BIOTUX COUGH SYRUP

(EXPECTORANT)

SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC)

1. NAME OF THE MEDICINAL PRODUCT

BIOTUX COUGH SYRUP (EXPECTORANT)

Diphenhydramine hydrochloride B.P.	14.0mg,
Ammonium Chloride B.P	135.0mg,
Sodium Citrate BP	57.0mg,
Menthol BP	1.1mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains:

Diphenhydramine hydrochloride B.P.	14.0mg,
Ammonium Chloride B.P	135.0mg,
Sodium Citrate BP	57.0mg,
Menthol BP	1.1mg

Excipients:

Sucrose B.P	3.00gm
Sodium CMC	15.00 mg
Menthol Solution	0.00375ml
Citric Acid	40.00mg
Propyl Paraben	1.00mg
Methyl Paraben	10.00mg
Lemon flavour	0.0025ml
Tetrazine Yellow	0.20mg
Purified Water B.P.	q.s

3. PHARMACEUTICAL FORM

Liquid Expectorant

Yellow viscous liquid syrup presented in 100ml pet bottle with customized metallic screw cap packed in an outer secondary pack, shrink-wrapped and shipped in a tertiary carton.

4. Clinical particulars

4.1 Therapeutic indications

Biotux cough syrup (expectorant) is good for the relief of cough, its congestive symptoms, and for the treatment of hay fever as well as other allergic conditions affecting the upper respiratory tract.

4.2 Posology and method of administration

Posology

12 years - Adults: 10ml three times a day
Children: (6 - 12years) 5 ml three times a day.
Children: (2 -5) 2.5ml three times daily

Method of administration

Liquid Oral
No special method of administration advised.

4.3 Contraindications

Biotux Cough Syrup (Expectorant) is contraindicated in individuals with known hypersensitivity to Diphenhydramine or L-menthol or to any of the excipients

4.4 Special warnings and precautions for use

This product may cause drowsiness. If affected individuals should not drive or operate machinery.

This product should not be used to sedate a child.

Diphenhydramine may enhance the sedative effects of central nervous system depressants including alcohol, sedatives, opioid analgesics, antipsychotics and tranquilizers.

Alcoholic beverages should be avoided while taking this medicine.

Do not use with any other product containing diphenhydramine, including topical formulations used on large areas of skin

4.5 Interaction with other medicinal products and other forms of interaction

Diphenhydramine:

CNS depressants: may enhance the sedative effects of CNS depressants including barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives, antipsychotics and alcohol.

Antimuscarinic drugs: may have an additive muscarinic action with other drugs, such as atropine and some antidepressants.

MAOIs: Not be used in patients taking MAOIs or within 14 days of stopping treatment as there is a risk of serotonin syndrome.

Menthol: There are no known drug interactions associated with menthol.

4.6 Pregnancy and Lactation

This product should not be used during pregnancy or breastfeeding unless the potential benefit of treatment to the mother outweighs the possible risks to the developing fetus or breastfeeding infant.

Diphenhydramine use in Pregnancy: Diphenhydramine has been in widespread use for many years without any apparent ill consequence. Diphenhydramine is known to cross the placenta and, therefore, should only be used during pregnancy if considered essential by a doctor. Breastfeeding Diphenhydramine is excreted into human breast milk, but levels have not been reported. Although the levels are not thought to be sufficiently high enough after therapeutic doses to affect the infant, the use of diphenhydramine during breast-feeding is not recommended.

Menthol: There are no adequate and well-controlled studies in pregnant women for menthol. Menthol is excreted in breast milk; when 100 mg of menthol was ingested, there was up to 5.87 ug/L of menthol in breast milk

4.7 Effects on ability to drive and use machines

This product may cause drowsiness. If affected, the patient should not drive or operate machinery.

4.8 Undesirable effects

- Flushing
- Tachycardia ·
- Blurred vision ·
- Delirium ·
- Toxic psychosis ·
- Urinary retention ·
- Respiratory depression ·
- Urticaria

4.9 Overdose

Symptoms and signs

Diphenhydramine

Mild to Moderate Symptoms: Drowsiness, anticholinergic syndrome (mydriasis, flushing, fever, dry mouth, urinary retention, decreased bowel sounds), tachycardia, mild hypertension, nausea and vomiting are common after overdose. Agitation, confusion and hallucinations may develop after moderate poisoning.

