PROSTATEC
Tamsulosin Hydrochloride Extended Release and Finasteride Tablets

COMPOSITION:
Each Film Coated Tablet Contains:

Tamsulosin Hydrochloride (as extended release)	USP	0.4 mg
Finasteride	USP	5 mg
Excipients		q.s.

Colours: Red Oxide of Iron & Titanium Dioxide BP

PHARMACODYNAMIC:
Pharmacotherapeutic Group: Drugs used in benign prostatic hypertrophy, Alpha-adrenoreceptor.

ATC code: G04CA02.

Mechanism of Action:
PROSTATEC is a combination of two medicines: Tamsulosin and Finasteride, which relieves the symptoms of benign prostatic hyperplasia. Tamsulosin is an alpha-blocker. It works by relaxing the muscle around the bladder exit and prostate gland so as to allow easy passage of urine. Finasteride is a 5-alpha-reductase inhibitor which helps in shrinking the prostate gland by decreasing the level of the hormone which helps the prostate gland grow.

Pharmacokinetics:
Tamsulosin Hydrochloride:
Absorption: After a single oral dose of 0.4 mg in the fasted state, the plasma concentration of Tamsulosin gradually increased reaching C_{max} at a median time of 6 hours. At steady state, which is reached by day 4 of multiple dosing, plasma concentrations of Tamsulosin peak at 4 - 6 hours in the fasted and fed state. Peak plasma concentrations increase from approximately 6 ng/ml after the first dose to 11 ng/ml in steady state. After C_{max} is reached, the plasma concentration decreases, but at approximately 16 - 24 hours post-dose, a small increase or second plateau is observed. Under fasted conditions the absolute bioavailability of Tamsulosin from **PROSTATEC** was estimated to be 57%. Plasma concentration-time profile in the fed state was bioequivalent to the fasted state, indicating the absence of a food effect, by a low fat meal. After a single oral dose of 0.4mg **PROSTATEC,** the extent of absorption is increased by 64% and 149% (AUC and C_{max} respectively) by a high-fat meal compared to fasted.

Distribution: In man, Tamsulosin is about 99% bound to plasma proteins. The volume of distribution is small (about 0.2 l/kg).

Biotransformation: Tamsulosin has a low first pass effect, being metabolized slowly. Most Tamsulosin is present in plasma in the form of unchanged active substance. It is metabolized in the liver.
None of the metabolites are more active than the original compound.

Elimination:
Tamsulosin and its metabolites are mainly excreted in the urine. The amount excreted as unchanged active substance is estimated to be about 4 - 6% of the dose, administered as Tamsulosin prolonged-release tablets. After a single dose of Tamsulosin and in steady state, elimination half-lives of about 19 and 15 hours, respectively, have been measured

Finasteride:
Absorption:
The oral bioavailability of finasteride is approx. 80%. Peak plasma concentrations are reached approx. 2 hours after drug intake, and absorption is complete after 6-8 hours.

Distribution:
Binding to plasma proteins is approx. 93%. Plasma clearance and volume of distribution are approx. 165 ml/min (70-279 ml/min) and 76 l (44-96 l), respectively. Accumulation of small amounts of finasteride is seen on repeated administration. After a daily dose of 5 mg the lowest steady-state concentration of finasteride has been calculated to be 8-10 ng/ml, which remains stable over time.

Biotransformation:
Finasteride is metabolised in the liver. Finasteride does not significantly affect the cytochrome P 450 enzyme system. Two metabolites with low 5α-reductase-inhibiting effects have been identified.

Elimination:
The plasma half-life averages 6 hours (4-12 hours) (in men >70 years of age, 8 hours, range 6-15 hours). After administration of radioactively labelled finasteride, approx. 39% (32-46%) of the given dose is excreted in the urine in the form of metabolites.
Virtually no unchanged finasteride is recovered in the urine. Approximately 57% (51-64%) of the total dose is excreted in the faeces.

