowed whole and should not be crunched or chewed.
- If the patient is unable to tolerate 400 mcg, then the patient should receive 200 mcg once daily.
- For patients who fail to respond to 400 mcg, the dose can be increased to 800 mcg once daily.
- If the drug administration is interrupted or discontinued for a few days due to any reason at either 400 mcg or 200 mcg dose, therapy should be started again with the same dose.
- If the patient is receiving 800 mcg once daily and the drug administration is interrupted or discontinued for few days due to any reason, therapy should be started again at 400 mcg once daily.

**CONTRAINDICATIONS:**
Tamsulosin Hydrochloride capsules are contraindicated in patients known to be hypersensitive to Tamsulosin HCl or any component of the capsules.

**WARNINGS AND PRECAUTIONS:**
**General**
Carcinoma of the prostate: Carcinoma of the prostate and BPH cause many of the same symptoms. These two diseases frequently co-exist. Patients should be evaluated prior to the start of Tamsulosin Hydrochloride capsules therapy to rule out the presence of carcinoma of the prostate.

**Information for Patients**
Patients should be told about the possible occurrence of symptoms related to postural hypotension such as dizziness and syncope when taking Tamsulosin and they should be cautioned about driving, operating machinery or performing hazardous tasks. Patients should be advised not to crush, chew or open the Tamsulosin Hydrochloride capsules. Patients should be advised about the possibility of priapism as a result of treatment with Tamsulosin and other similar medications. Patients should be informed that this reaction is extremely rare, but if not brought to immediate medical attention, it can lead to permanent erectile dysfunction (impotence).

**Laboratory Tests**
No laboratory test interactions with Tamsulosin HCl capsules are known. Treatment with Tamsulosin HCl capsules for up to 12 months had no significant effect on prostate-specific antigen (PSA).

**Renal Impairment**
Patients with renal impairment do not require any dosage adjustment in Tamsulosin.

**Hepatic Impairment**
Patients with moderate hepatic dysfunction do not require any dosage adjustment in Tamsulosin.

**PREGNANCY AND LACTATION:**
**Pregnancy**
Pregnancy Category B.
Tamsulosin Hydrochloride capsules are not indicated for use in women.

**Lactation**
Tamsulosin Hydrochloride capsules are not indicated for use in women.

**Pediatric Use**
Tamsulosin Hydrochloride capsules are not indicated for use in pediatric populations.

**DRUG INTERACTIONS**
The pharmacokinetic and pharmacodynamic interactions between Tamsulosin Hydrochloride and other alpha-adrenergic blocking agents have not been determined. However, interactions may be expected and Tamsulosin Hydrochloride should not be used in combination with other alpha-adrenergic blocking agents. Tamsulosin Hydrochloride should be used with caution in combination with cimetidine, particularly at doses higher than 400 mcg. Caution should also be exercised with concomitant administration of warfarin and Tamsulosin Hydrochloride.

**INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION:**
Interaction studies have only been performed in adults.
No interactions have been seen when Tamsulosin Hydrochloride was given concomitantly with either atenolol, enalapril, or theophylline. Concomitant administration with cimetidine brings about a rise in plasma levels of tamsulosin, and furosemide a fall, but as levels remain within the normal range posology need not be changed.
*In vitro* neither diazepam nor propranolol, trichlormethiazide, chlormadinon, amitryptyline, diclofenac, glibenclamide, simvastatin, and warfarin change the free fraction of tamsulosin in human plasma. Neither does tamsulosin change the free fractions of diazepam, propranolol, trichlormethiazide, and chlormadinon.
Diclofenac and warfarin, however, may increase the elimination rate of tamsulosin.
Concomitant administration of tamsulosin hydrochloride with strong inhibitors of CYP3A4 may lead to increased exposure to tamsulosin hydrochloride. Concomitant administration with ketoconazole (a known strong CYP3A4 inhibitor) resulted in an increase in AUC and $C_{max}$ of tamsulosin hydrochloride by a factor of 2.8 and 2.2 respectively.
Tamsulosin hydrochloride should not be given in combination with strong inhibitors of CYP3A4 (e.g., ketoconazole) in patients with poor metabolizer CYP2D6 phenotype.
Tamsulosin hydrochloride should be used with caution in combination with strong (e.g., ketoconazole) and moderate (e.g. erythromycin) inhibitors of CYP3A4.
Concomitant administration of tamsulosin hydrochloride with paroxetine, a strong inhibitor of CYP2D6, resulted in a $C_{max}$ and AUC of tamsulosin that had increased by a factor of 1.3 and 1.6, respectively, but these increases are not considered clinically relevant.
There is a theoretical risk of enhanced hypotensive effect when given concurrently with drugs which may reduce blood pressure including anaesthetic agents, other alpha1-adrenoceptor antagonists.

**ADVERSE DRUG REACTIONS:**
The more common side effects reported with Tamsulosin HCl include abnormal ejaculation, back pain, chest pain, cough, diarrhea, dizziness, headache, infection, nausea, runny nose, sinus problems, sleepiness, sore throat, weakness. The less common side effects may include decreased sex drive, insomnia, vision problems, priapism, syncope, constipation, orthostatic hypotension, vertigo, vomiting and palpitations.

**OVERDOSE AND TREATMENT:**
If overdosage of Tamsulosin HCl lead to hypotension, support of the cardiovascular system is of first importance. Restoration of blood pressure and normalization of heart rate may be accomplished by keeping the patient in the supine position. If this measure is inadequate, then administration of intravenous fluids should be considered. If necessary, vasopressors should then be used and renal function should be monitored and supported as needed. Laboratory data indicate that Tamsulosin HCl is 94% to 99% protein bound; therefore, dialysis is unlikely to be of benefit. One patient reported an overdose of thirty 400 mcg Tamsulosin HCl capsules. Following the ingestion of the capsules, the patient reported a severe headache.

**CAUTION:**
Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph. Seek medical attention immediately at the first sign of any adverse drug reaction.

**STORAGE CONDITION:**
Store at temperatures not exceeding 30°C.
Protect from light & moisture.

**Keep all medicines out of the reach of children.**

**AVAILABILITY:**
Alu/Alu Blister Pack x 10's (Box of 30's).

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