



Tamsulosin Hydrochloride
Modified Release Capsule

Presentation

Uroflo® Capsule: Each modified release capsule contains Tamsulosin Hydrochloride INN 0.4 mg.

Description

Tamsulosin is a sulfonamethylamine derivative α_{1A} -adrenergic blocking agent. The drug is pharmacologically related to doxazosin, prazosin, and terazosin; however, unlike these drugs, Tamsulosin has higher affinity and selectivity for the α_{1A} -adrenergic receptors, which are mainly located in nonvascular smooth muscle (e.g. prostate), than for α_{1A} -adrenergic receptors located in vascular smooth muscle (e.g. internal iliac artery). Such selectivity of Tamsulosin for α_{1A} -receptors may result in a reduced incidence of adverse cardiovascular effects (e.g. syncope, dizziness, and hypotension).

Indications

Uroflo® is used in Benign Prostatic Hyperplasia (BPH). It relaxes smooth muscle in benign prostatic hyperplasia producing an increase in urinary flow rate and an improvement in obstructive symptoms.

Dosage and Administration

Uroflo® Capsule 0.4 mg once daily is recommended as the dose for the treatment of the signs and symptoms

of BPH. It should be administered approximately one and half-hour following the same meal each day.

For those patients who fail to respond to the 0.4 mg dose after 2 to 4 weeks of dosing, the dose of Uroflo® Capsule can be increased to 0.8 mg once daily.

Contraindications

Tamsulosin should be avoid in patients with a history of orthostatic hypotension and micturition syncope.

Side Effects

Side effects of Tamsulosin include drowsiness, asthenia, depression, headache, dry mouth, nausea, vomiting, diarrhoea, constipation, edema, blurred vision, rhinitis, erectile disorders, tachycardia and palpitation. Hypersensitivity reactions including rash, pruritus, angioedema have been reported in some cases.

Precautions

Caution may be required in the elderly and in patients with hepatic impairment and severe renal impairment.

Use in Pregnancy and Lactation

Uroflo® Capsule is not indicated for use in women.

Drug Interactions

The pharmacokinetic and pharmacodynamic interactions

between Tamsulosin and other alpha-adrenergic blocking agents have not been determined. However, interactions may be expected and it should not be used in combination with other alpha-adrenergic blocking agents. The pharmacokinetic interaction between Cimetidine and Tamsulosin was investigated. The results indicate significant changes in Tamsulosin clearance (26% decrease) and AUC. Therefore, Tamsulosin should be used with caution in combination with Cimetidine, particularly at doses higher than 0.4 mg. Caution should be exercised with concomitant administration of Warfarin and Tamsulosin.

Commercial Pack

Uroflo® Capsule : Each Box containing 20 capsules in 2 x 10's blister strips. Each modified release capsule contains Tamsulosin Hydrochloride INN 0.4 mg.



Manufactured by
BEXIMCO PHARMACEUTICALS LTD.

TONGI, BANGLADESH
® REGISTERED TRADEMARK

BL 3448

3000305