PRINT
127 mm x 187 mm

TAMSULOSIN
AMSO

400 mcg Prolonged-Release Capsule
ALPHA-1-ADRENOCEPTOR BLOCKER

Formulation/Composition:
Each capsule contains:
Tamsulosin Hydrochloride BP.....400 mcg
(As modified release pellets)

Product Description:
Tamsulosin hydrochloride is an antagonist of alpha1A adrenoreceptors in the prostate. It works by relaxing muscles in the prostate and bladder, which helps to improve urine flow and reduce symptoms of BPH.

Pharmacology:
General
The symptoms associated with benign prostatic hyperplasia (BPH) are related to bladder outlet obstruction, which is comprised of two underlying components: static and dynamic. The static component is related to an increase in prostrate size caused, in part, by a proliferation of smooth muscle cells in the prostatic stroma. However the severity of BPH symptoms and the degree of urethral obstruction do not correlate well with the size of the prostrate. Tamsulosin Hydrochloride, an alpha1 adrenoreceptor blocking agent, exhibits selectivity for alpha1 receptors in the human prostrate. At least three discrete alpha 1 – adrenoreceptor subtypes have been identified: alpha 1A, alpha 1B and alpha 1D; their distribution differs between human organs and tissue. Approximately 70% of the alpha 1 – receptors in human prostrate are of the alpha 1A subtype. Tamsulosin Hydrochloride capsules are not intended for use as an antihypertensive drug.
Pharmacokinetics
Tamsulosin Hydrochloride is absorbed from the gastrointestinal tract and is almost completely bioavailable. The extend and rate of absorption are reduced by food. After oral doses of an immediate-release preparation, peak plasma concentration occur after about 1 hour. Tamsulosin Hydrochloride is about 99% bound to plasma proteins. It is metabolised slowly in the liver primarily by the cytochrome P450 isoenzymes CYP2D6 and CYP3A4; it is excreted mainly in the urine as metabolites and some unchanged drug. The plasma elimination half-life has been reported to be between 4 and 5.5 hours.
Some of the pharmacokinetic values cited above may be altered when Tamsulosin Hydrochloride is given as modified-release preparation, the form in which it is usually used; for instance, peak plasma concentrations occur about 6 hours after a dose and the apparent elimination half-life may be 10 to 15 hours.
Indications and Usage
Benign Prostatic Hyperplasia (BPH) Treatment
Tamsulosin Hydrochloride Capsules are indicated for the treatment of symptomatic BPH in men with an enlarged prostate. Relax smooth muscle in benign prostatic hyperplasia producing an increase in urinary flow-rate and an improvement in obstructive symptoms.
Dosage and Mode of Administration
Tamsulosin Hydrochloride Capsules 400 mcg 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 400 mcg dose after two to four weeks of dosing, the dose of Tamsulosin Hydrochloride capsules can be increase to 800 mcg once daily. If Tamsulosin Hydrochloride capsules administration is discontinued or interrupted for several days at either the 400 mcg or 800 mcg dose, therapy should be started again with the 400 mcg once daily dose.

Contraindications:
Patients with previously demonstrated, clinically significant hypersensitivity (e.g., serious skin reactions, angiodema) to, tamsulosin, other 5 alpha-reductase inhibitors, or any other component of Tamsulosin Hydrochloride blockers should be avoided in patients with a history of postural hypotension and micturition syncope.
Adverse Effects
The side-effects reported in ≥2% of patients with Tamsulosin Hydrochloride include abnormal ejaculation, back pain, chest pain, cough, include drowsiness, hypotension (notably postural hypotension), syncope, asthenia, depression, diarrhoea, constipation, dizziness, headache, infection, nausea, vomiting tooth disorder, libido decreased, insomnia, somnolence, rhinitis, pharyngitis, sinusitis, asthenia, blurred vision, dry mouth, gastro-intestinal disturbances oedema, blurred vision, rhinitis, erectile disorders (including priapism), tachycardia, and palpitations. Hypersensitivity reactions including rash, pruritus and angioedema have also been reported.
Swelling of face, tongue, or throat.
Decreased blood pressure. Tamsulosin Hydrochloride may cause a sudden drop in your blood pressure upon standing from a sitting or lying position, especially at the start of treatment.

Warnings:
Since selective alpha-blockers reduce blood pressure, patients receiving antihypertensive treatment may require reduced dosage and specialist supervision.
Thesigns and symptoms of orthostasis (postural hypotension, dizziness and vertigo) were detected more frequently in Tamsulosin Hydrochloride capsule treated patients than in placebo recipients. As with other alpha-adrenergic blocking agents there is a potential risk of syncope.
Patients beiginning treatment with Tamsulosin Hydrochloride capsules should be cautioned to avoid situations where injury could result should syncope occur. Rarely (probably less than one in fifty thousand patients), Tamsulosin Hydrochloride, like other alpha1 antagonists, has been associated with priapism (persistent painful penile erection unrelated to sexual activity). Because this condition can lead to permanent impotence if not properly treated, patients must be advised about the seriousness of the condition.

Precaution:
As with other α¬1-adrenoreceptor antagonists, a reduction in blood pressure can occur in individual cases during treatment with Tamsulosin Hydrochloride, as a result of which, rarely, syncope can occur. At the first signs of orthostatic hypotension (dizziness, weakness), the patient should sit or lie down until the symptoms have disappeared.
Use Tamsulosin Hydrochloride with caution. Do not drive or perform other possibly unsafe tasks until you know how you react to it. It may take up to 2 to 4 weeks for Tamsulosin Hydrochloride to work fully. Do not stop using Tamsulosin Hydrochloride or change your dose of Tamsulosin Hydrochloride without checking with your doctor. Caution may be required in the elderly and in patients with hepatic impairment.

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. Tamsulosin hydrochloride should be used with caution in combination with strong and moderate inhibitors of CYP3A4.
Overdose and Treatment
Over dosage with Tamsulosin Hydrochloride could potentially lead to hypotension due to the Tamsulosin Hydrochloride component. In case of hypotension, support of the cardiovascular system is of the 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. Dialysis is unlikely to be of benefit.

Availability: Alu – Alu Blister pack x 10's and 30's in a box.
Storage Condition: Store at Temperatures not exceeding 30°C.
Keep all medicines out of reach of children.
Caution: Foods, Drugs, Devices and Cosmetics Act, prohibits dispensing without prescription.
ADR Statement: For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph
Reg. No.: DRP-3940

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