

# 123® Pediatric Syrup

## COMPOSITION

Each teaspoonful (5 ml) contains:

Carbinoxamine maleate .....	1.00 mg
Phenylephrine HCl .....	1.00 mg
Sodium Salicylate.....	100.00mg
Excipient q.s.....	5.00 ml

## INDICATIONS & CLINICAL USE

For the symptomatic relief of mild to moderate pain, fever and inflammation. Carbinoxamine Maleate is an antimuscarinic, central sedative Serotonin antagonist agent. It is used to relieve hypersensitivity disorders and as ingredient in preparations for the symptomatic treatment of cough and common cold. Phenylephrine HCl moiety is a direct-acting sympathomimetic amine. It acts on alpha-adrenergic receptors of peripheral arterioles. It decreases congestion in allergic rhinitis and inhibits intestinal activity. It promotes relief of colds and other upper respiratory conditions. It is used subcutaneously or intramuscularly in the treatment of hypotensive states.

Sodium Salicylate is an analgesic, anti-inflammatory and antipyretic agent. It is used mainly in rheumatic fever and joint disorders.

## CONTRAINDICATIONS

123® Pediatric Syrup is contraindicated in patients:

- With hypersensitivity to any component of this product
- With hypersensitivity to other nonsteroidal anti-inflammatory drugs (NSAIDS) or to other antihistamines structurally similar to carbinoxamine.
- Who have had a bronchospastic reaction, generalized urticaria, angioedema, severe rhinitis, laryngeal edema or shock precipitated by acetylsalicylic acid (ASA) or nonsteroidal anti-inflammatory drugs. This also includes ASA sensitive asthmatics.
- With a history of hemophilia or other hemorrhagic disorders, those receiving anticoagulant drugs with severe anemia.
- With gastrointestinal ulceration.
- With narrow angle glaucoma.
- With hypertension.
- With urinary retention.
- With glucose-6-phosphate dehydrogenase deficiency (genetic).
- Less than 6 years old.

## WARNINGS

- Sodium salicylate (S.S.) is one of the most frequent causes of accidental poisoning in toddlers and infants. S.S containing preparations should therefore be kept well out of the reach of all children.
- Due to the presence of carbinoxamine, which is an antihistamine, the syrup causes drowsiness. However, antihistamines may cause excitability in children.
- Phenylephrine: use with caution in patients with hyperthyroidism, diabetes mellitus and cardio-vascular disorders.

## PRECAUTIONS

- Due to the sodium salicylate and to the carbinoxamine components, 123® Pediatric Syrup should be used with caution in patients with renal or hepatic dysfunction.
- Due to the Phenylephrine component, 123® Pediatric Syrup should not be used together with monoamine oxydase inhibitors.

## DRUG INTERACTIONS

- Sodium Salicylate can potentiate the following:
  - Anticoagulant effect of antivitamin K
  - Hypoglycemic effect of sulfonylureas
  - Methotrexate
  - Penicillin Antibiotics

Therefore, the dosage of these substances should be reduced.

- Carbinoxamine: 123® Syrup may potentiate the sedative effects of Central Nervous System depressants and may enhance the effects of anticholinergics such as atropine and tricyclic antidepressants. It may mask ototoxic symptoms associated with certain antibiotics.

- Phenylephrine: 123® Syrup should not be used together with monoamine oxidase inhibitors.

## ADVERSE REACTIONS

### • Salicylates

#### Gastrointestinal

Most common adverse effects of Salicylates are GI disturbances such as nausea, dyspepsia, vomiting. These are minimized by giving the medication with food. They are also dose dependent.

#### Hypersensitivity reactions

Urticaria and cross-sensitivity to other NSAID (non-steroidal anti-inflammatory drugs) might develop. Hepatotoxicity might be manifested in patients with juvenile arthritis.

## Blood disorders

Adverse reactions have been reported such as thrombocytopenia, agranulocytosis, aplastic anemia and increased bleeding time.

### Asthmatic patients

Some asthmatic patients might exhibit notable sensitivity to salicylates.

### Reye's Syndrome

Use of ASA may be associated with the development of Reye's syndrome in children with acute febrile illnesses, especially influenza and varicella. Although a direct causal relationship has not been established, salicylates should not be administered to, or used by, children or teenagers who have chicken pox or manifest flu symptoms before a physician or pharmacist is consulted about Reye's syndrome, a rare but serious illness.

### • Carbinoxamine Mateate.

#### Sedation

Sedation varies from slight drowsiness to deep sleep. These may diminish after a few days of treatment.

#### CNS Effects

Dizziness, diplopia.

#### GI tract disturbances

Reduction in tone and mobility of GI tract might develop with antihistamine administration, resulting in constipation and gastric reflux, vomiting, dry mouth, nose and throat, anorexia and dysuria.

#### Hypersensitivity reactions

Antihistamines may produce hypersensitivity reactions, specially of the skin, as well as a cross-sensitivity to related drugs.

### • Phenylephrine HCl

#### CNS effects

Fear, anxiety, restlessness, tremor, irritability, loss of appetite, nausea may occur.

#### Cardiovascular Effects

Stimulation of alpha-adrenergic receptors produces vasoconstriction with resultant hypertension. Palpitations.

#### Other Effects

Urinary retention, dyspnea, weakness, disturbances of glucose metabolism, sweating, heating, headaches might occur.

## SYMPTOMS & TREATMENT OF OVERDOSAGE

### Symptoms

In mild overdosage, these may include rapid and deep breathing, severe drowsiness, nausea, vomiting (leading to alkalosis), stomach pain, diarrhea, headache, hypernea, vertigo, tinnitus, flushing, sweating, thirst and tachycardia. (High blood levels of ASA lead to acidosis). Severe cases may show fever, hemorrhage, bloody urine, excitement, confusion, hallucinations, severe nervousness, convulsions, and respiratory failure.

### Treatment

Treatment is essentially symptomatic and supportive. Administer water, activated charcoal and ipecac syrup unless the patient is comatose, and remove by gastric lavage or emesis. Patients with mild intoxication should be encouraged to drink plenty of fluids. In patients with more severe intoxication forced alkaline diuresis may be required. Plasma electrolytes, especially potassium, and the acid-base balance should be monitored regularly. In the presence of cardiac or renal impairment or in very severe intoxication, hemodialysis or hemoperfusion may need to be considered. Respiratory depression may require intubation measures aimed at supporting respiration.

## DOSAGE

**Children above 6 years of age:** 1/2 to 1 teaspoonful three or four times daily, as directed by the physician

**Do not use in children under 6 years of age.**

**Do not use after the expiry date**

## STORAGE CONDITIONS:

Store in a dry place below 30°C, protected from light. Do not refrigerate.

## PRESENTATION

Bottles of 60 ml.

### This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.

- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold you the medicament.

- The doctor and the pharmacist are experts in medicine, its benefits and risks.

- Do not by yourself interrupt the period of treatment prescribed.

- Do not repeat the same prescription without consulting your doctor.

## KEEP MEDICAMENT OUT OF REACH OF CHILDREN.

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