

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Oxybutynin hydrochloride 5mg/5ml Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 mL of oral solution contains 5 mg Oxybutynin hydrochloride.

Excipient with known effect

Sorbitol (E420): This medicine contains 182 mg sorbitol in each ml which is equivalent to 910 mg per dose of 5ml dose.

Propylene Glycol (E1520): This medicine contains 0.8 mg propylene glycol in each ml which is equivalent to 4 mg per dose of 5ml dose.

Methyl Parahydroxybenzoate (E218): This medicine contains 1 mg methyl parahydroxybenzoate in each ml which is equivalent to 5 mg per 5 ml dose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution

A clear, colourless solution with characteristic raspberry odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Oxybutynin hydrochloride is indicated for the symptomatic treatment of urinary incontinence, urgency and frequency in the unstable bladder, whether due to neurogenic bladder disorders (detrusor hyperreflexia) in conditions such as multiple sclerosis and spina bifida, or to idiopathic detrusor instability (motor urge incontinence).

Paediatric population

Oxybutynin hydrochloride is indicated in children over 5 years of age for:

- Urinary incontinence, urgency and frequency in unstable bladder conditions due to idiopathic overactive bladder or neurogenic bladder disorders (detrusor overactivity).
- Nocturnal enuresis associated with detrusor overactivity, in conjunction with nondrug therapy, when other treatment has failed.

4.2 Posology and method of administration

Posology

The dosage should be determined individually.

Adults:

The usual dose is 5mg (5ml) two or three times a day. This may be increased to a maximum of 5mg (5ml) four times a day to obtain a clinical response provided that the side effects are tolerated.

Elderly (including frail elderly):

The elimination half-life is increased in the elderly. Therefore, a dose of 2.5mg (2.5ml) twice a day, particularly if the patient is frail, is likely to be adequate.

This dose may be titrated upwards to 5mg (5ml) twice a day to obtain a clinical response provided that the side effects are tolerated.

Paediatric population

Children (under 5 years of age):

Oxybutynin Hydrochloride is not recommended in children under 5 years of age due to the absence of data.

Children (over 5 years of age):

Neurogenic bladder instability:

The usual dose is 2.5mg (2.5ml) twice a day. This dose may be titrated upwards to 5mg (5ml) two or three times a day to obtain a clinical response provided that the side effects are tolerated.

Nocturnal enuresis:

The usual dose is 2.5mg (2.5ml) twice a day. This dose may be titrated upwards to 5mg (5ml) two or three times a day to obtain a clinical response provided that the side effects are tolerated. The last dose should be given before bedtime.

Method of administration

For oral use

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Myasthenia gravis.
- Narrow-angle glaucoma or shallow anterior chamber.
- Gastrointestinal obstruction including paralytic ileus, intestinal atony.
- Toxic megacolon.
- Severe ulcerative colitis.
- Bladder outflow obstruction where urinary retention may be precipitated.

4.4 Special warnings and precautions for use

- Oxybutynin Hydrochloride should be used with caution in patients with Parkinson's disease who are at greater risk of occurrence of adverse reactions to the product and in patients with autonomic neuropathy (such as those with Parkinson's disease), severe gastro-intestinal motility disorders, hepatic or renal impairment.
- Anticholinergic medicinal products may decrease gastrointestinal motility and should be used with caution in patients with gastrointestinal obstructive disorders, intestinal atony and ulcerative colitis.
- Oxybutynin Hydrochloride may aggravate cognitive disorders, symptoms of prostatic hypertrophy and tachycardia (thus be cautious in case of hyperthyroidism, congestive heart failure, cardiac arrhythmia, coronary heart disease, hypertension).
- Anticholinergic CNS effects (such as hallucinations, agitation, confusion, somnolence) have been reported. Monitoring recommended, particularly in first few months after initiating therapy or increasing the dose. If anticholinergic CNS effects develop, termination of treatment or dose reduction may be considered.
- Since Oxybutynin Hydrochloride can cause narrow-angle glaucoma, patients should be advised to contact a physician immediately if they are aware of a sudden loss of visual acuity or ocular pain.
- Oxybutynin Hydrochloride may reduce salivary secretions which could result in dental caries, parodontosis or oral candidiasis.
- Anticholinergic medicinal products should be used with caution in patients who have hiatus hernia/gastro-oesophageal reflux and/or who are concurrently taking medicinal products (such as bisphosphonates) that can cause or exacerbate oesophagitis.
- When Oxybutynin Hydrochloride is used in high environmental temperatures, this can cause heat prostration due to decreased sweating.

