

INDICATION AND DOSAGE

VESIcare tablets are indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency. The recommended dose of VESIcare is 5 mg once daily. If the 5-mg dose is well tolerated, the dose may be increased to 10 mg once daily.

IMPORTANT SAFETY INFORMATION

VESIcare is contraindicated in patients with urinary retention, gastric retention, uncontrolled narrow-angle glaucoma, and in patients with hypersensitivity to the product.

Angioedema of the face, lips, tongue and/or larynx have been reported with VESIcare. Cases of angioedema have been reported to occur hours after the first dose or after multiple doses. Angioedema associated with upper airway swelling may be life threatening. If involvement of the tongue, hypopharynx, or larynx occurs, VESIcare should be promptly discontinued and appropriate therapy and/or measures necessary to ensure a patent airway should be promptly provided. Anaphylactic reactions have been reported rarely in patients treated with VESIcare. In patients who develop anaphylactic reactions, VESIcare should be discontinued and appropriate therapy and/or measures should be taken.

VESIcare should be administered with caution to patients with bladder outflow obstruction, decreased gastrointestinal motility, controlled narrow-angle glaucoma, or reduced renal or hepatic function. Doses of VESIcare higher than 5 mg are not recommended in patients with severe renal impairment, moderate hepatic impairment, or when administered with ketoconazole or other potent CYP3A4 inhibitors. Use of VESIcare in patients with severe hepatic impairment is not recommended.

In placebo-controlled studies, for the 10-mg dose, three intestinal serious adverse events were reported (one fecal impaction, one colonic obstruction, and one intestinal obstruction). For the 5-mg dose, one case of angioneurotic edema was reported.

In placebo-controlled studies, the most common adverse events reported by patients were dry mouth (10.9%, 27.6%, 4.2%), constipation (5.4%, 13.4%, 2.9%), blurred vision (3.8%, 4.8%, 1.8%), and dyspepsia (1.4%, 3.9%, 1.0%) with VESIcare 5 mg, 10 mg, and placebo, respectively.