Prostanil MR

Tamsulosin Hydrochloride BP 0.4 mg

Composition:
Prostanil MR Capsule: Each capsule contains Tamsulosin Hydrochloride modified release pellets equivalent to Tamsulosin Hydrochloride BP 0.4 mg.

Pharmacology:
Tamsulosin is a selective alpha$_1$ adrenoceptor antagonist. Tamsulosin binds selectively and competitively to postsynaptic alpha$_1$ adrenoceptors, in particular to subtypes alpha$_{1A}$ and alpha$_{1D}$. It relieves obstruction by relaxing smooth muscle in prostate and urethra. Thus it increases the maximum urinary flow rate. It also improves the irritative symptoms in which bladder instability plays an important role. Tamsulosin is rapidly absorbed from the intestine and is almost completely bioavailable. Tamsulosin and its metabolites are mainly excreted in the urine with about 9% of a dose being present in the form of unchanged medicine.

Indications:
Prostanil MR is indicated for the treatment of the signs and symptoms of Benign Prostatic Hyperplasia (BPH).

Dosage & administration:
The recommended dose is 0.4 mg once daily. It should be taken after breakfast or the first meal of the day. If necessary, the dose may be increased to 0.8 mg once daily after 2-4 weeks. If 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. The capsule should be swallowed whole with a drink of water (about 150 ml). Uniformity of absorption can be promoted by the patient always taking tamsulosin after the same meal. It should not be crushed or chewed, as this will interfere with the modified release of the active ingredient. No dosage adjustment is warranted in hepatic insufficiency.

Side effects:
The following adverse reactions have been reported during the use of Tamsulosin: dizziness, abnormal ejaculation and less frequently headache, asthenia, postural hypotension and palpitations. During cataract surgery, a variant of small pupil syndrome known as Intra-operative Floppy Iris Syndrome (IFIS) has been reported during post-marketing surveillance in association with alpha$_1$ adrenoreceptor antagonist therapy.

Precautions:
As with other alpha$_1$ adrenoreceptor antagonist, 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. 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 BPH. Tamsulosin should be avoided in severe hepatic impaired patients. The treatment of severe renal impaired patients (creatinine clearance below 10 ml/min) should be approached with caution, as these patients have not been studied.
Prostate cancer and BPH frequently co-exist; therefore, patients should be screened for the presence of prostate cancer prior to treatment with Tamsulosin capsules and at regular intervals afterwards.

Contraindications:
It is contraindicated in patients known to be hypersensitive to Tamsulosin Hydrochloride or any component of the product, a history of orthostatic hypotension and severe hepatic insufficiency.

Drug interactions:
Concomitant treatment with Ketoconazole, Cimetidine and Paroxetine bring about a rise in plasma levels of Tamsulosin, and Frusemide a fall, but as levels remain within the normal range dosage schedule does not need to be changed. Interaction may be expected with alpha-adrenoceptor antagonists. Diclofenac & Warfarin, however, may increase the elimination rate of Tamsulosin.

Use in special groups:
Use in pregnancy and lactation: It is not indicated for use in women.
Use in children: It is not indicated for use in pediatrics.

Overdose:
Acute overdose with 5 mg Tamsulosin Hydrochloride has been reported. Acute hypotension (systolic blood pressure 70 mm Hg), vomiting and diarrhea were observed, which were treated with fluid replacement. If acute hypotension occurs after overdose, cardiovascular support should be given and maintained. Blood pressure can be restored and heart rate brought back to normal by lying the patient down. If this is insufficient then volume expander and, when necessary, vasopressors could be administered. Renal function should be monitored and general supportive measures should be applied. Dialysis is unlikely to be of help as tamsulosin is very highly bound to plasma proteins. Measures to impede absorption, such as emesis, can be taken. When large quantities of tamsulosin are involved, gastric lavage can be applied and activated charcoal and an osmotic laxative, such as sodium sulphate, can be administered.

Storage:
- Store below 30^{0}C, keep in dry place & protect from light.
- Keep out of the reach of children.

Packing:
Prostanil MR Capsule: Each box contains 30's capsule in alu-alu blister pack.

Manufactured by:
ARISTOPHARMA LTD.
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