	Biomedical Limited, **1, Ohimege Road, Industrial Estate, Ga-Imam, Ilorin, Kwara State**		
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Summary of Product Characteristics

For

IPEC-H syrup

(Ammonium chloride+ Chlorpheniramine maleate + Sodium citrate+ Ipecacuahna+ Menthol)

1. NAME OF MEDICINAL PRODUCT IPEC-H syrup

2. QUALITATIVE AND QUANTITATIVE DESCRIPTION

Each 5ml of the syrup contains

Ammonium chloride 50mg

Chlorpheniramine maleate 2mg Sodium citrate 50mg

Ipecacuahna 0.1ml

Menthol 1.0mg

3. PHARMACEUTICAL FORM

A brown viscous liquid with Sweet cherry flavour in 100ml amber PET bottle with pilfer proof cap and graduated dose measurement cup to facilitate easy dosing

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

IPEC-H is an antitussive and expectorant cough mixture. It is indicated for the relief of cough, sneezing, nasal congestion, nasal discharge, itchy and watery red eyes, hay fever and cold.

4.2 Posology and method of administration

Posology

The safety and efficacy of all active pharmaceutical ingredients used in the formulation of IPEC-H cough syrup has been established in adults and paediatric populations when taken at the prescribed doses

Method of Administration

Age group	**Dose**
1-5yr	2.5ml three times daily
6-12yrs	5ml three times daily
Adults	10ml three times daily

Or as directed by the physician. Note: A maximum of four doses per day should not be exceeded.

4.3 Contraindications

IPEC-H is contraindicated in patients with known hypersensitivity to any ingredient of the product.

4.4 Special warnings and Precautions for Use

Driving and Operation of Machinery

IPEC-H should not be taken in this case as some of the active ingredients of IPEC-H can cause extreme sedation.

Alcohol

Avoid concomitant use of alcohol with this medication.

4.5 Drug Interactions

Anxiolytics

Concomitant use of IPEC-H with alcohol, tricyclic antidepressant, opioids, benzodiazepines, anticholinergic and muscle relaxants lead to exaggerated sedation due to the presence of Chlorpheniramine maleate.

4.6 Pregnancy and Lactation

Pregnancy

There are no known defects with the use of any of the active ingredients of IPEC-H in pregnancy. Although, there have been insinuations that diphenhydramine causes birth defects when used in the first trimester, but the veracity of the claim is not substantial as the different studies undertaken to establish this claim do not all agree.

Lactation

IPEC-H would not be expected to cause any adverse effects in breastfed infants. Larger doses or more prolonged use may however cause effects in infants or decrease the milk supply. Mother may need to consider moderate dose after the last feeding of the day to minimize any effects of the drug.

4.7 Effects on ability to drive and use machine

IPEC-H can cause sedation and it should not be taken if there are plans to operate machine or drive.

4.8 Undesirable effects

There are no serious or deleterious effects with taking IPEC-H. The observed side effects with the ingredients of IPEC-H are such that are cleared up with completion of the drug therapy.

Chlorpheniramine maleate

Common side effects include dizziness, sedation, psychomotor impairment, cognitive impairment, Palpitations, tachycardia, dry mouth, blurred vision, constipation, urinary retention, and weight gain. Children and the elderly are more susceptible to neurological anticholinergic effects and paradoxical excitation (eg increased energy, restlessness, nervousness

Sodium citrate

Common side effects of Sodium citrate include diarrhoea, nausea, muscle spasms, metabolic acidosis, vomiting, stomach pain and fluid retention

Usually well tolerated, but may cause mild GI disturbances. Rarely, hypersensitivity reactions.

Menthol

Prolonged use of very high doses can lead to symptoms of menthol poisoning, such as rash, wheezing, tightness in the chest, swelling of the mouth, face or throat

4.9 Overdose

Ammonium Chloride

Over dosage of Ammonium Chloride has resulted in a serious degree of metabolic acidosis, disorientation, confusion and coma. Treatment Should metabolic acidosis occur following over dosage, the administration of an alkalinizing solution such as sodium bicarbonate or sodium lactate will serve to correct the acidosis. Over dosage with sodium salts may cause diarrhea, nausea and vomiting, hypernoia, and convulsions.

