# Maxrin™

Tamsulosin Hydrochloride BP 0.4 mg

**COMPOSITION**
Each modified release capsule contains Tamsulosin Hydrochloride BP 0.4 mg (as modified release pellets).

**PHARMACOLOGY**
Tamsulosin, a selective alpha$_1$ adrenoceptor blocking agent, exhibits its selectivity for alpha$_{1A}$ adrenoceptors in human prostate. Blockade of these adrenoceptors can cause smooth muscle in the bladder neck and prostate to relax, resulting in an improvement in urine flow rate and a reduction in symptoms of BPH. Absorption of Tamsulosin Hydrochloride capsules 0.4 mg is essentially complete (90%) following oral administration under fasting condition. The time to maximum concentration (Tmax) is reached by four to five hours under fasting conditions and by six to seven hours when administered with food. Tamsulosin Hydrochloride is extremely bound to human plasma protein (94% to 99%). Tamsulosin Hydrochloride is extensively metabolized by cytochrome P 450 enzymes in the liver and less than 10% of the dose is excreted in urine as unchanged form. Following intravenous or oral administration of an immediate-release formulation the elimination half-life of Tamsulosin Hydrochloride in plasma ranges from five to seven hours. Because of the absorption rate controlled pharmcokinetics with **Maxrin**™ Capsule, 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.

**INDICATION**
**Maxrin**™ (Tamsulosin Hydrochloride) capsule is indicated for the treatment of the signs and symptoms of Benign Prostatic Hyperplasia (BPH).

**DOSAGE AND ADMINISTRATION**
The recommended dose of **Maxrin**™ capsule is 0.4 mg once daily. It should be administered approximately half/hour following the same meal each day. For those patients who fail to respond to the 0.4 mg dose after two to four weeks of dosing, the dose of **Maxrin**™ capsules can be increased to 0.8mg once daily. If **Maxrin**™ 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.

**CONTRAINDICATION & PRECAUTION**
Hypersensitivity to Tamsulosin Hydrochloride. A history of orthostatic hypotension; severe hepatic insufficiency.
As with other alpha$_1$ blockers, a reduction in blood pressure can occur in individual cases during treatment with Tamsulosin, 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. And they should be cautioned to avoid situations where injury could result (like driving, operating machinery or performing hazardous tasks).
Before therapy with Tamsulosin is initiated the patient should be examined in order to exclude the presence of other conditions which can cause the same symptoms as Benign Prostatic Hyperplasia. Digital rectal examination and when necessary determination of Prostate Specific Antigen (PSA) should be performed before treatment and at regular intervals afterwards.
The treatment of severely renal impaired patients (creatinine clearance is less than 10 ml/min) should be approached with caution as these patients have not been studied.

**SIDE EFFECT**
The following adverse reactions have been reported during the use of Tamsulosin: dizziness, abnormal ejaculation, and less frequently (1-2%) headache, asthenia, postural hypotension, palpitations, and rhinitis.
Gastrointestinal reactions such as nausea, vomiting, diarrhoea, and constipation can occasionally occur. Hypersensitivity reactions such as rash, pruritus, and urticaria can occur occasionally. As with other alpha-blockers, drowsiness, blurred vision, dry mouth, or edema can occur. Syncope has been reported rarely, and there have been very rare reports of angioedema and priapism.

**DRUG INTERACTION**
No interactions have been seen when Tamsulosin was given concomitantly with either atenolol, enalapril, nifedipine or theophylline. Concomitant cimetidine brings about a rise in plasma levels of Tamsulosin, and frusemide a fall, but as levels remain within the normal range posology does not need to be changed.
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.
There is a theoretical risk of enhanced hypotensive effect when given concurrently with drugs which may reduce blood pressure, including anaesthetic agents and other alpha$_1$ adrenoceptor antagonists.

**USE IN PREGNANCY AND LACTATION**
Tamsulosin Hydrochloride capsules are not indicated for use in women.

**PEDIATRIC USE**
Tamsulosin Hydrochloride capsules are not indicated for use in pediatric populations.

**OVERDOSE**
As overdose of Tamsulosin Hydrochloride capsules lead to hypotension, support the cardiovascular system is of first importance. Restoration of blood pressure and normalization of heart rate may be accomplished by keeping the patient in supine position. If this measure is inadequate, then administration of intravenous fluid should be considered. Measures, such as emesis, can be taken to impede absorption. When large quantities are involved, gastric lavage can be applied and activated charcoal and an osmotic laxative, such as sodium sulphate, can be administered.

**STORAGE**
Store in a cool (below $30^0$ C) and dry place, protected from light and moisture. Keep out of reach of children.

**HOW SUPPLIED**
**Maxrin**™ Capsule: Box containing 30 capsules in blister pack.

*Manufactured by*
**SQUARE**
**PHARMACEUTICALS LTD.**
**BANGLADESH**