SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Oxybutynin hydrochloride Brillpharma 2.5mg/5ml Oral Solution
Oxybutynin hydrochloride Brillpharma 5mg/5ml Oral Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 mL of oral solution contains 2.5 mg Oxybutynin hydrochloride
Excipients with known effect: Each 5ml contains 1.25mg of sodium benzoate (E211).

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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

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 non-drug therapy, when other treatment has failed.

4.2 Posology and method of administration

Posology

Adults:
The usual dose is 5mg (10ml) two or three times a day. This may be increased to a maximum of 5mg (10ml) 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 (5ml) twice a day, particularly if the patient is frail, is likely to be adequate.
This dose may be titrated upwards to 5mg (10ml) twice a day to obtain a clinical response provided that the side effects are tolerated.

Paediatric population

Children (under 5 years of age):
Not recommended

Children (over 5 years of age):

Neurogenic bladder instability:
The usual dose is 2.5mg (5ml) twice a day. This dose may be titrated upwards to 5mg (10ml) 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 (5ml) twice a day. This dose may be titrated upwards to 5mg (10ml) 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
5 ml oral syringe (graduated at every 0.5 ml) together with the enclosed adaptor to attach the syringe to the bottle should be used to take the dose.
For oral use

4.3 Contraindications

- Hypersensitivity to oxybutynin or to any of the excipients listed in section 6.1
- Myasthenia gravis.
- Narrow-angle glaucoma or shallow anterior chamber.
- Gastrointestinal obstructive disorders including paralytic ileus, intestinal atony.
- Patients with toxic megacolon.
- Patients with severe ulcerative colitis.
- Patients with bladder outflow obstruction where urinary retention may be precipitated.

4.4 Special warnings and precautions for use

Oxybutynin should be used with caution in the frail elderly, patients with Parkinson's disease and children 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), hepatic or renal impairment and severe gastro-intestinal motility disorders.

Gastrointestinal disorders: 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 may aggravate tachycardia (and thus hyperthyroidism, congestive heart failure, coronary heart disease, cardiac arrhythmias, hypertension), cognitive disorders and symptoms of prostatic hypertrophy.

Anticholinergic CNS effects (e.g. hallucinations, agitation, confusion, somnolence) have been reported; monitoring recommended especially in first few months after initiating therapy or increasing the dose; consider discontinuing therapy or reducing the dose if anticholinergic CNS effects develop.

Since oxybutynin 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 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 is used in high environmental temperatures, this can cause heat prostration due to decreased sweating.

Elderly:
Anticholinergics 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
Oxybutynin hydrochloride is not recommended for use in children below age 5 years due to insufficient data on safety and efficacy.

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.

Important information regarding the excipients

Sodium benzoate - This medicine contains 2.5 mg Sodium benzoate in 10ml which is equivalent to 0.25 mg/ml.

Sodium - This medicine contains less than 1 mmol sodium (23 mg) per 10ml, that is to say essentially 'sodium-free'.

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. biperiden, 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 antagonise 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 hydrochloride 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 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 during breast feeding is therefore not recommended.

4.7 Effects on ability to drive and use machines

Oxybutynin hydrochloride oral solution may cause 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 drug.

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 (≥ 1 / 10), common (≥ 1 / 100 to <1 / 10), uncommon (≥ 1 /1000 to <1 / 100), rare (≥ 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

Body systems	**Very common** (≥1/10)	**Common** (≥1/100 to <1/10)	**Uncommon** (≥ 1 /1000 to <1 / 100)	**Not known**
Infections and infestations	-	-	-	urinary tract infection
Gastro - intestinal disorders	constipation, nausea, dry mouth	diarrhoea, vomiting	abdominal discomfort, anorexia, decreased appetite, dysphagia	gastroesophageal reflux disease, pseudo-obstruction in patients at risk (elderly or patients with constipation and treated with other drugs that decrease intestinal motility)
Psychiatric disorders	-	confusional state	-	agitation, anxiety, hallucinations, nightmares, paranoia, cognitive disorders in elderly, symptoms of depression, dependence to oxybutynin (in patients with history of drug or substance abuse)
Nervous system disorders	dizziness, headache, somnolence	-	-	Cognitive disorders, convulsions, drowsiness, disorientation
Cardiac disorders	-	Palpitation	-	tachycardia, arrhythmia
Injury, poisoning and procedural	-	-	-	heat stroke

complications				
Eye disorders	Vision blurred	dry eyes	-	Angle closure glaucoma, mydriasis, increased intraocular pressure
Renal and Urinary Disorders	-	urinary retention	-	Difficulty in micturition
Vascular disorders	-	Flushing (which may be more marked in children)	-	-
Respiratory, thoracic and mediastinal disorders	-	-	-	Epistaxis
Skin and subcutaneous tissue disorders	dry skin	-	-	angioedema, rash, urticaria, hypohidrosis, photosensitivity
Musculoskeletal and connective tissue disorders	-	-	-	Muscle disorders manifested as muscle weakness, myalgia and/ or muscle spasms
Immune system disorders	-	-	-	hypersensitivity

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 Website: 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 overdosage 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 5mg.

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

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 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.

Biotransformation
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
Sodium benzoate (E211)
Citric acid monohydrate (E330)
Sodium Citrate (E331)
Sucralose (E955)
Raspberry flavor
Purified water

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 150 mL amber colored Type III glass bottle with a child resistant 28 PP closure CRC-TE with EPE liner, packed in a carton.

Each carton contains 1 bottle and a 5 ml oral syringe with adaptor (graduated at every 0.5 ml).

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

Brillpharma Limited
6 Sovereign Park,
Luton, LU4 8EL, United Kingdom

8. MARKETING AUTHORISATION NUMBER(S)

PL 40496/0009
PL 40496/0010

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:10/04/2019
Renewal of the authorisation: 07/10/2025

10. DATE OF REVISION OF THE TEXT

07/10/2025