Prostam®

(Tamsulosin HCl)

Highnoon

COMPOSITION

Prostam 0.4mg Capsule: Each capsule contains:
Tamsulosin HCl (sustained release pellets) 0.4mg

DESCRIPTION

Tamsulosin hydrochloride is an alpha1- adrenoceptor blocking agent in prostate.

MECHANISM OF ACTION

Tamsulosin, an alpha1- adrenoceptor blocking agent, exhibits selectively for alpha1- receptors in the human prostate. Smooth muscle tone is mediated by sympathetic nervous stimulation of alpha1- adrenoceptors, which are abundant in the prostate, prostatic capsule, prostatic urethra and bladder neck. Blockage 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.

PHARMACOKINETICS

Tamsulosin is absorbed from the gastrointestinal tract and is almost completely bioavailable. The extent and rate of absorption are reduced by food. After oral doses of an immediate-release preparation, peak plasma concentrations occur after 1 hour. Tamsulosin is about 99% bound to plasma proteins. It is metabolised slowly in the liver primarily by the cytochrome P450 isoenzymes CYP2D6 and CYP3A4.

It is excreted mainly in the urine as metabolites and some unchanged drug. The plasma elimination half life has been reported to be between 4 and 5.5 hours.

INDICATIONS

- It is used in benign prostatic hyperplasia to relieve symptoms of urinary obstruction.
- It is not indicated for the treatment of hypertension.

DOSAGE AND ADMINISTRATION

In benign prostatic hyperplasia it is given orally in a modified release formulation, in a dose of 0.4 mg once daily. The dose may be increased after 2 to 4 weeks, if necessary, to 0.8 mg once daily. It should be administered approximately one-half hour following the same meal each day.

ADVERSE REACTIONS

The reported adverse events are; are dizziness, headache, malaise, hypotension, chest pain, back pain, infection (cold, common cold, flu and flu like symptoms), asthenia, somnolence, insomnia, decreased libido, rhinitis (nasal congestion, stuffy nose, runny nose, sinus congestion and hay fever), pharyngitis, increased cough, sinusitis, diarrhea, nausea, tooth disorder, abnormalities of ejaculation, blurred vision and Stevens-Johnson Syndrome very rarely. A syndrome of flaccidity of iris, progressive miosis, and potential prolapse (intraoperative floppy iris syndrome; IFIS) had been reported in some patients undergoing cataract surgery who were taking or had taken alpha blockers.

The additional reported adverse events are; allergic-type reactions such as skin rash, urticaria, pruritus, angioedema, dyspnea, palpitations, atrial fibrillation, arrhythmia, tachycardia, skin desquamation, erythema multiforme, dermatitis exfoliative, constipation, vomiting, dry mouth, and epistaxis.

CONTRAINDICATIONS

It is contraindicated in patients with;

- Known hypersensitivity to Tamsulosin hydrochloride or any of its components. Reactions have included skin rash, urticaria, pruritus, angioedema, and respiratory symptoms.
- History of orthostatic hypotension.
- Taking other alpha adrenergic blocking agents.
- Severe hepatic insufficiency.
- History of micturition syncope.

PRECAUTIONS

- A reduction in the blood pressure can occur in individual treated with alpha1- blockers (Tamsulosin hydrochloride), as a result of which syncope can occur. The sign and symptoms of orthostasis (postural hypotension, dizziness and vertigo), the patient should sit or lie down until the symptoms have disappeared. Patients beginning treatment with tamsulosin should be cautioned to avoid situations in which injury could result should syncope occur.
- It should be used with caution in combination with moderate inhibitors of CYP3A4 (e.g., erythromycin), in combination with strong (e.g., paroxetine) or moderate (e.g., terbinafine) inhibitors of CYP2D6, in patients known to be CYP2D6 poor metabolizers particularly at a dose higher than 0.4 mg (e.g., 0.8 mg). It should be used with caution in combination with cimetidine, particularly at a dose higher than 0.4 mg (e.g., 0.8 mg). It should not be used in combination with other alpha adrenergic blocking agents. Caution is advised when alpha adrenergic blocking agents including tamsulosin are co-administered with PDE5 inhibitors. Alpha-adrenergic blockers and PDE5 inhibitors are both vasodilators that can lower blood pressure. Concomitant use of these two drug classes can potentially cause symptomatic hypotension. Caution should be exercised with concomitant administration of warfarin and tamsulosin.
- Carcinoma of the prostate and BPH cause many of the same symptoms. These two diseases frequently co-exist. Patients should be evaluated prior to the start of tamsulosin therapy, to rule out the presence of carcinoma of the prostate and at regular interval after wards.
- Intraoperative Floppy Iris Syndrome (IFIS) has been observed during cataract surgery in some patients treated with alpha-1 blockers, including Prostam capsules.
- In patients with sulfa allergy, allergic reaction to Tamsulosin hydrochloride has been rarely reported. If a patient reports a serious or life threatening sulfa allergy, caution is warranted when administering Prostam capsules.
- The pharmacokinetic and Pharmacodynamics interactions between Prostam capsules and other alpha-adrenergic blocking agents have not been determined. Howev er, interactions may be expected and Prostam capsules should not be used in combination with other alpha-adrenergic blocking agents.
- Patients should be advised not to crush, chew or open the Prostam capsules.
- Patients should be advised about the possibility of priapism as a result of treatment with tamsulosin and other alpha 1 antagonist. Patients should be informed that this reaction is extremely rare, but if not brought to immediate medical attention, can lead to permanent erectile dysfunction (impotence).
- Patients with end stage renal disease (creatinine clearance <10mL/min/1.73m²) should be approached with caution as these patients have not been studied.
- Tamsulosin has not been studied in patients with severe hepatic dysfunction.

