Benzhexol Tablets BP 5 mg

Summary Product Characteristics (SPC)

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Benzhexol Tablets BP 5 mg, 5 mg per Tablets, Uncoated Tablets.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated tablet contains:
Benzhexol Hydrochloride BP 5 mg
Excipients Q.S.

For a full list of excipients, refer section 6.1

3. PHARMACEUTICAL FORM

Uncoated tablets

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Benzhexol is an antispasmodic drug which exerts a direct inhibitory effect on the parasympathetic nervous system. It also has a relaxing effect on smooth muscle.
It is indicated in all forms of Parkinsonism (postencephalitic, arteriosclerotic and idiopathic). It is often useful as adjuvant therapy when treating these forms of Parkinsonism with levodopa. Benzhexol is effective in reducing the rigidity of muscle spasm, tremor and excessive salivation associated with Parkinsonism. Benzhexol is also indicated to control extrapyramidal disorders (eg akathisia manifested by extreme restlessness and dyskinesia characterised by spastic contractions and involuntary movements) due to central nervous system drugs such as reserpine and the phenothiazines.

4.2 Posology and method of administration

Adults only: The usual dosage for Parkinsonism is 6-10mg per day although some patients chiefly in the post-encephalitic group may require an average total dose of 12-15mg daily. It should be given orally either three or four times a day at mealtimes.
Normal dosage for drug-induced Parkinsonism is usually between 5mg and 15mg per day, although some cases have been controlled by 1mg daily.
In all cases, Benzhexol dosage should be increased or decreased only by small increments over a period of several days. In initial therapy the dose should be 1mg the first day, 2mg the second day with further increases of 2mg per day at three to five-day intervals until the optimum dose is reached.
If patients are already being treated with other parasympathetic inhibitors, Benzhexol should be substituted as part of the therapy. When Benzhexol is used concomitantly with levodopa the usual dose of each may need to be reduced. Careful adjustment is necessary, depending on side effects and the degree of symptom control. Benzhexol dosage of 3-6mg daily in divided doses, is usually adequate.

Benzhexol may be taken before or after meals according to the way the patient reacts. If Benzhexol tends to dry the mouth excessively, it may be better to take it before meals, unless it causes nausea. If taken after meals, induced thirst can be allayed by peppermint, chewing gum or water.
Elderly: Patients over 65 years of age tend to be relatively more sensitive and require smaller amounts of the drug.
Children: Not recommended.
Method of administration: Route of administration is oral.

4.3 Contraindications

Hypersensitivity to Benzhexol or to any of the excipients.

4.4 Special warnings and precautions for use

Precautions: Since the Benzhexol may, in some cases, continue indefinitely, the patient should be under careful observation over the long term. It should be administered with care to avoid allergic or other untoward reactions.
Except in the case of vital complications, abrupt discontinuation of the drug should be avoided. Incipient glaucoma may be precipitated by para-sympatholytic drugs such as Benzhexol. Hypertension, cardiac, liver or kidney disorders are not contra-indicated, but such patients should be followed closely. As Benzhexol may provoke or exacerbate tardive dyskinesia, it is not recommended for use in patients with this condition.
Benzhexol should be used with caution in patients with glaucoma, obstructive disease of the gastro-intestinal or genito-urinary tracts, and in elderly males with possible prostatic hypertrophy. Since Benzhexol has been associated with the clinical worsening of myasthenia gravis, the drug should be avoided or used with great caution in patients with this condition.
Since certain psychiatric manifestations such as confusion, delusions and hallucinations, all of which may occur with any of the atropine-like drugs, have been reported rarely with Benzhexol, it should be used with extreme caution in elderly patients.
Warnings: Benzhexol may be the subject of abuse (on the basis of hallucinogenic or euphoriant properties, common to all anti-cholinergic drugs) if given in sufficient amounts.

4.5 Interaction with other medicinal products and other forms of interaction

Extra care should be taken when Benzhexol is given concomitantly with phenothiazines, clozapine, antihistamines, disopyramide, nefopam and amantadine because of the possibility of increased antimuscarinic side-effects. Synergy has been reported between Benzhexol and tricyclic antidepressants, probably because of an additive effect at the receptor site. This can cause dry mouth, constipation and blurred vision. In the elderly, there is a danger of precipitating urinary retention, acute glaucoma or paralytic ileus.
Monoamine oxidase inhibitors can interact with concurrently administered anticholinergic agents including t Benzhexol. This can cause dry mouth, blurred vision, urinary hesitancy, urinary retention and constipation. In general, anticholinergic agents should be used with caution in patients who are receiving tricyclic antidepressants or monoamine oxidase inhibitors. In patients who are already on antidepressant therapy the dose of Benzhexol should be initially reduced and the patient reviewed regularly. Benzhexol may be antagonistic with the actions of metoclopramide and domperidone on gastro-intestinal function. The absorption of levodopa

may possibly be reduced when used in conjunction with Benzhexol. Benzhexol may be antagonistic with the actions of parasympathomimetics.