Severe Symptoms: Effects may include delirium, psychosis, seizures, coma, hypotension, QRS widening, and ventricular dysrhythmias (including torsades de pointes), but are generally only reported in adults after large ingestions. Rhabdomyolysis and renal failure may rarely develop in patients with prolonged agitation, coma or seizure. Death may occur as a result of respiratory failure or circulatory collapse.
In children, CNS excitation, including hallucinations and convulsions may appear; with larger doses, coma or cardiovascular collapse may follow.

Menthol

Excessive use of menthol may lead to abdominal pain, vomiting, flushed face, dizziness, weakness, tachycardia, stupor, and ataxia.

Treatment

Treatment of overdose should be symptomatic and supportive. The benefit of gastric decontamination is uncertain. Consider activated charcoal (charcoal dose: 50 g for adults; 1 g/kg for children) only if the patient presents within 1 hour of ingestion of a potentially toxic amount Seizures may be controlled with Diazepam or Thiopental Sodium. The intravenous use of Physostigmine may be efficacious in antagonizing severe anticholinergic symptoms.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Diphenhydramine possesses antitussive, antihistaminic and anticholinergic properties. Experiments have shown that the antitussive effect (resulting from an action on the brainstem) is discrete from its antihistaminic effect.

The duration of activity of diphenhydramine is between 4 and 8 hours.

Menthol has mild local anesthetic and decongestant properties.

5.2 Pharmacokinetic properties

Absorption

Diphenhydramine and menthol are well absorbed from the gut following oral administration. Peak serum levels of diphenhydramine following a 50 mg oral dose are reached at between 2 and 2.5 hours.

Distribution

Diphenhydramine is widely distributed throughout the body, including the CNS. Following a 50 mg oral dose of diphenhydramine, the volume of distribution is in the range 3.3 - 6.8 l/kg, and it is some 78% bound to plasma proteins.

Metabolism and Elimination

Diphenhydramine undergoes extensive first pass metabolism. Two successive N demethylations occur, with the resultant amine being oxidised to a carboxylic acid. Values for plasma clearance of a 50 mg oral dose of diphenhydramine lie in the range 600-1300 ml/min and the terminal elimination half-life lies in the range 3.4 - 9.3 hours. Little unchanged drug is excreted in the urine. Menthol is hydroxylated in the liver by microsomal enzymes to p-methane-3,8 diol. This is then conjugated with glucuronide and excreted both in urine and bile as the Glucuronide.

The Elderly

Pharmacokinetic studies indicate no major differences in distribution or elimination of Diphenhydramine compared to younger adults.

Renal Dysfunction

The results of a review on the use of Diphenhydramine in renal failure suggest that in moderate to severe renal failure, the dose interval should be extended by a period dependent on Glomerular filtration rate (GFR).

5.3 Preclinical safety data

Mutagenicity
The results of a range of tests suggest that neither diphenhydramine nor menthol have mutagenic potential.

Carcinogenicity
There is insufficient information to determine the carcinogenic potential of diphenhydramine or menthol, although such effects have not been associated with these drugs in animal studies.

Teratogenicity
The results of a number of studies suggest that the administration of either diphenhydramine or menthol does not produce any statistically significant teratogenic effects in rats, rabbits and mice.

Fertility
There is insufficient information to determine whether diphenhydramine has the potential to impair fertility, although a diminished fertility rate has been observed in mice in one study.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Excipients:

Sucrose B.P	2.50gm
Sodium CMC	15.00 mg
Menthol Solution	0.00375ml
Citric Acid	40.00mg
Propyl Paraben	1.00mg
Methyl Paraben	10.00mg
Lemon flavour	0.0025ml
Tetrazine Yellow	0.20mg
Purified Water B.P.	Q.S

6.2 Incompatibilities

None

6.3 Shelf life

3 years (36months)

6.4 Special precautions for storage

Store in a cool, dry place below 30℃.

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

Primary pack: 100ml amber colored PET bottle with a customized **'Biopharma'** metallic cap

Equipment for administration: Transparent 10ml measuring cup

Secondary pack: customized 300gm outer pack

Shipping cartons

6.6 Special precautions for disposal <and other handling>

None

7. <APPLICANT/MANUFACTURER>

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