Elderly

Anticholinergic medicinal products should be used with caution in elderly patients due to the risk of cognitive impairment. They also have a higher risk of occurrence of adverse reactions to the product.

Paediatric population

The use of Oxybutynin Hydrochloride in children under 5 years of age is not recommended; it has not been established whether oxybutynin can be safely used in this age group. There is limited evidence supporting the use of Oxybutynin in children with monosymptomatic nocturnal enuresis (not related to detrusor overactivity).

In children over 5 years of age, Oxybutynin Hydrochloride should be used with caution as they may be more sensitive to the effects of the product, particularly the CNS and psychiatric adverse reactions.

Excipient warning:

This product contains:

Sorbitol (E420): This medicine contains 182 mg sorbitol in each ml which is equivalent to 910 mg per dose of 5ml dose.

Propylene Glycol (E1520): This medicine contains 0.8 mg propylene glycol in each ml which is equivalent to 4 mg per dose of 5ml dose.

Methyl Parahydroxybenzoate (E218): This medicine contains 1 mg methyl parahydroxybenzoate in each ml which is equivalent to 5 mg per 5 ml dose.

4.5 Interaction with other medicinal products and other forms of interaction

Care should be taken if other anticholinergic agents are administered together with Oxybutynin, as a potentiation of anticholinergic effects could occur.

The anticholinergic activity of oxybutynin is increased by concurrent use of other anticholinergics or medicinal products with anticholinergic activity, such as amantadine and other anticholinergic antiparkinsonian medicinal products (e.g. procyclidine, levodopa), antihistamines, antipsychotics (e.g. phenothiazines, butyrophenones, clozapine), quinidine, digitalis, tricyclic antidepressants, atropine and related compounds like atropinic antispasmodics and dipyridamole.

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

Oxybutynin is metabolised by cytochrome P450 isoenzyme CYP 3A4. Concomitant administration with a CYP3A4 inhibitor can inhibit oxybutynin metabolism and increase oxybutynin exposure.

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

Concomitant use with cholinesterase inhibitors may result in reduced cholinesterase inhibitor efficacy.

Patients should be informed that alcohol may enhance the drowsiness caused by anticholinergic agents such as oxybutynin (see section 4.7).

4.6 Fertility, pregnancy and lactation

Pregnancy:

There are no adequate data from the use of oxybutynin in pregnant women. Animal studies are insufficient with respect to effects on pregnancy, embryonic/foetal development, parturition or postnatal development (see section 5.3). The potential risk for humans is unknown. Oxybutynin Hydrochloride should not be used during pregnancy unless clearly necessary.

Breast-feeding:

When oxybutynin is used during lactation, a small amount is excreted in the mother's milk. Use of Oxybutynin Hydrochloride during breast feeding is therefore not recommended.

4.7 Effects on ability to drive and use machines

Oxybutynin Hydrochloride may produce drowsiness or blurred vision. Patients should be cautioned regarding activities requiring mental alertness such as driving operating machinery or performing hazardous work while taking this medicine.

4.8 Undesirable effects

Like all medicines, oxybutynin can cause undesirable effects, although not everybody gets them. The frequency of possible undesirable effects listed below are currently defined as: very common ($\geq 1 / 10$), common ($\geq 1 / 100$ to $<1 / 10$), uncommon ($\geq 1 / 1000$ to $<1 / 100$), rare ($\geq 1 / 10,000$ to $<1 / 1000$), very rare ($<1 / 10,000$), not known (cannot be estimated from the available data).

Table 1: Adverse effects and their frequencies

Infection and infestations:

Not known: urinary tract infection.

Immune system disorders

Not known: hypersensitivity.

Psychiatric disorders:

Common: confusional state.

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

Nervous system disorders:

Very common: dizziness, headache, somnolence.

Not known: cognitive disorders, convulsions, drowsiness, disorientation.

Eye disorders:

Very Common: vision blurred.

Common: dry eyes.

Not known: angle closure glaucoma, increased intraocular pressure, mydriasis.

