OXYBUTYNIN (Systemic)

Introduction

VA CLASSIFICATION (Primary)¾GU201

Commonly used brand name(s):Ditropan.

Note: For a listing of dosage forms and brand names by country availability, see Dosage Forms section(s).

Category

Antispasmodic (urinary tract).

Indications

Accepted

Urologic disorders, symptoms of (treatment) and

Irritative voiding, symptoms of (treatment)¾Oxybutynin is indicated for the relief of symptoms associated with voiding, such as frequent urination, urgency, urge incontinence, nocturia, and incontinence in patients with uninhibited neurogenic bladder contractions and in those patients with reflex neurogenic bladder. 1, 5

Unaccepted

Oxybutynin has been used as an antispasmodic in the symptomatic treatment of gastrointestinal disorders; however, its effectiveness has not been established. 2

Pharmacology/Pharmacokinetics

Physicochemical characteristics:

Molecular weight¾393.95
pKa¾6.96

Mechanism of action/Effect:

Exerts direct antispasmodic effect on smooth muscle and inhibits the action of acetylcholine at postganglionic cholinergic sites, thus increasing bladder capacity and delaying the initial desire to void by reducing the number of motor impulses reaching the detrusor muscle. It does not block acetylcholine effects at skeletal myoneural junctions or at autonomic ganglia; neither does it have effect on the smooth muscle of blood vessels. 1

Other actions/effects:

Oxybutynin has also shown (in animal studies) moderate antihistaminic, some local anesthetic, mild analgesic, and very low mydriatic and antisialagogue activity. 1, 2

Absorption:

Rapidly absorbed from gastrointestinal tract. 1

Biotransformation:

Hepatic. 2

Onset of action:

30 minutes to 1 hour. 1

Time to peak effect

3 to 6 hours. 2

Duration of action:

6 to 10 hours (antispasmodic effect).

Elimination:

Primarily renal. 2

Precautions to Consider

Pregnancy/Reproduction

Fertility¾Reproduction studies in the hamster, rabbit, rat, and mouse have not shown oxybutynin to impair fertility.
Pregnancy¾Adequate and well-controlled studies in humans have not been done.
Reproduction studies in the hamster, rabbit, rat, and mouse have not shown oxybutynin to harm the fetus. 1

FDA Pregnancy Category B. 1

Breast-feeding

Problems in humans have not been documented. However, oxybutynin may inhibit lactation. 1

Pediatrics

Appropriate studies on the relationship of age to the effects of oxybutynin have not been performed in children up to 5 years of age.

Geriatrics

Geriatric patients may be more sensitive than younger adults to the anticholinergic effects of oxybutynin. 1

Oxybutynin may also exacerbate underlying disease states in these patients 1

Dental

Prolonged use of oxybutynin may decrease or inhibit salivary flow, 1 thus contributing to the development of caries, periodontal disease, oral candidiasis, and discomfort. 6

Drug interactions and/or related problems

The following drug interactions and/or related problems have been selected on the basis of their potential clinical significance (possible mechanism in parentheses where appropriate)¾not necessarily inclusive (>> = major clinical significance):

Note: Combinations containing any of the following medications, depending on the amount present, may also interact with this medication.
>> Anticholinergics or other medications with anticholinergic activity (See Appendix II)

(concurrent use may intensify the anticholinergic effects of oxybutynin 1, 5)

Central nervous system (CNS) depression-producing medications, other (See Appendix II)

(concurrent use may increase the sedative effects of either these medications or oxybutynin 1)

Medical considerations/Contraindications

The medical considerations/contraindications included have been selected on the basis of their potential clinical significance (reasons given in parentheses where appropriate)¾ not necessarily inclusive (>> = major clinical significance).
Risk-benefit should be considered when the following medical problems exist

>> Cardiac disease, especially mitral stenosis, cardiac arrhythmias, congestive heart failure, coronary heart disease or 1

>> Hemorrhage, acute, with unstable cardiovascular status 1

(increase in heart rate may be undesirable)

>> Gastrointestinal tract obstructive disease as in achalasia and pyloroduodenal stenosis 1