DRUG INTERACTIONS

Prostam (Tamsulosin hydrochloride) is metabolised by cytochrome P450 isoenzymes CYP2D6 and inhibitors of these isoenzymes may increase exposure to Tamsulosin. It should be used with caution, if at all with strong inhibitors of CYP3A4 and such combinations should be avoided in patients who are CYP2D6 poor metaboliser. Caution is also required when giving Prostam with a moderate inhibitor of CYP3A4, with strong or moderate inhibitors of CYP2D6, or in CYP2D6 poor metabolisers, particularly at oral Prostam doses higher than 400 micrograms daily. Caution is also advised when Prostam is given with Warfarin or Diclofenac as the elimination of Tamsulosin may be increased and therefore the exposure reduced. Furosemide may also reduced exposure, but Tamsulosin concentrations remain within the normal range.

- Strong and Moderate Inhibitors of CYP3A4 or CYP2D6 Tamsulosin is extensively metabolized, mainly by CYP3A4 (ketoconazole) and CYP2D6.
- Concomitant administration of a moderate CYP3A4 inhibitor (e.g., erythromycin) have not been evaluated with tamsulosin. Concomitant treatment with paroxetine (a strong inhibitor of CYP2D6) resulted in an increase in the Cmax and AUC of tamsulosin. An increase in exposure is expected in CYP2D6 poor metabolizers as compared to extensive metabolizers (EM). Tamsulosin should not be used in combination with strong inhibitors of CYP3A4 (e.g., ketoconazole). Concomitant administration of a moderate CYP2D6 inhibitor (e.g., terbinafine) and co-administration of both a CYP3A4 and a CYP2D6 inhibitor with tamsulosin have not been evaluated. There is a potential for significant increase in tamsulosin exposure when tamsulosin is co-administered with a combination of both CYP3A4 and CYP2D6 inhibitors.
- Treatment with cimetidine resulted in a significant decrease in the clearance of tamsulosin hydrochloride, which resulted in a moderate increase in tamsulosin hydrochloride.
- Interactions between tamsulosin and other alpha adrenergic blocking agents have not been determined; however, interactions between tamsulosin and other alpha adrenergic blocking agents may be expected.
- Caution is advised when alpha adrenergic blocking agents including tamsulosin are co-administered with PDE5 inhibitors. Alpha-adrenergic blockers and PDE5 inhibitors are both vasodilators that can lower blood pressure. Concomitant use of these two drug classes can potentially cause symptomatic hypotension.
- Caution should be exercised with concomitant administration of warfarin and tamsulosin.
- Dosage adjustments are not necessary when tamsulosin are administered concomitantly with nifedipine, atenolol, or enalapril.
- Dosage adjustments are not necessary when a tamsulosin is administered concomitantly with digoxin or theophylline.
- Furosemide do not require adjustment when use with tamsulosin.

SPECIAL POPULATION

Pregnancy

Tamsulosin is not indicated for use in women.

Lactation

Tamsulosin is not indicated for use in women.

Pediatric Use

Tamsulosin is not indicated for use in pediatric populations.

Geriatrics Use

Intrinsic clearance is independent of Tamsulosin hydrochloride binding to AAG, but diminished with age, resulting in a 40% overall higher exposure (AUC) in subjects of age 55 to 75 years compared to subjects of age 20 to 32 years.

Renal Impairment

Patients with renal impairment do not require an adjustment in tamsulosin.

Hepatic Impairment

Patients with moderate hepatic impairment do not require an adjustment in tamsulosin. Tamsulosin has not been studied in patients with severe hepatic impairment.

OVER DOSAGE

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.

DOSAGE AND INSTRUCTIONS

To be sold and used on the prescription of a registered medical practitioner only. Keep out of reach of children. Do not store above 30°C. Keep in a dry place. Protect from light.

PRESENTATION

Prostam 0.4mg Capsules:

Alu. Alu. Blister Pack of 2 x 14's.

پروسٹیم®

(ٹیمسولوسن ہائیڈروکلورائیڈ)

خوراک و ہدایات:

صرف مستند ڈاکٹر کے نسخہ کے مطابق ہی دوا فروخت اور استعمال کی جائے۔

بچوں کی پہنچ سے دور رکھیں۔ 30°C سے زیادہ درجہ حرارت پر نہ رکھیں۔

خشک جگہ پر رکھیں۔ روشنی سے بچائیں۔

Manufactured by
HIGHNOON LABORATORIES LTD
17.5 KM, Multan Road, Lahore, Pakistan.
www.highnoon-labs.com

Item Code No. 14003046