Summary of product characteristics (SmPC)

1. Name of the drug product:

BENZHEXOL TABLETS 5 MG

2. Qualitative and quantitative composition :
Each Uncoated Tablet Contains:
Benzhexol Hydrochloride
(Trihexyphenidyl Hydrochloride BP)....5 mg
Excipients..... QS

Sr. No.	Ingredients	Specifi-cation	Label Claim / Tablet (In mg)	Over-ages added (In %)	Qty. / Tablet (In mg)	Reason for Inclusion
a)	**Dry Mixing**					
1.	Maize Starch	BP	NA	NA	133.00	Diluent
2.	Calcium Hydrogen Phosphate dihydrate	BP	NA	NA	141.00	Diluent
3.	Povidone K-30	BP	NA	NA	3.00	Binder
b)	**Binder Preparation**					
4.	Maize Starch	BP	NA	NA	8.00	Binder
5.	Purified Water	BP	NA	NA	---	Vehicle
c)	**For Lubrication and Incorp oration of Trihexyphenidyl Hydrochloride (Benzhexol Hydrochloride)**					
6.	Trihexyphenidyl Hydrochloride (Benzhexol Hydrochloride)	BP	5.00	NA	5.00	Medicament
7.	Magnesium Stearate	BP	NA	NA	2.00	Lubricant
8.	Purified Talc	BP	NA	NA	3.00	Glidant
9.	Croscarmellose Sodium	BP	NA	NA	4.00	Disintegrant
10.	Colloidal Anhydrous Silica	BP	NA	NA	1.00	Glidant
	Average Weight of Uncoated Tablet (In mg)				**300.00**	

3. Pharmaceutical form: Uncoated Tablet
Description: White, circular shaped, flat, uncoated tablet, breakline on one side, plain on other side.

4. Clinical Particulars
4.1 Therapeutic indications:
BENZHEXOL TABLETS 5MG 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. Trihexyphenidyl Hydrochloride (Benzhexol Hydrochloride) is effective in reducing the rigidity of muscle spasm, tremor and excessive salivation associated with Parkinsonism. Trihexyphenidyl Hydrochloride (Benzhexol Hydrochloride) 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

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 mealtime

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, Trihexyphenidyl Hydrochloride (Benzhexol Hydrochloride) 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.

4.3 Contraindications

- Hypersensitivity to Trihexyphenidyl Hydrochloride (Benzhexol Hydrochloride) or any other ingredients of the preparation;
- Narrow angle glaucoma. Blindness after long-term use due to narrow angle glaucoma has been reported.

4.4 Special warnings and precautions for use Precautions:

BENZHEXOL TABLETS 5MG 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. Trihexyphenidyl Hydrochloride (Benzhexol Hydrochloride) may provoke or exacerbate tardive dyskinesia, it is not recommended for use in patients with this condition.
Trihexyphenidyl Hydrochloride (Benzhexol Hydrochloride) 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 Trihexyphenidyl Hydrochloride (Benzhexol Hydrochloride) 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 Trihexyphenidyl Hydrochloride (Benzhexol Hydrochloride), it should be used with extreme caution in elderly patients.

Warnings:

Trihexyphenidyl Hydrochloride (Benzhexol Hydrochloride) 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 Trihexyphenidyl Hydrochloride (Benzhexol Hydrochloride) is given concomitantly with phenothiazines, clozapine, antihistamines, disopyramide, nefopam and amantadine because of the possibility of increased antimuscarinic side-effects.
Anticholinergic agents should be used with caution in patients who are receiving tricyclic antidepressants or monoamine oxidase inhibitors. This can cause dry mouth, blurred vision, urinary hesitancy, urinary retention and constipation. In the elderly, there is a danger of precipitating urinary retention, acute glaucoma or paralytic ileus.
Trihexyphenidyl Hydrochloride (Benzhexol Hydrochloride) 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 Trihexyphenidyl Hydrochloride (Benzhexol Hydrochloride).
Trihexyphenidyl Hydrochloride (Benzhexol Hydrochloride) may be antagonistic with the actions of parasympathomimetics.

4.6 Pregnancy and Lactation

Pregnancy

There is inadequate information regarding the use of Trihexyphenidyl Hydrochloride (Benzhexol Hydrochloride) 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. Trihexyphenidyl Hydrochloride (Benzhexol Hydrochloride) should not be used during pregnancy unless clearly necessary.

Lactation

It is unknown whether Trihexyphenidyl Hydrochloride (Benzhexol Hydrochloride) is excreted in human breast milk. The excretion of Trihexyphenidyl Hydrochloride (Benzhexol Hydrochloride) in milk has not been studies in animals. Infants may be very sensitive to the effects of antimuscarinic medications. Trihexyphenidyl Hydrochloride (Benzhexol Hydrochloride) 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

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 Trihexyphenidyl Hydrochloride (Benzhexol Hydrochloride) 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, 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

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
Trihexyphenidyl Hydrochloride (Benzhexol Hydrochloride) 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
Trihexyphenidyl Hydrochloride (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:

None stated.

6. Pharmaceutical particulars

6.1 List of excipients
- Calcium Hydrogen Phosphate Dihydrate
- Maize Starch
- Povidone K30
- Purified water
- Purified talc
- Magnesium stearate
- Colloidal anhydrous silica
- Croscarmellose sodium

6.2 Incompatibilities
Not applicable

6.3 Shelf life
36 months

6.4 Special precautions for storage Store below 30°C in a dry & dark place.
Keep all medicines out of reach of children.

6.5 Nature and contents of container
Primary packing: 500 Tablets are packed in a LDPE Bag and sealed.
Secondary packing: Sealed LDPE Bag containing 500 tablets are packed in a HDPE Jar along with silica gel sachet. Heat seal the poly laminated aluminium tagger over the mouth of jar and close with HDPE Cap. Stick printed sticker Label to the HDPE Jar.
Tertiary packing: Shrink individual HDPE Jar along with leaflet. Such 100 HDPE Jars are packed in a 5 ply corrugated box sealed with BOPP tape & strap with strapping roll.

6.6 Special precautions for disposal and other handling None.

7. Applicant / Manufacturer

Applicant

Applicant name and address	**M/s. OLITH FEM PHARM LTD.** 204, Onomonu Street, Awada Obosi, Onitsha, Anambra State, Nigeria.
Contact person's phone number	
Contact person's email	

Manufacturer

Manufacturer name and address	**M/s. IMPULSE PHARMA PVT. LTD.** J-201, J-202/1 , MIDC Tarapur, Boisar, Dist. Palghar - 401506, Maharashtra State, India.
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