**IBUCAP COLD AND FLU**

**(Chlorphenamine Maleate, Paracetamol &Phenylephrine Hydrochloride Syrup)**

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE MEDICINAL PRODUCT

**1.1 Product name:** IBUCAP COLD AND FLU SYRUP (Chlorphenamine Maleate, Paracetamol & Phenylephrine Hydrochloride Syrup)

**1.2 Dosage Strength:**

Each 5 ml contains

Chlorphenamine Maleate BP (1 mg)

Paracetamol BP (125 mg)

Phenylephrine Hydrochloride BP (2.5 mg)

**1.3 Dosage Form:** Syrup

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

| Name of constituent | Quantity per 5ml in mg | % of each ingredient is expressed as a percentage | Quantity in kg | % of each ingredient is expressed as a percentage | Role of ingredient |
|---|---|---|---|---|---|
| Chlorphenamine Maleate BP | 1.000 | 0.02 % | 0.600 | 0.02 % | Active ingredient |
| Paracetamol BP | 125.000 | 2.5 % | 75.000 | 2.5 % | Active ingredient |
| Phenylephrine Hydrochloride BP | 2.500 | 0.05 % | 1.500 | 0.05 % | Active ingredient |
| Colour Caramel IH | 3.000 | 0.06 % | 1.800 | 0.06 % | Colour |
| Bronopol BP | 0.500 | 0.01 % | 0.300 | 0.01 % | Stabilizer |
| Citric acid monohydrate BP | 7.500 | 0.15 % | 4.500 | 0.15 % | pH adjustment |
| Methyl Hydroxybenzoate (Methyl paraben) BP | 10.000 | 0.2 % | 6.000 | 0.2 % | Antimicrobial Preservative |
| Propyl Hydroxybenzoate (Propyl paraben) BP | 1.050 | 0.02 % | 0.630 | 0.02 % | Antimicrobial Preservative |
| Propylene Glycol BP | 1500.000 | 30.0 % | 900.000 | 30.0 % | Solvent |
| Saccharine Sodium BP | 2.000 | 0.04 % | 1.200 | 0.04 % | Sweetening Agent |
| Sodium Benzoate BP | 4.000 | 0.08 % | 2.400 | 0.08 % | Antimicrobial Preservative |
| Sodium Hydroxide BP | 4.000 | 0.08 % | 2.400 | 0.08 % | pH adjustment |
| Sorbitol 70% BP | 500.000 | 10.0 % | 300.000 | 10.0 % | Sweetening Agent |

| | | | | | |
|---|---|---|---|---|---|
| Sugar S 30 IH | 2500.000 | 50.0 % | 1500.000 | 50.0 % | Syrup base |
| Flavour Strawberry IH | 0.017 ml | 0.34 % | 10.200 | 0.34 % | Flavour |
| Flavour Coolmint "S" IH | 0.007 ml | 0.14 % | 4.200 | 0.14 % | Flavour |

BP: British Pharmacopoeia
IH: In-house Specification

## 3. PHARMACEUTICAL FORM

Syrup (Oral)

Dark brown coloured syrup with flavour of strawberry and cool mint.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

**IBUCAP COLD & FLU Syrup** is indicated for: Cold & Flu and its associated symptoms like pain, headache, nasal congestion and fever.

### 4.2 Posology and method of administration

**Dosage:** Children 5 to 12 years – 10ml to be given every 4 hours with a maximum of 6 doses in 24 hours unless directed by a physician.
Do not give for more than 5 days unless directed by a physician.

**Route of Administration:** Oral

### 4.3 Contraindications

**Ibucap Cold & Flu Syrup** is contraindicated in patients with impaired kidney or liver function, cardiac arrhythmias, active peptic ulcer. Concurrent administration of monoamine oxidase inhibitors and tri-cyclic antidepressants, severe hypertension, myocardial infarction, hyperthyroidism and pregnancy. **Ibucap Cold & Flu Syrup** is also not suitable for the patients with known hypersensitivity to any of the ingredients of the drug.

### 4.4 Special warnings and precautions for use

**Pregnant women:** because of potential promotion of uterine contractility and peripheral vasoconstriction, with the possibility of fetal hypoxia, Ibucap Cold & Flu Tablet/Syrup is best avoided in pregnancy.

**Nursing mothers:** Mothers taking Tablet/Syrup should not breastfed.

Children- Special care should be taken when using Tablet/Syrup in children and the elderly as they are more prone to developing neurological anti-cholinergic effects.

### 4.5 Interaction with other medicinal products and other forms of interaction

**Phenylephrine Hydrochloride** may cause hypertension, sometimes severe, where used concurrently with monoamine oxidase, tri-cyclic type antidepressants, ganglion blocking agents, adrenergic blocking drugs, and methyldopa.

**Chlorphenamine Maleate** may enhance the sedative effects of alcohol, hypnotics, anxiolytics, sedatives, opioid analgesics and neuroleptics. The antimuscarinic effects of Chlorpheniranine are enhanced by other antimuscarinic drugs and both antimuscarinic and sedative effects are enhanced by monoamine oxidase inhibitors and tricyclic antidepressants. Metabolism of phenytoin may be inhibited with the possible development of Phenytoin toxicity.