(decrease in motility and tone may occur, resulting in obstruction and gastric retention)

>> Glaucoma, angle-closure, or predisposition to 1

(possible mydriatic effect of oxybutynin resulting in increased intraocular pressure may precipitate an acute attack of angle-closure glaucoma)

Hepatic function impairment 1

(decreased metabolism of oxybutynin)

>> Hernia, hiatal, associated with reflux esophagitis 1, 4 or

Hypertension 1

(may be aggravated)

Hyperthyroidism 1

(characterized by tachycardia, which may be increased)

>> Intestinal atony in the elderly or debilitated patient or 1

>> Paralytic ileus

(use of oxybutynin may lead to obstruction)

>> Myasthenia gravis 1

(oxybutynin may aggravate condition because of inhibition of acetylcholine action)

Neuropathy, autonomic 1

(urinary retention and cycloplegia may be aggravated)

>> Prostatic hypertrophy, nonobstructive 1

(reduction in tone of urinary bladder may lead to complete urinary retention)

Renal function impairment 1

(decreased excretion may increase the risk of side effects)

Sensitivity to oxybutynin

>> Tachycardia 1

(may be increased)

Toxemia of pregnancy

(hypertension may be aggravated)

>> Ulcerative colitis, severe 1

(large doses may suppress intestinal motility and may cause paralytic ileus; also, use may precipitate or aggravate the serious complication of toxic megacolon)

>> Urinary retention or

>> Uropathy, obstructive, such as bladder neck obstruction due to prostatic hypertrophy 1

(urinary retention may be precipitated or aggravated)

Xerostomia

(prolonged use may further reduce limited salivary flow)

Caution in use is also recommended in patients over 40 years of age because of danger of precipitating undiagnosed glaucoma.

In patients with diarrhea the possibility of intestinal obstruction should be excluded before oxybutynin is administered. 1

Patient monitoring

The following may be especially important in patient monitoring (other tests may be warranted in some patients, depending on condition; >> = major clinical significance):
Cystometry

(recommended at periodic intervals to evaluate response to therapy 1)

Side/Adverse Effects

Note: When oxybutynin is given to patients where the environmental temperature is high, there is risk of a rapid increase in body temperature because of suppression of sweat gland activity. 1

The following side/adverse effects have been selected on the basis of their potential clinical significance (possible signs and symptoms in parentheses where appropriate)¾not necessarily inclusive:
Those indicating need for medical attention

Incidence rare 1

Allergic reaction (skin rash or hives); increased intraocular pressure (eye pain)
Those indicating need for medical attention only if they continue or are bothersome

Incidence more frequent 1

Constipation; decreased sweating; drowsiness; dryness of mouth, nose, and throat

Incidence less frequent or rare 1

Decreased flow of breast milk; decreased saliva secretion (difficulty in swallowing); decreased sexual ability 3; difficult urination; difficulty in accommodation (blurred vision); headache; mydriatic effect (increased sensitivity of eyes to light); nausea or vomiting; trouble in sleeping; unusual tiredness or weakness

Overdose

For specific information on the agents used in the management of oxybutynin overdose, see:
· Physostigmine (Systemic) monographFor more information on the management of overdose or unintentional ingestion, contact a Poison Control Center (see Poison Control Center Listing).

Clinical effects of overdose

The following effects have been selected on the basis of their potential clinical significance (possible signs and symptoms in parentheses where appropriate)¾not necessarily inclusive:
Clumsiness or unsteadiness; confusion; dizziness; severe drowsiness; fast heartbeat; feverflushing or redness of face hallucinations; respiratory depression (shortness of breath or troubled breathing)unusual excitement, nervousness, restlessness, or irritability
Treatment of overdose 1

To decrease absorption¾
Immediate gastric lavage.

Specific treatment¾
Slow intravenous administration of 0.5 to 2 mg of physostigmine, repeated as needed up to a total of 5 mg.

Supportive care¾
In the event of respiratory depression, starting and maintaining artificial respiration. Treating fever symptomatically with ice packs or alcohol sponging.

