Only for the use of Medical Professionals

Sasolin® MR

Tamsulosin hydrochloride

Description:

Sasolin® MR is the preparation of Tamsulosin Hydrochloride; which is a selective, potent and competitive a1-adrenoceptor antagonist and that it has a greater affinity for the a1A and a1D -receptor subtype, predominantly present in the prostate. Tamsulosin Hydrochloride binding to the a1-adrenoceptors in the prostate results in relaxation of prostate smooth muscle followed by improvements in urodynamics. Thus, Tamsulosin Hydrochloride increases maximum urinary flow rate by reducing smooth muscle tension in the prostate and urethra and thereby relieving obstruction. It also improves the symptoms related to bladder instability and tension of the smooth muscle of the lower urinary tract.

Indication:

Sasolin® MR capsule is indicated for the treatment of the signs and symptoms of Benign Prostatic Hyperplasia (BPH).

Dosage and administration:

Adults:

The recommended starting dose is 1 capsule (0.4mg) once daily, half an hour following the same meal each day. Patients who fail to respond after two to four weeks, the dose can be increased to 2 capsules (0.8mg) once daily. If therapy is discontinued or interrupted for several days at either the 0.4mg or 0.8mg dose, therapy should be started again with 1 capsule (0.4mg) once daily dose.

Children:

Sasolin® MR capsule is not indicated for use in pediatric populations.

Use in pregnancy & lactation:

Sasolin® MR capsule is intended for use only in males.

Precautions:

As with other alpha1-blockers, reduction in blood pressure can occur in individual cases during treatment with Tamsulosin Hydrochloride 0.4mg, as a result of which, very 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. Before therapy with Tamsulosin Hydrochloride 0.4mg 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 of < 10ml/min) should be approached with caution as these patients have not been studied.

Contraindications:

Hypersensitivity to Tamsulosin Hydrochloride or any other component of the product; patient with history of orthostatic hypotension and severe hepatic insufficiency.

Side effects:

The following adverse reactions have been reported during the use of Tamsulosin Hydrochloride: dizziness, abnormal ejaculation and less frequently headache, asthenia, postural hypotension, palpitations and rhinitis. Gastrointestinal reactions such as nausea, vomiting, diarrhea, and constipation can occasionally occur. Hypersensitivity reactions such as rash, pruritus, and urticaria can occur occasionally. As with other a1- 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 interactions:

No interactions have been seen when Tamsulosin was given concomitantly with 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. There is a theoretical risk of enhanced hypotensive effect when given concurrently with drugs which may reduce blood pressure, including anesthetic agents and other a1-adrenoceptor antagonists.

Overdose:

As overdose of Tamsulosin Hydrochloride leads 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.

Pharmaceutical precautions:

Store in a cool and dry place. Protect from light.

Presentation:

Sasolin® MR Capsule: Each capsule contains Tamsulosin Hydrochloride INN 0.4 mg as modified release pellets.

Package quantities: Sasolin® MR Capsule: Carton of 16 capsules in blister.

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ACI Limited

Narayanganj, Bangladesh