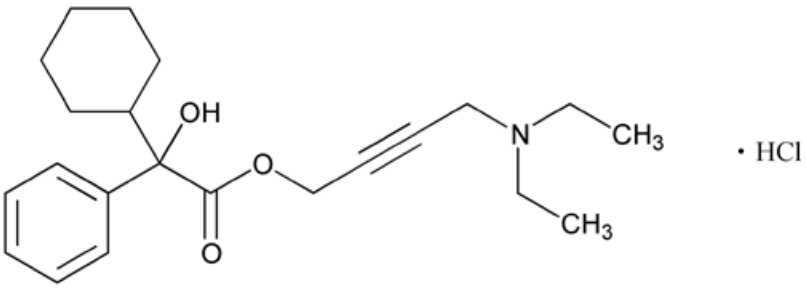
PRODUCT INFORMATION

OXYBUTYNIN SANDOZ

NAME OF THE MEDICINE

Each tablet contains oxybutynin hydrochloride 5mg.

The chemical structure of oxybutynin hydrochloride is the following:



CAS: 1508-65-2

DESCRIPTION

Oxybutynin hydrochloride is 4-diethylamino-2-butynyl phenylcyclohexylglycolate hydrochloride. It is a white crystalline solid (MW 393.9), which is readily soluble in water and acids, but relatively insoluble in alkalis.

The excipients contained in each tablet are calcium stearate, microcrystalline cellulose, anhydrous lactose and brilliant blue FCF aluminium lake.

PHARMACOLOGY

Oxybutynin hydrochloride exerts a direct antispasmodic effect on smooth muscle and inhibits the muscarinic action of acetylcholine on smooth muscle. Oxybutynin hydrochloride exhibits four to ten times the antispasmodic potency of atropine, but only one fifth of the anticholinergic activity of atropine on the rabbit detrusor muscle. No blocking effects occur at skeletal neuromuscular junctions or autonomic ganglia (antinicotinic effects).

Oxybutynin Sandoz relaxes bladder smooth muscle. In patients with conditions characterised by involuntary bladder contractions, cystometric studies have demonstrated that Oxybutynin Sandoz increases bladder (vesical) capacity, diminishes the frequency of uninhibited contractions of the detrusor muscle, and delays the initial desire to void. Oxybutynin Sandoz thus decreases urgency and the frequency of both incontinent episodes and voluntary urination.

Class

Antispasmodic, anticholinergic.

Pharmacokinetics

Oxybutynin hydrochloride is readily absorbed (peak plasma concentration in approx. 1 hour) and rapidly eliminated (plasma half life about 2 hours). Absolute bioavailability after oral dosing has been reported to be about 6%. Oxybutynin hydrochloride undergoes significant first pass metabolism. Very little unchanged drug or metabolites are detected in the urine suggesting the importance of biliary excretion.

INDICATIONS

Treatment of detrusor over-activity where conservative measures have failed.

CONTRAINDICATIONS

Oxybutynin Sandoz is contraindicated in patients with increased intraocular pressure associated with angle closure (glaucoma) or shallow anterior chamber since anticholinergic drugs may aggravate this condition. It is also contraindicated in partial or complete obstruction of the gastrointestinal tract, paralytic ileus, intestinal atony of the elderly or debilitated patient, megacolon, toxic megacolon complicating ulcerative colitis, severe colitis, and myasthenia gravis. It is contraindicated in patients with obstructive uropathy and in patients with unstable cardiovascular status in acute haemorrhage.

Oxybutynin Sandoz is contraindicated in patients who have demonstrated hypersensitivity to the product.

PRECAUTIONS

Avoid dosage in high environmental temperatures and excessive exercise in high temperatures since oxybutynin hydrochloride administered under these conditions can cause heat prostration (fever and heat stroke due to decreased sweating).

Diarrhoea may be an early symptom of incomplete intestinal obstruction, especially in patients with ileostomy or colostomy. In this instance, treatment with Oxybutynin Sandoz would be inappropriate and possibly harmful.

Oxybutynin may produce drowsiness or blurred vision. The patient should be cautioned regarding activities requiring mental alertness, such as operating a motor vehicle or other machinery or performing hazardous work while taking this drug.

Alcohol or other sedative drugs may enhance the drowsiness caused by Oxybutynin Sandoz.

Pretreatment examinations should normally include cystometry, and other appropriate diagnostic procedures. Cystometry should be repeated at appropriate intervals to evaluate response to therapy. The appropriate antibiotic therapy should be instituted in the presence of infection.

Oxybutynin should be used with caution and only where there is evidence of detrusor overactivity in the elderly. Use with caution in patients with Parkinson's disease as they are at greater risk of adverse reactions. Use with caution in patients with autonomic neuropathy, hepatic or renal disease. Administration of oxybutynin in large doses to patients with ulcerative colitis may suppress intestinal motility to the point of producing a paralytic ileus and precipitate or aggravate toxic megacolon, a serious complication of the disease.

Oxybutynin may aggravate cognitive disorders, symptoms of prostatic hypertrophy and tachycardia (thus be cautious in case of hyperthyroidism, coronary heart disease, congestive heart failure, cardiac arrhythmias, and hypertension). The drug should be administered with caution to patients with hiatus hernia associated with reflux esophagitis since anticholinergic drugs may aggravate this condition.

Use in Pregnancy

Category B1

Animal studies showed no clear evidence of teratogenicity or other embryotoxic effects in rats and rabbits at oral doses up to 160 and 100mg/kg/day respectively. However, the incidence of abortion was slightly increased at the highest dose level in rabbits.