INDICATION:
PROSTATEC (Tamsulosin Hydrochloride Extended Release & Finasteride Tablets) is a combination drug containing 'urinary bladder relaxant' medication, used primarily in treating the enlarged prostate gland. Benign prostatic hyperplasia (enlarged prostate gland) is a non-cancerous growth of the prostate gland caused due to overproduction of a dihydrotestosterone hormone in men. As the gland enlarges, it can lead to urinary problems, such as difficulty passing urine and frequent urination. **PROSTATEC** helps in getting relief from these symptoms.
PROSTATEC contains Tamsulosin (alpha-blockers) and Finasteride (5-alpha reductase inhibitor), primarily used to treat enlarged prostate gland. Tamsulosin makes it easy to pass urine by relaxing the muscles of the prostate gland. On the other hand, Finasteride reduces the enlarged prostate gland's size by lowering the production of dihydrotestosterone hormone, thereby relieving urinary incontinence symptoms and leading to a decrease in the size of the prostate gland. Collectively, both of them improve the symptoms of Benign Hyperplasia Prostate (BPH).

POSOLOGY AND METHOD OF ADMINISTRATION:
Posology
Take the tablet of **PROSTATEC** with or without food or as directed by your physician.

Method of Administration:
Oral use.

The tablet must be swallowed whole and not be crunched or chewed as this interferes with the prolonged release of the active substance.

SPECIAL WARNING AND PRECAUTION FOR USE:
Do not take PROSTATEC if you are allergic to PROSTATEC or any of the ingredients. PROSTATEC should not be taken if you have low blood pressure, which makes you feel dizzy, lightheaded, or faint, prostate (gland that produces some of the fluid that carries sperm) cancer. It is advisable to wear a male contraceptive (like a condom) while having sex if your wife is pregnant as PROSTATEC is known to pass in semen. In rare cases, problems of penis erection, ejaculation, and pain in the penis can occur. So, if the symptoms are for a longer time, immediately contact your doctor. Contact your doctor for advice if you are pregnant or plan to get pregnant before taking PROSTATEC as it may affect the development of male genitals. Women or children should not take this medication.

CONTRAINDICATION:
Hypersensitivity to the active substance, including drug induced angioedema, or to any of the excipients listed.
A history of orthostatic hypotension.
Severe hepatic insufficiency.

DRUG INTERACTIONS:
Drug-Drug Interactions: PROSTATEC is known to contra-indicate with medicines used to treat benign prostate hyperplasia (doxazosin), medicines for heart disease (amiodarone), high blood pressure (diltiazem), medicines for eczema (tacrolimus), antifungal medicines (fluconazole, itraconazole), and antidepressants (fluoxetine, paroxetine).
Drug-Food Interactions: PROSTATEC is known to interact when taken along with alcohol and St John's Wort (a natural remedy to treat depression). Also, keep your doctor informed about all the OTC medicines you are using while taking PROSTATEC.
Drug-Disease Interactions: PROSTATEC should not be given to the patients with eye problems (like glaucoma or cataract), liver/kidney disease, hypotension (low blood pressure).

PREGNACY AND LACTATION:
PROSTATEC is only for use in male-only and not female.

SIDE EFFECTS:
Side Effects of PROSTATEC:
- Impotence (not able to achieve or maintain an erection)
- Ejaculation disorder (reduced amount of emen/sperm)
- Breast pain
- Low sexual desire
- Headache
- Nausea
- Vomiting

EFFECT ON ABILITY TO DRIVE OR TO USE MACHINES:
Patients taking **PROSTATEC** should be cautioned about driving, operating machinery, or performing hazardous tasks as it can cause drowsiness or dizziness.

OVERDOSE:
Overdosage with **PROSTATEC** can potentially result in severe hypotensive effects. Severe hypotensive effects have been observed at different levels of overdosing.

INCOMPATIBILITY:
None

SHELF LIFE:
3 years

PACKAGING:
10 Tablets packed in Alu Alu Blister and such 3 Blister are packed in a carton along with pack insert.

STORAGE CONDITION:
Store at room temperature (15°C to 30°C).

MARKETED BY:
METPHARM
Agence De Produits Pharmaceutiques
PORT-AU-PRINCE, HAITI

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