Cardiac disorders:

Common: palpitation

Not known: arrhythmia, tachycardia.

Vascular disorders:

Common: flushing (which may be more marked in children).

Respiratory, thoracic and mediastinal disorders

Not known: epistaxis

Gastro-intestinal disorders:

Very common: constipation, nausea, dry mouth.

Common: diarrhoea, vomiting.

Uncommon: abdominal discomfort, anorexia, decreased appetite, 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)

Skin and subcutaneous tissue disorders:

Very common: dry skin.

Not known: angioedema, hypohidrosis, rash, urticaria, photosensitivity.

Musculoskeletal and connective tissue disorders

Not known: muscle disorders manifested as muscle weakness, myalgia and/or muscle spasms.

Renal and urinary disorders:

Common: urinary retention.

Not known: difficulty in micturition.

Injury, poisoning and procedural complications:

Not known: heat stroke.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the yellow card scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms of intoxication

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

Management

Measures to be taken are:

1. Immediate gastric lavage
2. physostigmine by slow intravenous injection

Adults: 0.5 to 2.0mg of physostigmine by slow intravenous administration.

Repeat after 5 minutes, if necessary up to a maximum total dose of 5 mg.

Paediatric Population: 30micrograms/kg of physostigmine by slow intravenous administration. Repeat after 5 minutes, if necessary up to a maximum total dose of 2 mg.

Fever should be treated symptomatically with tepid sponging or ice packs.

In pronounced restlessness or excitation, diazepam 10mg may be given by intravenous injection, tachycardia may be treated by intravenous injection of propranolol and Urinary retention can be managed by catheterisation.

In the event of progression of the curare- like effect to the paralysis of the respiratory muscles, mechanical ventilation will be required.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: anticholinergic as well as antispasmodic
ATC Code: G04B D04

Mechanism of action

Oxybutynin has both direct antispasmodic action on the smooth muscle of the bladder detrusor muscle as well as an anticholinergic action in blocking the muscarinic effects of acetylcholine on smooth muscle. These properties cause relaxation of the detrusor muscle of the bladder in patients with an unstable bladder. Oxybutynin Hydrochloride increases bladder capacity and reduces the incidence of spontaneous contractions of the detrusor muscle.

5.2 Pharmacokinetic properties

Absorption

Oxybutynin is rapidly absorbed from the gastrointestinal tract, the peak plasma level is reached between 0.5 to 1 hour after administration.

Distribution

It is highly bound to plasma proteins.

Metabolism

Oxybutynin undergoes extensive first-pass metabolism, particularly by the cytochrome P450 isoenzyme CYP3A4, and systemic oral bioavailability has been reported to be only 6%. N-desethyloxybutynin is an active metabolite.

Elimination

The half-life is biexponential, the first phase being about 40 minutes and the second about 2 – 3 hours. Oxybutynin and its metabolites are excreted in the faeces and urine. There is no evidence of accumulation. The elimination half-life may be increased in the elderly, particularly if they are frail.

5.3 Preclinical safety data

No data of therapeutic relevance

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Para Hydroxybenzoate (E218)
Citric acid monohydrate
Sodium citrate
Liquid Sorbitol (70% Non-Crystallizing) (E420)
Glycerin BP, RSPO/MB (E422)
Raspberry flavour (L8863)
Purified water

Raspberry flavour (L8863) –
Contains:
Purified water
Propylene Glycol (E1520)
Natural Aroma Chemicals

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

36 months
Discard after 30 days of first opening. Store in the original packaging after first opening.

6.4 Special precautions for storage

Store in the original container in order to protect from light.
For storage conditions after first opening of the medicinal product, see section 6.3.

6.5 Nature and contents of container

Oxybutynin hydrochloride Oral Solution is packaged in amber glass bottles with a Child Resistant Cap.

Each carton contains 1 bottle and double ended white polypropylene plastic spoon with 2.5ml and 5ml measuring ends.

Pack size: 150ml

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Relonchem Limited,
Cheshire House,
Gorse Lane, Widnes,
Cheshire,
WA8 0RP,
UK.

8 MARKETING AUTHORISATION NUMBER(S)

PL 20395/0346

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18/06/2025

10 DATE OF REVISION OF THE TEXT

18/06/2025

