FESTBENX (BENZHEXOL TABLETS BP 5 MG)

Summary of Product Characteristics (SmPC)

1. Name of the medicinal product

1.1 (Invented) name of the medicinal product

FESTBENX

INN (GENERIC NAME)

BENZHEXOL TABLETS BP 5 MG

1.2 Strength:- 5 MG

1.3 Pharmaceutical form:- Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

FESTBENX (BENZHEXOL TABLETS BP 5 MG)
Each uncoated tablet contains:
- Benzhexol Hydrochloride BP (5 mg)
- Excipients: (0 QS)

Sr. No.	Ingredients	Specification	Quantity/ Tablet (mg)	% overages	Reason for inclusion
Active					
1.	Benzhexol HCL	BP	5.00	0 %	Active

BP = British Pharmacopoeia

3. PHARMACEUTICAL FORM. :

White coloured, circular, flat, uncoated tablets, having a breakline on one side & ”BENX 5”on other side of each tablet

4. CLINICAL PARTICULARS

4.1 Therapeutic indications:

Trihexyphenidyl is indicated in the management of the symptoms of post-encephalitic arteriosclerotic and idiopathic Parkinsonism and also to control extrapyramidal disorders which may be caused by certain drugs acting on the central nervous system, such as phenothiazines and reserpine (these include tremor, rigidity and increased salivation which are commonly encountered in the disease; also dyskinesia manifested by spastic contractions and involuntary movements and akathisia characterised by troublesome restlessness. Through decreasing sialorrhoea it is especially valuable as an adjunct in the treatment of arteriosclerotic Parkinsonism).

4.2 Posology and method of administration:

Adults:
In all patients alterations in dosage either upward or downwards should only be by small increments over a period of days. At the commencement of therapy the dose should be 1 mg on the first day 2 mg on the second day and thereafter by increments of 2 mg per day at 3-5 day intervals, continued until the optimum dose is reached.

The maximum daily dose is 20mg.

The relationship of Trihexyphenidyl therapy with meals will vary according to the reaction of the patient. If when taken after meals thirst is induced this can be allayed by chewing gum, peppermints or drinking water. Should Trihexyphenidyl tend to dry the mouth excessively, it is wiser taken before meals unless nausea is troublesome.

The usual dosage for Parkinsonism is 6-10 mg per day, however patients, particularly those in the post-encephalitic group may require on average a daily dose of 12-15 mg. This should be given at mealtimes either three or four times a day

On drug-induced Parkinsonism the normal dose usually lies between 5 mg and 15 mg per day. Some patients have been controlled by as little as 1 mg daily.

Children:
Trihexyphenidyl is not recommended for children.

The Elderly:
Patients over 60 years of age will be more sensitive and therefore require smaller amounts of Trihexyphenidyl.

Trihexyphenidyl tablets are to be taken by mouth.

4.3 Contraindications:

Sensitivity to Trihexyphenidyl or to any of the excipients in Trihexyphenidyl. Trihexyphenidyl is contra-indicated for patients with glaucoma and is also contra-indicated for patients with obstructive disease of the genitourinary and gastro-intestinal tracts, particularly in patients with a history of prostatic hypertrophy and prostatism.

This medicine contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.4 Special warnings and precautions for use:

The Patient should be under careful observation over the long term. It should be administered with care to avoid allergic or other untoward reactions.

Abrupt discontinuation of treatment should be avoided.
Incipient glaucoma may be precipitated by parasympatholytic drugs such as Trihexyphenidyl.
Hypertension, cardiac, liver or kidney disorders are not contra-indications, but such patients should be followed closely.

Trihexyphenidyl 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.

Trihexyphenidyl may be the subject of abuse due to its euphoric effect.

4.5 Interaction with other medicinal products and other forms of interaction:

Extra care should be taken when trihexyphenidyl 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 trihexyphenidyl 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 trihexyphenidyl. 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 trihexyphenidyl should be initially reduced and the patient reviewed regularly.

Trihexyphenidyl 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.

Trihexyphenidyl may be antagonistic with the actions of parasympathomimetics.

4.6 Pregnancy and lactation:

Problems in humans have not been documented and it is not known whether the drug is excreted in breast milk. However, lactation may be inhibited.

4.7 Effects on ability to drive and use machines:

May affect performance at skilled tasks (e.g. driving).

4.8 Undesirable Effects:

Dryness of mouth, gastro-intestinal disturbances, blurring of vision, dizziness and mild nausea or nervousness will be experienced by 30-50% of all patients. These reactions tend to become less pronounced as treatment continues.

Patients with a history of drug idiosyncrasies may exhibit reactions of mental confusion, agitation, or nausea and vomiting. Such patients should be allowed to develop a tolerance using the smaller initial dose, with gradual increases until the effective level is reached.

Less common side effects include: urinary retention, tachycardia, hypersensitivity and with high doses in susceptible patients, confusion, excitement, agitation, hallucinations, insomnia and psychiatric disturbances which may necessitate discontinuation of treatment; impaired memory also reported.

4.9 OVERDOSE:

No specific antidote. Gastric lavage, emetic, high enema. Usual general treatment plus cold compress and forcing of fluid are mandatory. Atropine antagonists may be useful.

5 Pharmacological Properties:

5.1 Pharmacodynamic properties:

It is believed that Trihexyphenidyl acts through partially blocking central (striatal) cholinergic receptors. Trihexyphenidyl has a direct anti-spasmodic effect on smooth muscles and in small doses depresses the Central Nervous System but larger doses may cause cerebral excitation.

ATC Code: N04A A01. **Classification:** Anticholinergic agents, Tertiary amines.

5.2 Pharmacokinetic properties:

Trihexyphenidyl is absorbed in the gastro-intestinal tract with an onset of action of 1 hour and duration of action of 6 to 12 hours.

5.3 Preclinical safety data:

No additional data of relevance to the prescriber.

6 Pharmaceutical Particulars

6.1 List of Excipients.

Sr. No.	Excipients	Quality standard
1.	Dibasic Calcium Phosphate	BP
2.	Lactose	BP
3.	Maize Starch	BP
4.	Maize Starch	BP
5.	Gelatin	BP
6.	Methyl paraben	BP
7.	Propyl Paraben	BP
8.	Purified Talc	BP
9.	Magnesium Stearate	BP
10.	Sodium Starch Glycolate	BP

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 Years

6.4 Special precautions for storage

Store in cool & dry place

6.5 Nature and contents of container

Jar pack of 500 tablets.

6.6 Special precautions for disposal and other handling
None.

7 Applicant
MANFES PHARMACEUTICAL COMPANY LIMITED,
11, ANAMBRSTREET, FEGGE, ONITSHA,
ANAMBRA, ONITSHA, , ANAMBRA

Manufacturer:
MEDICO REMEDIES PVT.LTD., 8&9,
DEWAN & SONS UDYOG NAGAR,
PALGHAR, MAHARASHTRA-401 404,
INDIA.