SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Orphenadrine Hydrochloride 50mg/5ml Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Orphenadrine hydrochloride 50mg/5ml

3 PHARMACEUTICAL FORM

Oral Solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Anticholinergic, for the treatment of all forms of Parkinsonism, including drug induced (neuroleptic syndrome).

4.2 Posology and method of administration

Adults and the elderly:
Initially, 150mg daily in divided doses, increasing by 50mg every two or three days until maximum benefit is obtained. Optimal dosage is usually 250mg to 300mg daily in divided doses in idiopathic and post-encephalitic Parkinsonism; 100mg to 150mg daily in divided doses in arteriosclerotic parkinsonism; and 150mg to 300mg daily in divided doses in the neuroleptic syndrome.

Maximal dosage is 400mg daily in divided doses. The elderly may be more susceptible to side effects at doses which are clinically optimal.

Children:
Not recommended for use in children.

4.3 Contraindications

Hypersensitivity to orphenadrine or to any of the excipients.

In patients with prostatic hypertrophy, tardive dyskinesia, porphyria, urinary retention and must also be used with caution in elderly men.

Also in patients with paralytic ileus or pyloric stenosis, where use may lead to obstruction.

Do not use in patients with glaucoma or too narrow an angle between iris and cornea, as it may raise intra-ocular pressure. Not indicated for use in patients at risk of developing hyperpyrexia.

4.4 Special warnings and precautions for use

Use with caution in the elderly (see Section 4.2).

When used alone or with analgesics, pain or skeletal muscle spasms have been reported.

Use with caution in conditions characterised by tachycardia. Anti-muscarinic agents, such as orphenadrine, should be used with caution in patients with pre-existing tachycardia (e.g. in heart failure, thyrotoxicosis) as they may cause further acceleration of the heart rate.

Anti-muscarinic agents such as orphenadrine are not effective in the treatment of tardive dyskinesia which may be made worse, and should not be used in patients with this condition.

Care should be taken when using in patients with concomitant hypertension, cardiac, renal or hepatic dysfunction.

Use with caution in patients with micturition difficulties and in pregnancy and breastfeeding.

Avoid abrupt discontinuation of treatment. For some patients orphenadrine may be a drug of abuse.

Excipient Warnings

Orphenadrine Oral Solution 50mg/5ml contains methyl and propyl hydroxybenzoates (preservatives) which may cause allergic reactions (possibly delayed).

The product also contains liquid maltitol and sorbitol solution. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Effects may be enhanced by concomitant administration of anticholinergic drugs. May be provocation of dextropropoxyphene side effects during concurrent administration.

As with other similar agents, the anti-muscarinic effects of orphenadrine may be enhanced by the concomitant administration of other medications with anti-muscarinic properties, such as antihistamines, antispasmodics, tricyclic antidepressants, phenothiazines, dopaminergic anti parkinsonian drugs including amantadine, and anti-arrhythmics such as disopyramide.

Although the additional effects may be minor, there is the potential for the development of severe constipation and ileus, atropine-like psychoses and heat stroke.

Due to the anti-muscarinic effects of orphenadrine on the gastrointestinal tract, a reduction in gastric motility may occur which may affect the absorption of other orally administered drugs.

4.6 Fertility, pregnancy and lactation

There is inadequate evidence of safety in human pregnancy, and, although it has been widely used for many years without apparent ill consequence, if considered necessary orphenadrine should be used with caution during pregnancy. Animal studies have not revealed any hazard.

It is probably excreted in milk during lactation. Although the quantity is unlikely to be significant at normal therapeutic doses, if considered necessary orphenadrine should be used with caution during breast feeding.

4.7 Effects on ability to drive and use machines

Orphenadrine may cause blurred vision or slight euphoria. If patients experience these side effects, driving or operating machinery is not recommended.

4.8 Undesirable effects

System Organ Class	**Common** **>1/100** **<1/10**	**Uncommon** **>1/1000** **<1/100**	**Rare** **>1/10,000** **<1/1000**
Immune system disorder		Hypersensitivity	
Nervous system disorder	Dizziness, restlessness	Sedation, confusion, nervousness, hallucinations, convulsions, insomnia, euphoria, co-ordination disturbances, light-headedness	Memory disturbances
Eye disorders	Accommodation disorders		
Cardiac disorders		Tachycardia	
Gastrointestinal disorders	Dry mouth, nausea, gastrointestinal disturbances	Constipation	
Renal and urinary disorders		Urinary retention	

4.9 Overdose

Toxicity:
Adults: 2 – 3g can be fatal for an adult though patients have survived doses of 5g and 7.5g.

Children: A 23 month old had severe toxicity after ingesting 300mg.

Toxicity is mainly due to anticholinergic effects at autonomic nerve endings and in the brain.

Features:
Common: Nausea, vomiting, flushing, dilated pupils, dry mouth and tongue, hot dry skin, fever, sinus tachycardia, hypertension, ataxia, nystagmus, drowsiness, delirium, agitation and visual hallucinations.

Uncommon: Myoclonic jerking, coma, convulsions, cardiac conduction abnormalities and dysrhythmias, cardiovascular collapse, paralytic ileus, urinary retention.

Treatment:
Activated charcoal or gastric lavage may be of benefit if the patient presents within 1 hour of having taken a potentially toxic amount.

Forced diuresis, haemodialysis and haemoperfusion are of no benefit.

Observe the mildest cases for at least 6 hours.

Monitor for and treat the following as clinically indicated: Airway patency, arterial blood gases (hypoxia and/or hypercapnoea may require oxygen or ventilation to correct), hypothermia or hyperthermia, hypotension (intravascular volume expanders or dopamine may be required), skin blisters (treat as burns), convulsions or delirium (can be treated with diazepam).

Cardiac dysrhythmias: Resist the temptation to use antiarrythmic drugs. Correct hypoxia and administer sodium bicarbonate (even in the absence of acidosis).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code – N04A B

5.2 Pharmacokinetic properties

None stated

5.3 Preclinical safety data

Orphenadrine is a drug on which extensive clinical experience has been obtained. Relevant information for the prescriber is provided elsewhere in the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl hydroxybenzoate, propyl hydroxybenzoate, propylene glycol, liquid maltitol, sorbitol solution 70%, saccharin sodium, blackcurrant flavour, aniseed flavour, citric acid monohydrate, sodium citrate and purified water.

6.2 Incompatibilities

Incompatible with alkali, protect from light.

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store below 25ºC and avoid exposure to direct sunlight. Only dispense in amber glass bottles.

6.5 Nature and contents of container

Bottles:	Amber (Type III) glass.
Closures:	HDPE, EPE wadded, tamper evident, child resistant closure.
Capacity:	150ml

6.6 Special precautions for disposal

Keep out of the reach of children.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

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9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15/05/90 / 09/04/97

10 DATE OF REVISION OF THE TEXT

29/07/2013