Chlorpheniramine maleate

The estimated lethal dose of chlorpheniramine is 25 to 50mg/kg body weight. Symptoms and signs include sedation, paradoxical excitation of the CNS, toxic psychosis, convulsions, apnoea, anticholinergic effects, dystonic reactions and cardiovascular collapse including arrhythmias.

Symptomatic and supportive measures should be provided with special attention to cardiac, respiratory, renal and hepatic functions and fluid and electrolyte balance. If over dosage is by the oral route, treatment with activated charcoal should be considered provided there are no contraindications for use and the overdose has been taken recently (treatment is most effective if given within an hour of ingestion). Treat hypotension and arrhythmias vigorously.

Menthol

Menthol overdose is rare, except taken at extremely large doses. Orally, the lethal dose of Menthol has been estimated as 50-150mg/kg. Chronic exposure to menthol ingestion has been reported to be associated with cutaneous, gastrointestinal and neurological manifestations. Renal dysfunction is

common probably because of interstitial nephritis. An excessive amount of menthol is also reported to have caused agitation, dizziness, ataxia, hallucination, convulsion and coma.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: Antitussive/expectorant

ATC code:

Mechanism of Action/Pharmacodynamics effects

Ammonium chloride

Ammonium chloride is an effective expectorant due to its irritative action on the bronchial mucosa. This effect causes the production of respiratory tract fluid which in order facilitates the effective cough.

Chlorpheniramine maleate

Chlorpheniramine is a potent antihistamine (H1-antagonist).

Antihistamines diminish or abolish the actions of histamine in the body by competitive reversible blockade of histamine H1-receptor sites on tissues. Chlorpheniramine also has anticholinergic activity.

Antihistamines act to prevent the release of histamine, prostaglandins and leukotrienes and have been shown to prevent the migration of inflammatory mediators. The actions of chlorpheniramine include inhibition of histamine on smooth muscle, capillary permeability and hence reduction of oedema and wheal in hypersensitivity reactions such as allergy and anaphylaxis.

Sodium citrate

Sodium citrate is a decongestant mucolytic agent which thins and loosens mucus (phlegm), making it easier to cough out.

Menthol

Menthol is a topical agent that acts as a counter-irritant by imparting a cooling effect and by initially stimulating nociceptors and then desensitizing them

5.2 Pharmacokinetics Properties

Ammonium chloride

Ammonium chloride is absorbed from the gastro-intestinal tract. The ammonium ion is converted into urea in the liver, the anion thus liberated into the blood stream and extracellular fluid causes a metabolic acidosis and decreases the pH of the urine; this is followed by transient diuresis.

Chlorpheniramine maleate

Chlorpheniramine is well absorbed from the gastro-intestinal tract, following oral administration. The effects develop within 30 minutes, are maximal within I to 2 hours and last 4 to 6 hours. The plasma half-life has been estimated to be 12 to 15 hours.

Chlorpheniramine is metabolized to the monodesmethyl and didesmethyl derivatives. About 22% of an oral dose is excreted unchanged in the urine

Sodium citrate

Sodium citrate is a weak base. After absorption, it is metabolized to produce bicarbonate, and the generated bicarbonate is neutralized by the hydrogen ions in the blood.

Menthol

Menthol is rapidly absorbed from the small intestine and extracted in the urine predominantly (approximately 65%) as menthol glucuronide.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Sucrose, Sodium benzoate, Sorbitol, Sodium carboxyl methyl cellulose, Sweet cherry flavour, Anise oil, Ethanol 96%, Glycerol, Citric acid, Caramel,

6.2 Incompatibilities

None

6.3 Shelf life

3 years

6.4 Special Precautions for Storage

IPEC-H should be stored in a cool dry place at temperatures not more than 30^{o}C

6.5 Nature and Contents of Container

Plain Amber-coloured Polyethylene terephthalates (PET) bottle with ROPP cap placed inside a paperboard carton

6.6 Special Precautions for disposal

Container and/or any unused product should be disposed in accordance with the local requirement

7. MANUFACTURER

BIOMEDICAL LTD
1, Ohimege Road, Industrial Estate
Ilorin Kwara State, PMB 1449