1.3.1 Summary of product characteristics (SmPC)

1. NAME OF THE MEDICINAL PRODUCT

Product Name : **PATRICKLINGO BENZHEXOL TABLETS**

Generic Name : **Benzhexol Tablets 5 mg**

Strength : Each Uncoated Tablet Contains:
Benzhexol BP…5 mg
Excipients….q.s.

Pharmaceutical Form : Uncoated Tablet

Packaging : 500 Tablets are packed in Alu-PVC Blister and such 1 Blister ispacked in a printed inner carton along with pack insert.

2. QUALITY AND QUANTITATIVE COMPOSITION

Batch size: 1,00,000 Tablets

Component and quality standard (and grade, if applicable)	Function	Strength (label claim)					
		Benzhexol Tablets 5 mg					
		Quant. per unit or per Tablets	%	Quant. per unit or per mL	%	Quantity per unit or per mL	%
Contents							
Benzhexol	API	5.10	----				
Starch**	Binder/ Diluent	40.5	----				
Dibasic Calcium Phosphate	Binder/ Diluent	40.43	----				
Microcrystalline Cellulose	Disintegrant	9.14	----				
Starch	Binder/ Diluent	4.73					
Sodium Benzoate	Preservative	0.1	----				
Microcrystalline Cellulose PH-102	Disintegrant	20	----				
Magnesium Stearate	Lubricant	2	----				
Talcum	Glidant	4					
Sodium Starch Glycolate	Diluent	4	----				
Purified Water*	Solvent	Q.S.	----				

Component and quality standard (and grade, if applicable)	Function	Strength (label claim)					
		Benzhexol Tablets 5 mg					
		Quant. per unit or per Tablets	**%**	**Quant. per unit or per mL**	**%**	**Quantity per unit or per mL**	**%**

Total weight of tablet		**130 mg**	----				

* The materials that will not remain in the final product.

** To maintain the average weight, use starch BP for compensation

3. PHARMACEUTICAL FORM VISUAL DESCRIPTION:

Round shape, uncoated, white coloured, flat tablet having plain surface on one side & score line on one side of the tablet.

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: Optimal dosage should always be determined empirically, usually by initiating therapy at a relatively low level and by subsequent graduated increments.

The usual dosage for Parkinsonism is 6-10mg per day although some patients chiefly in the postencephalitic 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.

Treatment of drug-induced extrapyramidal disorder: The size and frequency of dose of Benzhexol needed to control extrapyramidal reactions to commonly employed tranquillisers, notably the phenothiazines, thioxanthenes, and butyrophenones must be determined empirically. The total daily dosage usually ranges between 5 and 15mg, although in some cases, these reactions have been controlled by as little as 1mg daily.

Satisfactory control may sometimes be more rapidly achieved by temporarily reducing the dosage of both drugs until the desired ataractic effect is retained without concomitant extrapyramidal reactions.

It is sometimes possible to maintain the patient on reduced Benzhexol dosage after the reactions have remained under control for several days. Since these reactions may remain in remission for long periods after discontinuation of Benzhexol therapy, such therapy should be of minimal duration and discontinued after symptoms have subsided for a reasonable period of time.

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

Tablet for oral administration.

4.3 Contraindications

- Hypersensitivity to the active substance or any of the excipients.

4.4 Special warnings and precautions for use:

Precautions: Since the use of 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 (see Dosage and Administration).

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 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 Fertility, 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 / side effects

Modern clinical data required to determine the frequency of undesirable effects are lacking for Benzhexol. Minor side effects such as 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 (see section 4.4).

Eye disorders: Dilatation of the pupils with loss of accommodation and photophobia, raised

intraocular pressure (see section 4.4).

Cardiac disorders: Tachycardia.

Respiratory, thoracic 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

Symptoms of overdose with antimuscarinic 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

Benzhexol is an anticholinergic agent. It is an antispasmodic drug which exerts a direct inhibitory effect on the parasympathetic nervous system. It diminishes salivation, increases the heart rate, dilates the pupils and reduces spasm of smooth muscle.

5.2 Pharmacokinetic properties

Benzhexol 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 Pre-clinical safety data: N/A

6. PHARMACEUTICAL PARTICULARS:

6.1 List of Excipients

Starch, Dibasic calcium phosphate, Microcrystalline cellulose, Sodium Benzoate Magnesium Stearate, Talc& Sodium starch Glycolate.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years or 36 months

6.4 Special precautions for storage

Store at a temperature not exceeding 30°C in a dry place.Protect from light.

6.5 Nature and contents of container

1 x 500 Tablets Bag in 1 HDPE Jar..

6.6 Special precautions for disposal and other handling

No special requirements

7. MANUFACTURER:

WINTECH PHARMACEUTICALS LTD.

Address: Office No. 2 & 3, 3rd floor, Broadway Shopping Centre, Dr. Ambedkar Road, Dadar T.T. Mumbai- 400014, India. Tel: (+ 9122) 42123456 (100 lines).

8. DISTRIBUTED BY:

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