SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Oxybutynin hydrochloride 2.5mg /5ml oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml of oral solution contains 2.5mg of oxybutynin hydrochloride.

Excipients with known effect:

Sorbitol (E420): This medicine contains 125 mg sorbitol in each ml which is equivalent to 625 mg per dose of 5 ml.

Maltitol (E 965): This medicine contains 125 mg maltitol in each ml, which is equivalent to 625 mg per dose of 5 ml.

Methyl parahydroxybenzoate (E218): This medicine contains 1.2 mg methyl parahydroxybenzoate, which is equivalent to 6 mg per dose of 5 ml.

Propylene glycol (E 1520): This medicine contains approximately 1.47 mg propylene glycol in each ml, which is equivalent to 7.35 mg per dose of 5 ml.

Ethanol (E1510): This medicinal product contains small amounts of ethanol (alcohol), less than 100 mg per 5 ml.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution.
Clear, colourless solution, with strawberry 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

Dosage and administration:

Adults: The usual dose is 5 mg (10 ml) two or three times a day. This may be increased to a maximum of 5 mg (10 ml) 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 2.5 mg (5 ml) twice a day, particularly if the patient is frail, is likely to be adequate. This dose may be titrated upwards to 5 mg (10 ml) two times a day to obtain a clinical response provided the side effects are well tolerated.

Children (under 5 years of age): Not recommended

Children (over 5 years of age): Neurogenic bladder instability: the usual dose is 2.5 mg (5 ml) twice a day. This dose may be titrated upwards to 5 mg (10 ml) two or three times a day to obtain a clinical response provided the side effects are well tolerated.
Nocturnal enuresis: the usual dose is 2.5 mg (5 ml) twice a day. This dose may be titrated upwards to 5mg (10 ml) two or three times a day to obtain a clinical response provided the side effects are tolerated. The last dose should be given before bedtime.

4.3 Contraindications

Hypersensitivity to oxybutynin or any component.
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), severe gastro-intestinal motility disorders, hepatic or renal impairment (see also section 4.3).

• Gastrointestinal disorders: Anticholinergic medicinal products may decrease gastrointestinalmotility and should be used with caution in patients with gastrointestinal obstructive disorders, intestinal atony and ulcerative colitis.

• Oxybutynin may aggravate tachycardia (and thus be cautious in case of hyperthyroidism, congestive heart failure, cardiac arrhythmia, coronary heart disease, hypertension), cognitivedisorders 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 therapyor 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 aphysician 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, parodontosisor 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 (suchas bisphosphonates) that can cause or exacerbate oesophagitis.

• When oxybutynin is used in high environmental temperatures, this can cause heatprostration 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 in children under 5 years of age is not recommended; it has not beenestablished whether oxybutynin can be safely used in this age group.

There is limited evidence supporting the use of Oxybutynin in children withmonosymptomatic 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 psychiatricadverse reactions.

Excipient warnings
Sorbitol: 125 mg sorbitol in each ml, which is equivalent to 625 mg per dose of 5 ml. Sorbitol is a source of fructose. The additive effect of concomitantly administered productscontaining sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be takeninto account.
The content of sorbitol in medicinal products for oral use may affect the bioavailability ofother medicinal products for oral use administered concomitantly.
Patients with hereditary fructose intolerance (HFI) should not take/be given this medicinalproduct.
Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

Maltitol: 125 mg maltitol in each ml, which is equivalent to 625 mg per dose of 5 ml. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

Propylene glycol: approximately 1.47 mg propylene glycol in each ml, which is equivalent to
7.35 mg per dose of 5 ml.

Sodium: This medicine contains less than 1 mmol sodium (23mg) per 5 ml, that is to sayessentially “sodium-free”.

Methyl parahydroxybenzoate (E218): May cause allergic reactions (possibly delayed), andexceptionally, bronchospasm.

Ethanol (E1510): This medicinal product contains small amounts of ethanol (alcohol), less than100 mg per 5 ml.

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 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 P 450 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, embryonal/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.

Lactation: when oxybutynin is used during lactation, a small amount is excreted in mother's milk. Use of oxybutynin during breast feeding is therefore not recommended.

4.7 Effects on ability to drive and use machines

Oxybutynin 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 (≥1/1,000 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).

ADVERSE REACTIONS REPORTED		
System Organ Class	**Frequency**	**Adverse Reaction (MedDRA Terms)**
Infections 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	Not known	Arrhythmia, tachycardia
	Common	Palpitation
Vascular Disorders	Common	Flushing (which may be more marked in children)
Respiratory, Thoracic, and Mediastinal Disorders	Not known	Epistaxis

ADVERSE REACTIONS REPORTED		
System Organ Class	**Frequency**	**Adverse Reaction (MedDRA Terms)**
Gastrointestinal Disorders	Very common	Constipation, dry mouth, nausea
	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

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.

Measures to be taken are:

1) Immediate gastric lavage

2) physostigmine by slow intravenous injection

Adults: 0.5 to 2.0 mg of physostigmine by slow intravenous administration. Repeat after 5 minutes, if necessary up to a maximum total dose of 5mg.

Children: 30 micrograms/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 bladder 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: Urologicals, Drugs for urinary frequency and incontinence, ATC code: G04BD04

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

Sorbitol (E 420)

Maltitol (E 965)

Glycerol (E 422)

Xanthan gum

Methyl parahydroxybenzoate (E218)

Citric acid monohydrate

Sodium citrate dihydrate

Strawberry flavour (contains propylene glycol)

Citric acid Solution 30%

Ethanol

Purified water

6.2 Incompatibilities

None known.

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 below 25oC.

For storage conditions after first opening of the medicinal product, see section 6.3.

6.5 Nature and contents of container

150 ml amber type III glass bottles with child resistant tamper-evident screw cap and a polypropylene measuring cup of 15ml with 5 ml and 10 ml graduations.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 49578/0002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

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