

## Dacof<sup>®</sup> paediatric Cough Syrup

### Qualitative and quantitative composition:

Each 5ml contains: Diphenhydramine HCl BP 7.0 mg, Sodium Citrate BP 28.5 mg and Menthol BP 0.55 mg.

### Excipients:

Sodium methyl paraben, Sodium propyl paraben, Sodium saccharin, Sugar, Glycerine, Alcohol, Citric acid, Natrosol, Ponceau, Strawberry flavour and purified water.

### Pharmacology:

Antihistamines Combinations with expectorants - R05C

*Diphenhydramine* HCl, a monoethanolamine derivative, is a sedating antihistamine with antimuscarinic and pronounced sedative properties. It is frequently used as cough suppressants in compound preparations. Suggested mechanisms of action have included reduction in cholinergic nerve transmission, or cough suppression as a result of their sedative effects. Their sedative effects are a disadvantage for daytime use but may be a short-term advantage for night coughs

*Sodium Citrate* is an expectorant.

*Menthol* is used as a hydrating agent to liquefy mucus and also have a demulcent effect. It has also been suggested that the apparent benefits of menthol in nasal congestion may be due to an effect on calcium channels of sensory nerves

### Pharmacokinetics:

*Diphenhydramine* hydrochloride is well absorbed from the gastrointestinal tract, although high first-pass metabolism appears to affect systemic availability. Peak plasma concentrations are achieved about 1-4 hours after oral administration. Diphenhydramine is widely distributed throughout the body including the CNS. It crosses the placenta and has been detected in breast milk. Diphenhydramine is highly bound to plasma proteins. Metabolism is extensive. It is excreted mainly in the urine as metabolites; little is excreted as unchanged drug. The elimination half-life has been reported to range from 2.4 to 9.3 hours.

*Sodium citrate* is metabolised, after absorption, to bicarbonate.

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

### Therapeutic indications:

Dacof<sup>®</sup> Paediatric Syrup is indicated for treatment of chesty productive coughs in children.

### Posology and method of administration

#### Method of administration: Oral use

Dacof<sup>®</sup> Paediatric Syrup is to be taken three to four times a day as follows or as directed by the physician:

*Children: 6 – 12 yrs:* Two 5 ml spoonful

2 – 5 yrs: One 5 ml spoonful

#### Contraindications:

Its use is contraindicated in acute asthmatic attack and epilepsy.

Not to be administered to children below 2 years of age.

#### Warning & precautions:

Dacof may cause drowsiness and impaired concentration, which may be aggravated by the simultaneous intake of alcohol or other central nervous system depressant agents. Patients should be warned against performing potentially hazardous tasks where loss of concentration may lead to accidents.

Due precautions should be taken in hepatic failure, prostate hypertrophy, narrow-angle glaucoma and urinary retention.

The product should be used cautiously in patients with congestive heart failure, hypertension and those receiving corticosteroid therapy.

Dacof paediatric is administered in children aged 2 – 12 years, thus not recommended for pregnant & breast feeding mothers.

#### Drug interactions:

**Drug-drug.** Antihistamines, opioids, sedative-hypnotics: additive CNS depression.

Disopyramide, quinidine, tricyclic antidepressants: increased anticholinergic effects.

MAO inhibitors: intensified and prolonged anticholinergic effects.

**Drug-diagnostic tests.** *Skin allergy tests:* false-negative results.

*Hemoglobin, platelets:* decreased values.

**Drug-herbs.** *Angel's trumpet, jimson weed, scopolia:* increased anticholinergic effects.

*Chamomile, hops, kava, skullcap, valerian:* increased CNS depression.

**Drug-behaviors.** *Alcohol use:* increased CNS depression.

### Pregnancy and lactation:

Diphenhydramine HCl is not recommended for pregnant & breast feeding mothers since is known to cross the placenta and has also been detected in breast milk

### Effects on ability to drive and use machines:

This product may cause drowsiness hence patients receiving it should refrain from driving or operating machinery.

### Side effects:

Diphenhydramine may give rise to the following side-effects: sedation, varying from slight drowsiness to deep sleep, and including lassitude, dizziness, hypotension, muscular weakness and incoordination.

Other side-effects include gastro-intestinal disturbances such as nausea, vomiting, diarrhoea or constipation, anorexia or increased appetite and epigastric pain.

Diphenhydramine may also cause headache, blurred vision, tinnitus, elation or depression, difficulty in micturition, dysuria, dryness of the mouth, tightness of the chest, and tingling, heaviness and weakness of the hands.

Symptoms of cerebral stimulation may arise in some children and they include insomnia, nervousness, tachycardia, tremors, muscle twitching and convulsions.

Large doses of diphenhydramine may precipitate fits in epileptics. Diphenhydramine hydrochloride may cause thrombocytopenia.

Diphenhydramine may enhance the sedative effect of central nervous system depressants including alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and tranquillisers. It should be used with care in conditions which can be exacerbated or otherwise adversely affected by atropine, such as glaucoma, urinary retention and prostatic hypertrophy. The effects of anticholinergic drugs such as atropine and tricyclic antidepressants may be enhanced by concomitant administration.

Sodium citrate may cause shortness of breath, muscle weakness and mental disturbances such as restlessness, convulsions, and coma. Muscle hypertonicity, twitching and tetany may develop especially in the absence of sufficient calcium.

### Overdosage and treatment:

The symptoms are as under side-effects. In addition the symptoms of overdosage in children may include ataxia, excitement, hallucinations, muscle tremor, convulsions, dilated pupils, dry mouth, flushed face and hyperpyrexia.

Treatment is symptomatic and supportive. Contact a doctor or the nearest hospital without delay. The health care provider will measure and monitor the patient's vital signs, including temperature, pulse, breathing rate, and blood pressure. Symptoms will be treated as appropriate. The patient may receive: Activated charcoal, Breathing support, Intravenous infusion of fluids and / or gastric lavage.

### Shelf-life:

Three years from the date of manufacture.

The product to be used within 30 days after opening.

### Storage:

Store in a dry place, below 30°C, protected from direct sunlight.

Keep all medicines out of reach of children.

### Nature and contents of container:

100ml syrup in amber colored bottle in a unit carton.

### Marketing authorization holder:

DAWA Limited,

Plot No. 7879/8, Baba Dogo Road, Ruaraka.

P. O. Box 16633 – 00620, Nairobi, Kenya

**Legal category:** Prescription only medicine, (POM).

### Manufactured by:



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P. O. Box 16633 – 00620, Nairobi, Kenya.

Ref: Lf /DL/ Dacof Paediatric/06

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