Front - 110mm

Back - 110mm

140mm

Pediatric Bencodyl Linctus

Name and Strength of Active Ingredient(s)
Each 5 ml contains:
Diphenhydramine HCl ..... 7 mg
Ammonium Chloride ..... 67.5 mg
Levomenthol ..... 0.9 mg

Preservative:
Sodium Benzoate ..... 0.1% w/v

Product Description
Brown liquid with strawberry flavour.

Pharmacodynamics
Diphenhydramine Hydrochloride is a sedating antihistamine and the mechanism of the antitussive action may involve reduction in cholinergic nerve transmission and reduction of nasal secretions. It is useful in the management of children with an acute allergic cough.
Ammonium Chloride is an expectorant and increases the volume of secretions in the respiratory tract thereby facilitating the removal by ciliary action and coughing.

Pharmacokinetics
Diphenhydramine hydrochloride is well absorbed from the gastrointestinal tract and peak plasma concentrations are achieved about 1-4 hours after oral doses. It is excreted mainly in the urine as metabolites.
Ammonium Chloride is absorbed from the gastrointestinal tract and converted into urea in the liver.

Indications
For productive cough and complication associated with allergic disorders and allergic manifestation of respiratory illness e.g. common cold, Flu, and Bronchitis.

Recommended Dose
2 to 6 years : 5 ml, 3 - 4 times a day.
6 to 12 years : 5 - 10 ml, 3 - 4 times a day.
The usage of Pediatric Bencodyl Linctus on children below age of 2 is not recommended.

Route of Administration
Oral

Contraindications
In patients with known hypersensitivity to antihistamines.

Warnings and Precautions
When used for the treatment of cough and cold:
(a) Not to be used in children less than 2 years of age.
(b) To be used with caution and doctor's/pharmacist's advice in children 2 to 6 years of age.

This medication may lead to drowsiness and impaired concentration.

Interactions with Other Medicaments
- Additive CNS depressant effects with alcohol and other CNS depressants including barbiturates, hypnotics, opiod analgesics, anxiolytic sedatives and anti-psychotics.
- Additive anti-muscarinic effects with other drugs of similar properties such as atropine and some anti-depressants.
- Not to be taken in patients taking monoamine oxidase inhibitors (MAOIs) or within 14 of stopping treatment as there is a risk of serotonin syndrome.
- Diphenhydramine can inhibit the oxidative metabolism of some drugs.
- Diphenhydramine may enhance the effects of ephedrine.
- Diphenhydramine may mask the response of the skin to allergenic skin tests and also the ototoxic symptoms associated with certain antibiotics.

Pregnancy and Lactation
Pregnancy
In view of the potential risks versus small benefits, it is recommended that Pediatric Bencodyl Linctus should not be used during pregnancy particularly as the safety of Pediatric Bencodyl Linctus in human pregnancy is not established.

Lactation
In view of the potential risks versus small benefits, it is recommended that Pediatric Bencodyl Linctus should not be used during lactation particularly as the safety of Pediatric Bencodyl Linctus during lactation is not established.

Side Effects
The overall percentage of treated patients expected to experience adverse reactions is unknown.

Common side effects include:
CNS effects such as nervous drowsiness (usually diminishes within a few days), paradoxical stimulation, nervous headache, nervous psychomotor impairment.
Anti-muscarinic effects such as urinary retention, dry mouth, blurred vision, gastrointestinal disturbances and thickened respiratory tract secretions.

Rare side effects include:
Hypotension, extrapyramidal effects, dizziness, confusion, depression, sleep disturbances, tremor, convulsions, palpitation, arrhythmia, hypersensitivity reactions, blood disorders and liver dysfunction.

Organ System Class	Common ADRs, >1/100, <1/10	Uncommon ADRs, >1/1000, <1/100	Rare ADRs >1/10000, <1/1000
Blood Lymphatic System Disorder			Blood Disorders NOS
Cardiac Disorder			Palpitation, arrhythmia
Eye Disorders	Blurred vision		
Gastrointestinal Disorder	Dry mouth, gastrointestinal disturbance		
General Disorder	Paradoxical drug reaction		
Hepatobiliary Disorder			Liver Disorder
Immune System Disorders			Hypersensitivity
Nervous System Disorders	Psychomotor skills impairment, drowsiness, headache		Tremor, convulsions, extrapyramidal disorder, dizziness
Psychiatric Disorders			Confusion, depression, sleep disturbances.
Renal and Urinary Disorders	Urinary retention		
Respiratory Disorder	Increased upper airway secretion		
Vascular Disorders			Hypotension

Overdose and Treatment
Symptoms of overdosage include those due to diphenhydramine or Levomenthol (drowsiness, dizziness, ataxia, anti-cholinergic effects, pyrexia, headaches, convulsions, hallucinations, excitement and respiratory depression).

Treatment consists of gastric lavage and aspiration. Administration of activated charcoal may help. Other symptomatic and supportive measures should be provided.

Storage Conditions
Keep container tightly closed. Store below 30ºC. Protect from light.
Keep out of reach of children.

Dosage Forms
Oral liquid.

Pack Size
60ml and 100ml

Registration Number
MAL16065027AZ

Manufactured by & Product Registration Holder
KCK PHARMACEUTICAL INDUSTRIES SDN. BHD.
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Date of Revision of Package Insert
29 APRIL 2022