1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

1. Name of the medicinal product
TEKAXOL TAB.

2. Qualitative and quantitative composition

2.1 Label Claim
Each Uncoated tablet contains:
Benzhexol BP…..…….…. 5 mg
Excipients……q.s.

Colour: Approved colours used

2.2 Quantitative Composition
Batch Size: 10.40 Lac Tablets

Sr. No.	Ingredients	Claim	Spec.	Qty/Tab. (mg)	(%) Overages	Qty./100000 Tab. (Kg)	Function
Active Ingredient							
1.		5 mg	BP	5.55	11%	0.555	Active
Excipients							
1.	Di - Calciurn Phosphate	-	BP	46.00	NIL	4.600	Diluent & Disintegrant
2.	Starch	-	BP	78.71	NIL	7.871	Diluent & Disintegrant
3.	MicrocrystalIine Cellulose	-	BP	26.00	NIL	2.600	Disintegrant
4.	Col. Titaniurn Dioxide	-	BP	0.50	NIL	0.050	Preservative
5.	Purified Water	-	BP	0.06ml	NIL	6 liters	Vehical
6.	Methyl Hydroxy Benzoate	-	BP	0.20	NIL	0.020	Diluent & Disintegrant
7.	Propyl Hydroxy Benzoate	-	BP	0.04	NIL	0.400	Binder
8.	Starch	-	BP	4.00	NIL	0.400 liters	Diluent
9.	Purified Talc	-	BP	1.50	NIL	0.150	Lubricant
10.	Magnesium Stearate	-	BP	1.50	NIL	0.150	Lubricant
11.	Sodium Starch Glycolate	-	BP	5.00	NIL	0.500	Disintegrant
12.	Colloidal Anhydrous Silica	-	BP	1.00	NIL	1.000	Disintegrant

3. Pharmaceutical form

Tablets

White colored, circular, flat uncoated tablet
having a break line on one side of each tablets

4. Clinical particulars

4.1 Therapeutic indications

Benzhexol Hydrochloride is indicated for the treatment of acute postoperative and postpartum nonobstructive (functional) urinary retention and for neurogenic atony of the urinary bladder with retention.

4.2 Posology and method of administration

As directed by the physician.

4.3 Contraindications

- intestine infection due to the Shigella bacteria.
- diarrhea from an infection with Clostridium difficile bacteria.
- thyrotoxicosis.
- tardive dyskinesia, a disorder characterized by involuntary movements of the face, mouth and tongue.
- autonomic neuropathy.

4.4 Special warnings and precautions for use

1. Carefully read and follow all directions on the medicine bottle and box. ...
2. Take the minimum effective dose. ...
3. Call your doctor if you think you are having a problem with your medicine. ...
4. Do not take a medicine if you have had an allergic reaction to it in the past.

4.5 Interaction with other medicinal products and other forms of interaction

- Fat Soluble Vitamins/Colesevelam.
- Ascorbic Acid (Vitamin C)/Deferoxamine.
- Fat Soluble Vitamins/Orlistat.
- Pyridoxine/Levodopa.
- Folic Acid; Pyrimethamine/Hydantoins.

4.6 Fertility, pregnancy and lactation

Since no adequate and well-controlled studies of fetal effects using risperidone in pregnant women have been done, Benzhexol Hydrochloride should be used during pregnancy only if the benefit to the mother justifies the potential risk to the fetus. Risk to the infant during breast-feeding.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

- Dizziness Or Blurred Vision.
- Dry Mouth.
- Upset Stomach.
- Vomiting.
- Constipation.
- Headache.
- Difficulty Urinating.

4.9 Overdose

You Could Have Dangerous Levels Of The Drug In Your Body. Symptoms Of An Overdose Of This Drug Can Include:

- Dilated Pupils
- Dry Skin
- Fever
- Fast Heart Rate
- Trouble Urinating
- Bloating
- Bad Breath
- Confusion
- Hallucinations

5. Pharmacological properties

5.1 Pharmacodynamic properties

Benzhexol hydrochloride is an antimuscarinic indicated as an adjunct in the treatment of parkinsonism or as a treatment for drug-induced extrapyramidal symptoms. It has a long duration of action as it does not need to be given every day.It has a wide therapeutic window, with acute toxicity being non fatal in doses as high as 300 mg.[1]Patients should have their

iridocorneal angle examined before and intraocular pressure monitored during therapy. Patients should be counselled regarding the risk of anhidrosis and hyperthermia.[13]

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

NA

6. Pharmaceutical particulars

6.1 List of excipients

- Lactose
- Microcrystalline Cellulose
- Cross Carmellose Sodium
- Methyl Hydroxybenzoate
- Propyl Hydroxybenzoate
- Starch
- Povidone
- Purified Water
- Purified Talc
- Magnesium Stearate
- Sodium Starch Glycolate
- Colloidal Anhydrous Silica

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Keep out of reach of children
Protect from light.
Store in a cool, &y and dark place.

6.5 Nature and contents of container

500 Tablet packed in plastic polybag. Such plastic polybag packed in a box.
1 x 500Tab.

6.6 Special precautions for disposal and other handling

None stated.

7. Manufactured by

Hab Pharmaceuticals & Research Ltd.,
10, Pharmacity, Selaqui, Dehradun,
Uttarakhand - 248011,
India

8. Marketing authorisation holder

Hab Pharmaceuticals & Research Ltd.,
10, Pharmacity,
Selaqui, Dehradun,
Uttarakhand - 248011,
India