**Paracetamol:** Cholesyramine reduces absorption. Activated charcoal: administered immediately after administration of Paracetamol, reduces absorption of Paracetamol. Domperidone & Metoclopramide: Enhance absorption of Paracetamol. Alcohol: Chronic excessive ingestion of alcohol potentiates hepatotoxicity of paracetamol. Effects of Zidovudine may be decreased.

## 4.6 Pregnancy and lactation

**Pregnant women:** because of potential promotion of uterine contractility and peripheral vasoconstriction, with the possibility of fetal hypoxia, Ibucap Cold & Flu Tablet is best avoided in pregnancy.

**Nursing mothers:** Mothers taking Tablet should not breastfed. Children- Special care should be taken when using Tablet in children and the elderly as they are more prone to developing neurological anti-cholinergic effects.

## 4.7 Effects on ability to drive and use machines

Drowsiness, dizziness, blurred vision has been reported which can seriously hamper the patient's ability to drive and use machinery.

## 4.8 Adverse Reactions

**Chlorphenamine Maleate:** drowsiness, dizziness, dryness of mouth.

**Phenylephrine hydrochloride:** Rarely may elevate blood pressure with headache, palpitation and vomiting; tachycardia or reflex bradycardia; tingling and coolness of the skin.

**Paracetamol:** Adverse effects are rare but hypersensitivity including skin rash may occur. There have been reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily causally related to Paracetamol.

## 4.9 Symptoms of Overdosage & Treatment

**Chlorphenamine Maleate:** Symptoms and signs include sedation, paradoxical stimulation of the CNS, toxic psychosis, seizures, apnoea, convulsions, anticholinergic effects, dystonic reactions and cardiovascular collapse including arrhythmias.

Treatment includes gastric lavage or emesis using Ipecacuanha syrup. Following these measures activated charcoal and cathartics may be administered to minimise absorption. Other symptomatic and supportive measures should be provided with special attention to cardiac, respiratory, renal and hepatic functions and fluid and electrolyte balance.

**Phenylephrine Hydrochloride:** Severe over dosage may produce hypertension and associated reflex bradycardia. Treatment measures include early gastric lavage and symptomatic and supportive measures.

**Paracetamol:** Symptoms of Paracetamol over dosage in the first 24 hours are pallor, nausea, vomiting, diarrhoea, anorexia, abdominal pain, and increased sweating. Liver damage may become apparent 12 to 48 hours after ingestion. Gastric lavage or induced emesis may be used for the treatment. Specific therapy with an antidote such as Acetylcysteine or Methionine may be necessary.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

**Pharmacotherapeutic group:**

Paracetamol: Analgesics and Antipyretics

Phenylephrine: Decongestants For Systemic Use

Chlorphenamine maleate: HI histamine receptor for systemic use

**ATC code:**

Paracetamol: N02BE01

Phenylephrine: R01BA53

Chlorphenamine maleate: R06AB04

**Pharmacological action:**

**Chlorphenamine Maleate** is an H1histamine receptor antagonist.

**Phenylephrine** is a sympathomimetic amine; selectively acting on adrenergic receptor causing vasoconstriction mediated nasal decongestant effect.

**Paracetamol** exhibits analgesic action by peripheral blockage of pain impulse generation. It produces anti-pyresis effect by inhibiting the hypothalamic heat-regulating centre.

### 5.2 Pharmacokinetic properties

| | Chlorpheniramine Maleate | Paracetamol | Phenylephrine Hydrochloride |
|---|---|---|---|
| Absorption - oral: | >80% | > 95% | Irregular |
| Pre-systemic Metabolism: | <20% | 20% | 60% |
| Range: | 13.2 - 43 hours | 1.5 - 3.0 hours | 2.1 - 3.4 hours |
| Mean: | 30 hours | 2.3 hours | --- |
| Volume of distribution: | 1-10 l.kg-1 | 0.9 l.kg-1 | 340 l.kg-1 |
| Plasma protein binding: | 69-72% | < 20% | unknown |
| Elimination: | via urine | via urine | via urine |

## 5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on studies of safety pharmacology, genotoxicity and toxicity to reproduction.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

| | |
|---|---|
| Bronopol | BP |
| Citric acid monohydrate | BP |
| Methyl Hydroxybenzoate (Methyl paraben) | BP |
| Propyl Hydroxybenzoate (Propyl paraben) | BP |
| Propylene Glycol | BP |
| Saccharine Sodium | BP |
| Sodium Benzoate | BP |
| Sodium Hydroxide | BP |
| Sorbitol 70% | BP |
| Sugar S 30 | IH |
| Flavour Strawberry | IH |
| Flavour Coolmint “S” | IH |

### 6.2 Incompatibilities

None.

### 6.3 Shelf life

36 months

### 6.4 Special precautions for storage

Do not store above 30°C. Protect from sunlight and moisture. Keep out of reach of children.

### 6.5 Nature and contents of container

Amber coloured PET Bottle: 1 x 100 ml

(With 10 ml measuring cup)

Carton: - 1 x 100 ml Bottle

## 7. MARKETING AUTHORISATION HOLDER

**SHALINA HEALTHCARE DMCC,**

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Jumeirah Lakes Towers Dubai-UAE.

**Local Applicant in Nigeria:**

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