



ALLIANCE

SUMMARY OF PRODUCT CHARACTERISTICS

1. TRADE NAME OF THE MEDICINAL PRODUCT

Biorphen

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Orphenadrine Hydrochloride BP 25 mg/5mL

3. PHARMACEUTICAL FORM

An anise scented and flavoured clear colourless aqueous liquid.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Parkinsonism, particularly with apathy and depression, and drug induced extrapyramidal syndrome.

4.2. Posology and method of administration

Oral dose

Adult and Elderly:

150 mg daily in divided doses. Maximum dose 400mg daily. Optimal dose range 150 to 300 mg; this is usually achieved by raising the dose to 50 mg every two to three days.

Children:

Not recommended.

4.3. Contraindications

Hypersensitivity to orphenadrine, or to any of the excipients.

Glaucoma, prostatic hypertrophy, urinary retention, porphyria.

4.4. Special warnings and precautions for use

Caution in renal and hepatic disease.

Antimuscarinic agents, including 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.

Avoid abrupt discontinuation of treatment.

Contains sorbitol. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

4.5. Interactions with other medicinal products and other forms of Interaction

May additionally increase anticholinergic activity.

As with other similar agents, the antimuscarinic effects of orphenadrine may be enhanced by the concomitant administration of other medications with antimuscarinic properties, such as antihistamines, antispasmodics, tricyclic antidepressants, phenothiazines, dopaminergic anti-parkinsonian drugs including amantadine, and anti-arrhythmics such as disopyramide. Although the additive effect may be minor, there is the potential for 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. Pregnancy and lactation

No studies with Biorphen have been carried out, therefore the drug should only be used in pregnancy if there is no safer alternative.

It is not known whether orphenadrine passes into the breast milk, therefore mothers should refrain from breast feeding whilst taking Biorphen.

4.7. Effects on ability to drive and use machines

Patients should be warned of the potential hazards of driving or operating machinery if they experience blurred vision.

4.8. Undesirable effects

Occasionally dry mouth, disturbances of visual accommodation, gastro-intestinal disturbances, dizziness and micturition difficulties may occur; these usually disappear spontaneously or may be controlled by a slight reduction in dosage. Less commonly,

tachycardia, hypersensitivity, nervousness, euphoria, hallucinations, confusion and co-ordination disturbances and insomnia may be seen.

4.9. Overdose

Effects seen on overdose are anti-cholinergic in nature and include agitation, confusion, hallucinations, incoordination, delirium, tachycardia and occasionally convulsions. Fatalities have been reported. Gastric lavage, emetic and high enema is recommended. Cholinergics may be useful.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Orphenadrine is a tertiary amine antimuscarinic agent.

5.2. Pharmacokinetic properties

Orphenadrine is readily absorbed from the gastro-intestinal tract and is almost completely metabolised, to at least 8 metabolites. It is mainly excreted in the urine.

5.3. Preclinical safety data

No formal preclinical studies have been undertaken with Biorphen, as its active ingredient is a well established pharmaceutical.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Sorbitol, glycerol, anise water condensed, saccharin sodium, Tween 20, benzoic acid solution, water.

6.2. Incompatibilities

None known.

6.3. Shelf life

24 months.

6.4. Special precautions for storage

None.

6.5. Nature and contents of container

200 ml and 1000 ml amber glass bottles with polycone lined closures.

6.6. Instruction for use/handling

None stated.

7. MARKETING AUTHORISATION HOLDER

Alliance Pharmaceuticals Ltd
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8. MARKETING AUTHORISATION NUMBER

PL16853/0022

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

04 April 2002

10. DATE OF REVISION OF THE TEXT

28th May 2008

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