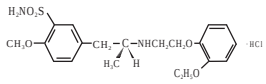
TAMISO™ MR Capsules

(Tamsulosin HCl)

DESCRIPTION:

Tamsulosin HCl is an antagonist of alpha-lA adrenoceptors in the prostate. Tamsulosin HCl is (-)-(R)-5-[2-[[2-(o-Ethoxyphenoxy)ethyl]amino]propyl]-2- methoxybenzenesulfonamide, monohydrochloride. Tamsulosin HCl is a white crystalline powder that melts with decomposition at approximately 230°C. It is sparingly soluble in water and methanol, slightly soluble in glacial acetic acid and ethanol, and practically insoluble in ether. The empirical formula of tamsulosin HCl is $C_{20}H_{28}N_2O_5S$ HCl. The molecular weight of tamsulosin HCl is 444.98. Its structural formula is:



COMPOSITION:

Each capsule contains:

Modified release Tamsulosin HCl pellets MS equivalent to Tamsulosin HCl USP.....0.4mg

CLINICAL PHARMACOLOGY:

Mode of Action:

Tamsulosin HCl, an alpha-I adrenoceptor blocking agent, exhibits selectivity for alpha-I receptors in the human prostate. Smooth muscle tone is mediated by the sympathetic nervous stimulation of alpha-I adrenoceptors, which are abundant in the prostate, prostatic capsule, prostatic urethra and bladder neck. Blockade of these adrenoceptors can cause smooth muscles in the bladder neck and prostate to relax, resulting an improvement in urine flow rate and a reduction in symptoms of BPH

Pharmacokinetics:

Absorption

Absorption of tamsulosin HCl capsules 0.4mg is essentially complete (>90%) following oral administration under fasting conditions. The time to maximum concentration (T_{max}) is reached by four to five hours under fasting conditions and by six to seven hours when tamsulosin HCl capsules are administered with food. Taking tamsulosin HCl capsules under fasted conditions results in a 30% increase in bioavailability (AUC) and 40% to 70% increase in peak concentrations (C_{max}) compared to fed conditions. Tamsulosin HCl is extensively bound to human plasma proteins (94% to 99%), primarily alpha-1 acid glycoprotein (AAG), with linear binding over a wide concentration range (20 to 600ng/mL)

Metabolism

Tamsulosin HCl is extensively metabolized by cytochrome P450 enzymes in the liver and less than 10% of the dose is excreted in urine unchanged. The metabolites of tamsulosin HCl undergo extensive conjugation to glucuronide or sulfate prior to renal excretion

Excretion

The elimination half-life of in plasma ranged from five to seven hours

For Geriatrics Population

Pharmacokinetic disposition of tamsulosin HCl may be slightly prolonged in geriatric males compared to young healthy males

INDICATIONS AND USAGE:

TAMISO™ MR (Tamsulosin HCl) capsules are indicated for the treatment of the signs and symptoms of Benign Prostatitis Hyperplasia (BPH)

CONTRAINDICATIONS:

Tamsulosin HCl capsules are contraindicated in patients known to be hypersensitive to tamsulosin HCl or any component of tamsulosin HCl capsules

DOSAGE AND ADMINISTRATION:

TAMISO™ MR (Tamsulosin HCl) capsules 0.4mg 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 0.4mg dose after two to four weeks of dosing, the dose of tamsulosin HCl capsules can be increased to 0.8mg once daily. If tamsulosin HCl capsules administration is discontinued or interrupted for several days at either the 0.4mg or 0.8mg dose, therapy should be started again with the 0.4mg once daily dose

OR

As directed by the physician

Patients with renal dysfunction and hepatic dysfunction do not require an adjustment in tamsulosin HCl dosage

ADVERSE REACTION:

The following adverse reactions have been reported during the use of tamsulosin HCl:

Headache, infection, asthenia, back pain, chest pain, dizziness, somnolence, insomnia, decreased libido, rhinitis, pharyngitis, increased cough, sinusitis, diarrhoea, nausea, tooth disorder, abnormal ejaculation and blurred vision

WARNINGS:

- The signs and symptoms of orthostasis (postural hypotension, dizziness and vertigo) are found more frequently in tamsulosin HCl capsule-treated patients
- Patients beginning treatment with tamsulosin HCl capsules should be cautioned to avoid situations where injury could result should syncope occur
- Doses of tamsulosin HCl capsule higher than 0.4mg (e.g. 0.8mg) should not be used in combination with strong inhibitors of CYP3A4 (e.g. ketoconazole)
- Rarely (probably less than 1 in 50,000 patients), tamsulosin HCl, like other alpha-I 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

PRECAUTIONS:

Carcinoma of the Prostate: Patients should be evaluated prior to the start of tamsulosin HCl capsules therapy to rule out the presence of carcinoma of the prostate

DRUG INTERACTIONS:

Cytochrome p450 Inhibition: Tamsulosin HCl should be used with caution in combination with moderate or strong inhibitors of CYP2D6 or CYP3A4, particularly at doses higher than 0.4mg

Warfarin: Caution should be exercised with concomitant administration of warfarin and tamsulosin HCl capsules

Cimetidine: Tamsulosin HCl capsules should be used with caution in combination with cimetidine, particularly at doses higher than 0.4mg

PRESENTATION:

TAMISO™ MR 0.4mg capsules in a pack of 10's

STABILITY:

See expiry on the pack

INSTRUCTION:

Keep out of reach of children

Avoid exposure to heat, light and humidity

Store between 15 to 30°C

Improper storage may deteriorate the medicine

Manufactured by:
SAMI Pharmaceuticals (Pvt.) Ltd.
F-95, S.I.T.E., Karachi-Pakistan
www.samipharmapk.com

ٹیمیسو™ ایم آر کیپسول

(ٹیمسولوسن ہائیڈروکلورائیڈ)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں

بچوں کی پہنچ سے دور رکھیں

دوا کو دھوپ، گرمی اور نمی سے محفوظ ۱۵ سے ۳۰ ڈگری سینٹی گریڈ کے درمیان میں رکھیں ورنہ دوا خراب ہو جائیگی