There are no adequate data from animal studies with respect to effects on pregnancy, embryonal/foetal development, parturition or postnatal development.

Embryo/foetal studies in pregnant rats showed malformed hearts, and higher doses were associated with extra thoracolumbar ribs and increased neonatal toxicity. The relevance of these observations were difficult to access.

The safety of oxybutynin hydrochloride in women who are or who may become pregnant has not been established, it should be given only when the potential benefits outweigh the possible hazards.

Use in Lactation

There is some evidence from animal studies that oxybutynin or its metabolites are excreted in milk. Oxybutynin Sandoz is not recommended for administration to a nursing woman.

Use in Children

Oxybutynin Sandoz should be used with caution in children as they may be more sensitive to the effects of the product. Oxybutynin should not be used in children with enuresis without definitive evidence of detrusor overactivity. As there is insufficient clinical data for children under age five, Oxybutynin Sandoz is not recommended for this age group.

The safety and efficacy of Oxybutynin Sandoz administration have been demonstrated for children five years of age and older (see Dosage and Administration).

INTERACTIONS WITH OTHER MEDICINES

The anticholinergic effect of Oxybutynin Sandoz is enhanced by its concomitant use with other agents with anticholinergic properties. These include the phenothiazines, butyrophenones, L—dopa, digitalis, tricyclic antidepressants, amantadine, scopolamine and some of the antihistamines.

By reducing gastric motility, oxybutynin may affect the absorption of other drugs.

Oxybutynin, as an anticholinergic agent, may antagonise the effect of prokinetic therapies.

ADVERSE EFFECTS

Following administration of Oxybutynin Sandoz, the symptoms that can be associated with the use of other anticholinergic drugs may occur.

Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare(<1/10,000), not known (cannot be estimated from the available data).

Cardiovascular:

Not known: palpitations, cardiac arrhythmia, tachycardia, vasodilation

Dermatologic:

Very common: dry skin

Common: flushing.

Not known: angio-oedema, rash, urticaria, decreased sweating

Gastrointestinal

Very common: constipation, nausea, dry mouth

Common: diarrhoea, vomiting

Uncommon: abdominal discomfort, anorexia, dysphagia

Not known: gastroesophageal reflux, pseudo-obstruction in patients at risk (elderly or patients with constipation and treated with other drugs that decrease intestinal motility), decreased gastrointestinal motility,

Renal and urinary disorders

Common: Urinary hesitance and retention

Nervous System:

Very common: dizziness, headache, drowsiness, confusion

Not known: cognitive disorders in elderly, convulsions, agitation, nightmares, anxiety, paranoia, symptoms of depression, hallucinations, asthenia, insomnia, restlessness, dependence to oxybutynin (in patients with history of drug or substance abuse)

Ophthalmic:

Very common: blurred vision

Common: dry eyes

Not known: onset of narrow-angle glaucoma, mydriasis, intraocular hypertension

amblyopia, cycloplegia, decreased lacrimation

Other: impotence, suppression of lactation, heat stroke, hypersensitivity

DOSAGE AND ADMINISTRATION

Adults: The usual dose is one 5 mg tablet two to three times a day. The maximum recommended dose is one 5 mg tablet four times a day.

In the frail and elderly patient it is advisable to initiate treatment at a low dose and, if necessary to increase the dose carefully according to tolerance and response. Initial doses for geriatric patients of 2.5 mg twice daily have been reported in the literature.

Children over 5 years of age: The usual dose is one 5 mg tablet twice a day. The maximum recommended dose is one 5 mg tablet three times a day.

OVERDOSAGE

Symptoms

The symptoms of overdosage progress from an intensification of the usual side effects of CNS disturbances (from restlessness and excitement to psychotic behaviour) and circulatory changes (flushing, fall in blood pressure, circulatory failure) to respiratory failure, paralysis and coma.

Treatment

Measures to be taken are immediate emptying of the stomach (emesis is contraindicated if patient is comatose, drowsy, convulsing or psychotic). Consider injection of physostigmine to reverse symptoms of anticholinergic intoxication. Adult doses are 0.5 to 2 mg i.m. or i.v. repeated as necessary up to a total of 5 mg. I.V. administration should be at a slow, controlled rate of no more than 1 mg/minute. For children the dose of physostigmine is 0.02 mg/kg at no more than 0.5 mg/minute - not to exceed 2 mg. Elevated temperature may be treated symptomatically (alcohol sponging, ice packs).

Excessive excitement may require management, for example with sodium thiopental 2% solution given slowly via i.v. or Diazepam 10 mg by i.v. Tachycardia may be treated with intravenous propranolol and urinary retention managed by bladder catheterisation. In the event of progression of the curare-like effect to paralysis of the respiratory muscles, artificial respiration is required.

For information on the management of overdosage, contact the Poisons Information Centre on 131126 (Australia).

PRESENTATION

Light blue, round, single scored tablet, blank on both sides.

Bottles containing 30, 90 and 100◆ tablets.

STORAGE CONDITIONS

Protect from light.

Store below 25ºC.

NAME AND ADDRESS OF THE SPONSOR

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Macquarie Park NSW 2113
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Supplier

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Tel: 1800 634 500

DATE OF FIRST INCLUSION IN THE ARTG

9 January 2007

DATE OF MOST RECENT AMENDMENT

3 May 2016

◆Marketed pack