Ditropan XL (oxybutynin chloride) - Drug Summary

Janssen Pharmaceuticals, Inc.

Related Drug Information

Ditropan XL (oxybutynin chloride)

THERAPEUTIC CLASS

Anticholinergic

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Overactive Bladder

Initial: 5 or 10mg qd at the same time each day
Titrate: May adjust dose in 5mg increments weekly
Max: 30mg/day

PEDIATRIC DOSAGE & INDICATIONS

Detrusor Overactivity

Associated w/ a Neurological Condition (eg, Spina Bifida) :
≥6 Years:
Initial: 5mg qd at the same time each day
Titrate: May adjust dose in 5mg increments
Max: 20mg/day

ADMINISTRATION

Oral route

May be taken w/ or w/o food
Swallow tab whole w/ aid of liquids; do not chew, divide, or crush

HOW SUPPLIED

Tab, Extended-Release: 5mg, 10mg, 15mg

CONTRAINDICATIONS

Urinary retention, gastric retention and other severe decreased GI motility conditions, uncontrolled narrow-angle glaucoma.

WARNINGS/PRECAUTIONS

Angioedema of the face, lips, tongue, and/or larynx reported; d/c promptly and provide appropriate therapy if angioedema occurs. Associated w/ anticholinergic CNS effects; consider dose reduction or discontinuation if any occur. Caution w/ preexisting dementia treated w/ cholinesterase inhibitors, Parkinson's disease, myasthenia gravis, autonomic neuropathy, clinically significant bladder outflow obstruction, GI obstructive disorders, ulcerative colitis, intestinal atony, GERD, and preexisting severe GI narrowing (pathologic or iatrogenic). May decrease GI motility. May impair mental/physical abilities. Not recommended in pediatric patients who cannot swallow tab whole w/o chewing, dividing, or crushing.

ADVERSE REACTIONS

Dry mouth, constipation, diarrhea, headache, somnolence, dizziness, dyspepsia, nausea, blurred vision, dry eyes, insomnia.

DRUG INTERACTIONS

Concomitant use w/ other anticholinergic drugs may increase the frequency and/or severity of anticholinergic-like effects. May alter GI absorption of other drugs due to GI motility effects; caution w/ drugs w/ narrow therapeutic index. May antagonize effects of prokinetic agents (eg, metoclopramide). Increased levels w/ ketoconazole. Caution w/ CYP3A4 inhibitors (eg, antimycotics, macrolides); may alter mean pharmacokinetic parameters. Caution w/ drugs that may cause/exacerbate esophagitis (eg, bisphosphonates).

PREGNANCY AND LACTATION

Category B, caution in nursing.

MECHANISM OF ACTION

Antispasmodic/anticholinergic agent; exerts direct antispasmodic effect on smooth muscle and inhibits muscarinic action of acetylcholine on smooth muscle. Relaxes smooth muscle of bladder.

PHARMACOKINETICS

Absorption: C_{max}=1.0ng/mL (R-oxybutynin), 1.8ng/mL (S-oxybutynin); AUC=21.3ng•hr/mL (R-oxybutynin), 39.5ng•hr/mL (S-oxybutynin); T_{max}=12.7 hrs (R-oxybutynin), 11.8 hrs (S-oxybutynin). Refer to PI for pediatric parameters. **Distribution:** (IV) V_d=193L; plasma protein binding (>99%, >97% metabolites). **Metabolism:** Liver (extensive) via CYP3A4; desethyloxybutynin (active metabolite). **Elimination:** Urine (<0.1% unchanged, <0.1% metabolite); $T_{1/2}$=13.2 hrs (R-oxybutynin), 12.4 hrs (S-oxybutynin).

ASSESSMENT

Assess for urinary/gastric retention, bladder outflow obstruction, GI narrowing/obstructive disorder, GERD, ulcerative colitis, uncontrolled narrow-angle glaucoma, Parkinson's disease, myasthenia gravis, autonomic neuropathy, dementia, hypersensitivity to the drug substance or other components of the product, any other conditions where treatment is contraindicated or cautioned, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for aggravation of myasthenia gravis or autonomic neuropathy, angioedema, hypersensitivity reactions, anticholinergic CNS effects, GI adverse reactions (eg, urinary retention, esophagitis, gastric retention), and other adverse reactions.

PATIENT COUNSELING

Inform that angioedema may occur and could result in life-threatening airway obstruction; advise to promptly d/c therapy and seek medical attention if experiencing swelling of the tongue, edema of the laryngopharynx, or difficulty breathing. Inform that heat prostration may occur when administered in high environmental temperature. Inform that drug may produce drowsiness, dizziness, or blurred vision; advise to exercise caution. Inform that alcohol may enhance drowsiness. Advise not to drive or operate heavy machinery until effects have been determined.

STORAGE

25°C (77°F); excursions permitted to 15-30°C (59-86°F). Protect from moisture and humidity.

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