Patient Consultation

As an aid to patient consultation, refer to Advice for the Patient, Oxybutynin (Systemic)¾Introductory Version.
In providing consultation, consider emphasizing the following selected information >> = major clinical significance):
Before using this medication

>> Conditions affecting use, especially:

Sensitivity to oxybutynin
Use in the elderly¾Increased sensitivity to anticholinergic effects
Dental¾Possible development of dental problems because of decreased salivary flow
Other medications, especially other anticholinergics

Other medical problems, especially cardiac diseases, glaucoma, hemorrhage, hiatal hernia, intestinal atony, myasthenia gravis, paralytic ileus, prostatic hypertrophy, obstruction in gastrointestinal or urinary tract, tachycardia, ulcerative colitis, urinary retention
Proper use of this medication

Taking medication on an empty stomach with water, or with food or milk to reduce gastric irritation

>> Importance of not taking more medication than the amount prescribed

>> Proper dosing
Taking as soon as possible; if almost time for next dose, not taking at all; not doubling doses
>> Proper storage
Precautions while using this medication

>> Avoiding use of alcohol or other CNS depressants

Possible increased sensitivity of eyes to light

>> Caution if drowsiness or blurred vision occurs

>> Caution during exercise and hot weather; overheating may result in heat stroke

Possible dryness of mouth, nose, and throat; using sugarless gum or candy, ice, or saliva substitute for relief of dry mouth; checking with physician or dentist if dry mouth continues for more than 2 weeks

Side/adverse effects

Signs of potential side effects, especially allergic reaction or increased intraocular pressure

General Dosing Information

Oxybutynin may be taken on an empty stomach with water; however, if gastric irritation occurs it may be taken with food or milk.
Cystometry and other appropriate diagnostic procedures should precede treatment with oxybutynin. 1, 2

If urinary tract infection is present, appropriate antibacterial therapy should be administered. 2

Oral Dosage Forms

OXYBUTYNIN CHLORIDE SYRUP USP

Usual adult and adolescent dose

Antispasmodic (urinary tract)¾
Oral, 5 mg two or three times a day, the dosage being adjusted as needed and tolerated. 1, 5

Usual adult prescribing limits

Antispasmodic (urinary tract)¾
Oral, 5 mg four times a day or 20 mg daily. 1, 5

Usual pediatric dose

Antispasmodic (urinary tract)¾
Children up to 5 years of age: Dosage has not been established. 1

Children 5 years of age and over: Oral, 5 mg two or three times a day, not to exceed 15 mg per day. 1

Usual geriatric dose

See Usual adult and adolescent dose .

Note: Geriatric patients may be more sensitive to the effects of the usual adult dose. 1

Strength(s) usually available

U.S.¾5 mg per 5 mL (Rx)[Ditropan (methylparaben) (sucrose)] [Generic]

Canada¾5 mg per 5 mL (Rx)[Ditropan (methylparaben) (sucrose)]

Packaging and storage:

Store below 40 °C (104 °F), preferably between 15 and 30 °C (59 and 86 °F), unless otherwise specified by manufacturer. Store in a tight, light-resistant container. Protect from freezing.

Auxiliary labeling:

· May cause drowsiness or blurred vision.

OXYBUTYNIN CHLORIDE TABLETS USP

Usual adult and adolescent dose

See Oxybutynin Chloride Syrup USP.

Usual adult prescribing limits

See Oxybutynin Chloride Syrup USP.

Usual pediatric dose

See Oxybutynin Chloride Syrup USP.

Usual geriatric dose

See Oxybutynin Chloride Syrup USP.

Note: Geriatric patients may be more sensitive to the effects of the usual adult dose. 1

Strength(s) usually available

U.S.¾5 mg (Rx)[Ditropan (scored)] [Generic]

Canada¾5 mg (Rx)[Ditropan (scored)]

Packaging and storage:

Store below 40 °C (104 °F), preferably between 15 and 30 °C (59 and 86 °F), unless otherwise specified by manufacturer. Store in a tight, light-resistant container.

Auxiliary labeling:

· May cause drowsiness or blurred vision.