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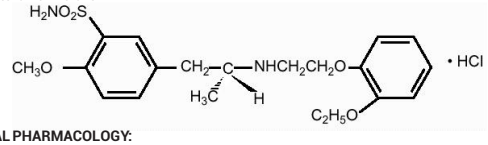
MAXFLOW™ 0.4 mg Capsule
(Tamsulosin HCl)

میکس فلو

COMPOSITION:
Each capsule contains:
Sustained release pellets of Tamsulosin HCl eq. to
Tamsulosin HCl USP ..... 0.4 mg.

Product Specs.: USP

DESCRIPTION:
Tamsulosin hydrochloride is an antagonist of alpha1A adrenoceptors in the prostate. Tamsulosin hydrochloride is (-)-(R)-5-[2-[[2-(o-Ethoxyphenoxy) ethyl]amino]propyl]-2-methoxybenzenesulfonamide, monohydrochloride. Tamsulosin hydrochloride 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 hydrochloride is $C_{20}H_{28}N_2O_5S$ HCl. The molecular weight of tamsulosin hydrochloride is 444.98
Its structural formula is:



CLINICAL PHARMACOLOGY:
Mechanism of Action:
Tamsulosin, an alpha1 adrenoceptor blocking agent, exhibits selectivity for alpha1 receptors in the human prostate. At least three discrete alpha1 adrenoceptor subtypes have been identified: alpha1A, alpha1B, and alpha1D; their distribution differs between human organs and tissue. Approximately 70% of the alpha1 receptors in the human prostate are of the alpha1A subtype. MAXFLOW capsules are not intended for use as an antihypertensive drug.
Pharmacokinetics:
Absorption:
Absorption of tamsulosin hydrochloride from MAXFLOW capsules 0.4 mg is essentially complete (>90%) following oral administration under fasting conditions. Tamsulosin hydrochloride exhibits linear kinetics following single and multiple dosing, with achievement of steady-state concentrations by the fifth day of once-a-day dosing.
Distribution:
The mean steady-state apparent volume of distribution is 16 L, which is suggestive of distribution into extracellular fluids in the body. Tamsulosin hydrochloride is extensively bound to human plasma proteins (94% to 99%).
Metabolism:
Tamsulosin hydrochloride is extensively metabolized by cytochrome P450 enzymes in the liver and less than 10% of the dose is excreted in urine unchanged.
Elimination:
On oral administration urine (76%) representing the primary route of excretion compared to feces (21%) over 168 hours,
The apparent half-life of tamsulosin hydrochloride is approximately 9 to 13 hours in healthy volunteers and 14 to 15 hours in the target population.
Pharmacokinetics in Special Populations :
Renal Impairment:
The pharmacokinetics of tamsulosin hydrochloride have been compared in 6 subjects with mild-moderate (30 CLcr <70 mL/min/1.73 m^2) or moderate-severe (10 CLcr <30 mL/min/1.73 m^2) renal impairment and 6 normal subjects (CLcr >90 mL/min/1.73 m^2). Patients with renal impairment do not require an adjustment in MAXFLOW capsules dosing. However, patients with end-stage renal disease (CLcr <10 mL/min/1.73 m^2) have not been studied.

INDICATIONS AND USAGE:
MAXFLOW (tamsulosin hydrochloride) capsules are indicated for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH). MAXFLOW capsules are not indicated for the treatment of hypertension.

DOSAGE AND ADMINISTRATION:
MAXFLOW capsules 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 one-half hour following the same meal each day.
***Administration*:**
For those patients who fail to respond to the 0.4 mg dose after 2 to 4 weeks of dosing, the dose of MAXFLOW capsules can be increased to 0.8 mg once daily. MAXFLOW capsules 0.4 mg should not be used in combination with strong inhibitors of CYP3A4 (e.g., ketoconazole)
If MAXFLOW 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.

