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Flomax (tamsulosin hydrochloride) - Drug Summary

Boehringer Ingelheim Pharmaceuticals, Inc.

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Flomax
(tamsulosin hydrochloride)

THERAPEUTIC CLASS

Alpha$_1$ antagonist

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Benign Prostatic Hyperplasia

0.4mg qd 30 min after the same meal each day
Titrate: May increase to 0.8mg qd after 2-4 weeks if response is inadequate

If therapy is discontinued or interrupted for several days at either the 0.4mg or 0.8mg dose, restart w/ 0.4mg qd

ADMINISTRATION

Oral route

Do not crush, chew, or open cap

HOW SUPPLIED

Cap: 0.4mg

WARNINGS/PRECAUTIONS

Orthostasis/syncope may occur; caution to avoid situations in which injury could result should syncope occur. May cause priapism. Prostate cancer and BPH frequently coexist. Intraoperative floppy iris syndrome (IFIS) observed during cataract and glaucoma surgery; initiation of therapy in patients who are scheduled for cataract or glaucoma surgery is not recommended. Allergic reaction reported (rare) in patients with sulfa allergy.

ADVERSE REACTIONS

Headache, dizziness, rhinitis, infection, abnormal ejaculation, asthenia, back pain, diarrhea, pharyngitis, chest pain, cough increased, somnolence, insomnia, sinusitis, nausea.

DRUG INTERACTIONS

Avoid with other α-adrenergic blockers. Caution with cimetidine, particularly at a dose >0.4mg, and warfarin. Avoid with strong inhibitors of CYP3A4 (eg, ketoconazole). Caution with moderate inhibitors of CYP3A4 (eg, erythromycin), with strong (eg, paroxetine) or moderate (eg, terbinafine) inhibitors of CYP2D6, and in patients known to be CYP2D6 poor metabolizers, particularly at a dose >0.4mg. Caution with PDE-5 inhibitors; may cause symptomatic hypotension.

PREGNANCY AND LACTATION

Category B, not for use in nursing.

MECHANISM OF ACTION

α_1-antagonist; selective blockade of α_1 receptors in the prostate results in relaxation of the smooth muscles of the bladder neck and prostate, improving urine flow and reducing symptoms.

PHARMACOKINETICS

Absorption: Complete. Administration of variable doses with light/high breakfast or fasted resulted in different pharmacokinetic parameters. **Distribution:** (IV) V_d=16L; plasma protein binding (94-99%). **Metabolism:** Liver (extensive); CYP3A4, CYP2D6. **Elimination:** Urine (76%, <10% unchanged), feces (21%); $T_{1/2}$=14-15 hrs.

ASSESSMENT

Assess for BPH, known hypersensitivity, sulfa allergy, and possible drug interactions. Assess if patient is planning to undergo cataract/glaucoma surgery. Screen for the presence of prostate cancer.

MONITORING

Monitor for signs/symptoms of orthostasis, syncope, priapism, IFIS, allergic reactions, and other adverse reactions. Monitor for the presence of prostate cancer at regular intervals.

PATIENT COUNSELING

Advise patient about the possible occurrence of symptoms related to orthostatic hypotension; caution about driving, operating machinery, or performing hazardous tasks. Advise that therapy should not be used in combination with strong inhibitors of CYP3A4. Advise about the possibility of priapism and to seek immediate medical attention if it occurs. Inform of the importance of screening for prostate cancer prior to therapy and at regular intervals afterwards. Advise to inform ophthalmologist of drug use if considering cataract or glaucoma surgery.

STORAGE

25°C (77°F); excursions permitted to 15-30°C (59-86°F).

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