4.6 pregnancy and lactation

Pregnancy:
There is inadequate information regarding the use of Benzhexol in pregnancy. Animal studies are insufficient with regard to effects on pregnancy, embryonal/foetal development, parturition and postnatal development. The potential risk for humans is unknown. Benzhexol should not be used during pregnancy unless clearly necessary.
Lactation:
It is unknown whether Benzhexol is excreted in human breast milk. The excretion of Benzhexol in milk has not been studies in animals. Infants may be very sensitive to the effects of antimuscarinic medications. Benzhexol should not be used during breast-feeding

4.7 Effects on ability to drive and use machines

Can cause blurring of vision, dizziness and mild nausea. Also mental confusion in some cases.

4.8 Undesirable effects

Minor side effects: dryness of mouth, constipation, blurring of vision, dizziness, mild nausea or nervousness will be experienced by 30-50% of all patients. These reactions tend to become less pronounced as treatment continues. Patients should be allowed to develop a tolerance using the smaller initial dose until an effective level is reached.
Immune system disorders: Hypersensitivity.
Psychiatric disorders: Nervousness, restlessness, confusional states, agitation, delusions, hallucinations, insomnia, especially in the elderly and patients with arteriosclerosis. The development of psychiatric disturbances may necessitate discontinuation of treatment.
Euphoria may occur. There have been reports of abuse of Benzhexol due to its euphoric and hallucinogenic properties.
Nervous system disorders: Dizziness.
Impairment of immediate and short-term memory function has been reported.
Worsening of myasthenia gravis may occur.
Eye disorders: Dilatation of the pupils with loss of accommodation and photophobia, raised intraocular pressure.
Cardiac disorders: Tachycardia.
Respiratory, toracic and mediastinal disorders: Decreased bronchial secretions.
Gastrointestinal disorders: Dry mouth with difficulty swallowing, constipation, nausea, vomiting.
Skin and subcutaneous tissue disorders: Flushing and dryness of skin, skin rashes.
Renal and urinary disorders: Urinary retention, difficulty in micturition.
General disorders: Thirst, pyrexia.

4.9 Overdose

Symptoms of overdose with anti-muscarinic agents include flushing and dryness of the skin, dilated pupils, dry mouth and tongue, tachycardia, rapid respiration, hyperpyrexia, hypertension, nausea, vomiting. A rash may appear on the face or upper trunk. Symptoms of CNS stimulation

include restlessness, confusion, hallucinations, paranoid and psychotic reactions, incoordination, delirium and occasionally convulsions. In severe overdose, CNS depression may occur with coma, circulatory and respiratory failure and death.
Treatment: Treatment should always be supportive. An adequate airway should be maintained. Diazepam may be administered to control excitement and convulsions but the risk of central nervous system depression should be considered. Hypoxia and acidosis should be corrected. Antiarrhythmic drugs are not recommended if dysrhythmias occur.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anticholinergic.
Mode of action
Benzhexol Hydrochloride is the substituted piperidine salt, 3-(1-piperidyl)-1-phenyl-cyclohexyl-1-propanol hydrochloride, which exerts a direct inhibitory effect upon the parasympathetic nervous system. It also has a relaxing effect on smooth musculature; exerted both directly upon the muscle tissue itself and indirectly through an inhibitory effect upon the parasympathetic nervous system. Its therapeutic properties are similar to those of atropine although undesirable side effects are ordinarily less frequent and severe than with the latter.

5.2 Pharmacokinetic properties

Benzhexol hydrochloride is well absorbed from the gastrointestinal tract. It disappears rapidly from the plasma and tissues and does not accumulate in the body during continued administration of conventional doses.

5.3 Preclinical safety data

No relevant data.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch
Lactose
Dibasic Calcium Phosphate
Sodium Benzoate
Purified Water
Magnesium Stearate
Purified Talc
Colloidal Anhydrous Silica
Sodium Starch Glycolate

6.2 Incompatibilities

Not applicable

6.3 Shelf life

48 months

6.4 Special precautions for storage

Store in a dark, dry place, Not exceeding 30^0C temp.
Keep all medicines out of reach of children.

6.5 Nature and contents of container

500 Tablets are packed in Jar pack.

6.6 Special precautions for disposal and other handling

No Special Requirements.

7. APPLICANT/MANUFACTURER

MARKETED BY:

M/s. EXCEL CHARIS PHARMACEUTICAL CHEMICAL LTD
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