

BENCODYL LINCTUS

Name and Strength of Active Ingredient(s)

Each 5 ml contains:

Diphenhydramine HCl BP.....	14 mg
Ammonium Chloride BP.....	135 mg
Sodium Citrate BP.....	57 mg
Menthol BP.....	1.1 mg

Preservative:

Sodium Benzoate BP.....	0.1% w/v
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Product Description

Dark brown liquid with raspberry 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.

Menthol is for subjective relief of upper respiratory congestion. It has mild anesthetic and cooling effect.

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.

After absorption, menthol is excreted in the urine and bile as a glucuronide.

Indications

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

Recommended Dosage

Adults: 10ml, 3 - 4 times daily

Children 6 to 12 years: 2.5 - 5ml, 3 - 4 times daily

Children 2 to 6 years: 2.5ml, 3 - 4 times daily

The usage of 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:

- Not to be used in children less than 2 years of age.
- To be used with caution and doctor's or pharmacist's advice in children 2 to 6 years of age.

It may cause drowsiness and mental dulling of alertness. Patients should not drive or operate machinery if affected and should abstain from alcoholic beverages.

Interactions with Other Medicaments

- Additive CNS depressant effects with alcohol and other CNS depressants including barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives and anti-psychotics.
- Additive antimuscarinic 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 days 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.

Statement on Usage During Pregnancy and Lactation

Pregnancy

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

Lactation

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

Adverse Effects/Undesirable 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	Uncommon ADRs	Rare ADRs
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 Disorder	Urinary retention		
Respiratory Disorder	Increased upper airway secretion		
Vascular Disorders			Hypotension

Overdose and Treatment

Symptoms of overdose include those due to diphenhydramine or menthol (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.

Effects on Ability to Drive and Use Machine

Bencodyl Linctus may cause drowsiness. Do not drive or operate machinery. Avoid alcoholic drink.

Storage Conditions

Keep container tightly closed. Store below 30°C. Protect from light.

Dosage Forms and Packaging Available

Oral liquid in 90ml and 100ml bottle.

Registration Number

MAL19860108AZ

Manufactured by & Product Registration Holder

KCK PHARMACEUTICAL INDUSTRIES SDN. BHD.
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Pulau Pinang, Malaysia.

Date of Revision of Package Insert

14 June 2022