CONTRAINDICATIONS:
MAXFLOW capsules are contraindicated in patients known to be hypersensitive to tamsulosin hydrochloride. Reactions have included skin rash, urticaria, pruritus, angioedema, and respiratory symptoms

WARNINGS AND PRECAUTIONS:
***Orthostasis*:**
As with other alpha adrenergic blocking agents there is a potential risk of syncope . Patients beginning treatment with MAXFLOW capsules should be cautioned to avoid situations in which injury could result should syncope occur.
Priapism:
Rarely tamsulosin, 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.
Screening for Prostate Cancer:
Prostate cancer and BPH frequently co-exist; therefore, patients should be screened for the presence of prostate cancer prior to treatment with MAXFLOW capsules and at regular intervals afterwards.
Intraoperative Floppy Iris Syndrome:
Intraoperative Floppy Iris Syndrome (IFIS) has been observed during cataract and glaucoma surgery in some patients on or previously treated with alpha1 blockers, including tamsulosin. IFIS may increase the risk of eye complications during and after the operation.
Sulfa Allergy:
If a patient reports a serious or life-threatening sulfa allergy, caution is warranted when administering MAXFLOW capsules.

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DRUG INTERACTIONS:
Cytochrome P450 Inhibition: Strong and Moderate Inhibitors of CYP3A4 or CYP2D6 Tamsulosin is extensively metabolized, mainly by CYP3A4 and CYP2D6. There is a potential for significant increase in tamsulosin exposure when MAXFLOW 0.4 mg is co -administered with a combination of both CYP3A4 and CYP2D6 inhibitors.
Cimetidine: Treatment with cimetidine results in a significant decrease in the clearance of tamsulosin hydrochloride, which results in a moderate increase in tamsulosin hydrochloride AUC.
Other Alpha Adrenergic Blocking Agents: Interactions between MAXFLOW capsules and other alpha adrenergic blocking agents may be expected.
PDE5 Inhibitors: Caution is advised when alpha adrenergic blocking agents including MAXFLOW are co-administered with PDE5 inhibitors. Concomitant use of these two drug classes can potentially cause symptomatic hypotension.
Warfarin: Caution should be exercised with concomitant administration of warfarin and MAXFLOW capsules
Nifedipine, Atenolol, Enalapril: Dosage adjustments are not necessary.
Digoxin and Theophylline: Dosage adjustments are not necessary.
Furosemide: Concomitant administration do not require adjustment of the MAXFLOW capsules dosage.

USE IN SPECIFIC POPULATIONS:
Pregnancy Category B: MAXFLOW capsules are not indicated for use in women.
***Nursing Mothers*:** MAXFLOW capsules are not indicated for use in women.
***Pediatric Use*:** MAXFLOW capsules are not indicated for use in pediatric populations.
***Geriatric Use*:** No overall differences in safety or effectiveness observed elderly subjects and younger patients, but greater sensitivity of some older individuals cannot be ruled out
***Patients with Renal Impairment*:** Patients with renal impairment do not require an adjustment in tamsulosin dosing. However, patients with end-stage renal disease (CLcr <10 mL/min/1.73 m^2) have not been studied.
***Patients with Hepatic Impairment*:** Patients with moderate hepatic impairment do not require an adjustment in MAXFLOW capsules dosage. MAXFLOW has not been studied in patients with severe hepatic impairment.

ADVERSE REACTIONS:
The most common adverse events noted are headache, dizziness, rhinitis, infection, abnormal ejaculation, asthenia, back pain, diarrhea, pharyngitis, chest pain, cough increased, somnolence, nausea, sinusitis, insomnia, libido decreased, tooth disorder, and blurred vision

OVERDOSAGE:
Should over dosage of MAXFLOW capsules 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 hydrochloride is 94% to 99% protein bound; therefore, dialysis is unlikely to be of benefit.

INSTRUCTIONS:
- Store below 30°C.
- Protect from heat, sunlight & moisture.
- Keep out of the reach of children.
- To be sold on prescription of a registered medical practitioner only.

PRESENTATION:
MaxFlow Capsules 0.4 mg : Pack of 2 x 10 capsules.

ہدایات:
۳۰ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
گرمی، دھوپ اور نمی سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔
صرف ڈاکٹر کے نسخہ پر فروخت کریں۔

FOR FURTHER INFORMATION PLEASE CONTACT:

Manufactured by:
CCL Pharmaceuticals (Pvt.) Ltd.
62 Industrial Estate, Kot Lakhpat, Lahore, Pakistan.
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