VEGATAM CAPSULES

(Tamsulosin Hydrochloride 0.4 mg)

COMPOSITION

Each Vegatam capsule contains Tamsulosin Hydrochloride 0.4 mg. Excipients: as per approved formulation.

DESCRIPTION & PHARMACOLOGY

Tamsulosin is an alpha-1 adrenergic receptor antagonist with selectivity for alpha-1A receptors in the prostate, bladder neck and prostatic urethra. It relaxes smooth muscle in these tissues, improving urine flow and reducing symptoms of bladder outlet obstruction due to benign prostatic hyperplasia (BPH).

INDICATIONS

Treatment of lower urinary tract signs and symptoms associated with benign prostatic hyperplasia in adult men. Tamsulosin is not indicated for the treatment of hypertension.

DOSAGE & ADMINISTRATION

The recommended starting dose is one 0.4 mg capsule orally once daily, approximately 30 minutes after the same meal each day. Swallow whole; do not crush, chew or open the capsule.

If response is inadequate after 2-4 weeks, the prescriber may increase the dose to 0.8 mg once daily (two 0.4 mg capsules), after reviewing tolerability and interactions.

ADDITIONAL DOSAGE GUIDANCE

If treatment is interrupted for several days, restart at 0.4 mg once daily under medical advice, even if the previous dose was 0.8 mg. Do not take a double dose to compensate for a missed capsule.

ELDERLY & ORGAN IMPAIRMENT

No routine adjustment is generally needed solely due to age. Caution is advised in severe renal impairment and moderate hepatic impairment; use in severe hepatic impairment has not been adequately studied. Assess concurrent medication and risk of low blood pressure.

CONTRAINDICATIONS

Known hypersensitivity to tamsulosin hydrochloride or any excipient, including previous serious allergic reactions such as angioedema.

WARNINGS & PRECAUTIONS

Postural hypotension, dizziness and rarely syncope may occur, particularly when starting or changing treatment. Rise slowly from sitting or lying positions and avoid activities where fainting could cause injury.

Prostate cancer may coexist with BPH. Appropriate clinical assessment and prostate cancer screening should be undertaken before treatment and periodically as indicated.

Rare prolonged painful erection (priapism) requires immediate emergency treatment.

EYE SURGERY PRECAUTION

Intraoperative floppy iris syndrome (IFIS) has been reported during cataract and glaucoma surgery in patients currently or previously treated with tamsulosin. Patients must tell their ophthalmologist about present or past tamsulosin use before eye surgery. Do not independently stop treatment.

DRUG INTERACTIONS

Avoid concomitant strong CYP3A4 inhibitors such as ketoconazole. Use caution with CYP2D6 inhibitors such as paroxetine, other alpha blockers, and medicines that lower blood pressure, including phosphodiesterase-5 inhibitors such as sildenafil or tadalafil.

Use caution with cimetidine and warfarin; review all prescription and nonprescription medicines. Concurrent blood-pressure-lowering medicines may increase symptomatic hypotension.

ADVERSE REACTIONS

Common adverse reactions include dizziness, headache, abnormal ejaculation, rhinitis, fatigue and weakness. Other reported effects include nausea, diarrhoea, back pain, drowsiness and blurred vision.

Serious reactions may include fainting, angioedema, severe skin reactions and priapism. Seek urgent medical attention for these symptoms.

PREGNANCY & LACTATION

Not indicated for use in women. Pregnancy and breastfeeding use are not applicable to the approved BPH indication.

OVERDOSAGE

Overdose may cause pronounced hypotension, dizziness or fainting. Seek emergency medical care. Management is supportive, including monitoring blood pressure and heart rate. Dialysis is unlikely to be effective because of high protein binding.

STORAGE CONDITIONS

Store according to the approved product specifications, protected from moisture and excessive heat. Keep out of reach of children. Do not use after expiry.

PRESENTATION

Vegatam Capsules 0.4 mg: pack of 10 capsules.

PATIENT ADVICE

Take at the same time after the same meal every day. Swallow capsules intact. Avoid driving until you know how the medicine affects you. Tell your surgeon before cataract or glaucoma surgery, even if you stopped tamsulosin previously. Contact a physician for fainting, facial swelling or prolonged painful erection.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.