Summary of product characteristics.

1. Name of the medicinal product.
Dacof paediatric syrup

2. Qualitative and quantitative composition
Each 5 ml contains: Diphenhydramine HCl BP 7.0 mg and Sodium Citrate BP 28.5 mg
For more information on excipients see section 6.1

3. Pharmaceutical form
A pink coloured syrup, free from any visible evidence of contamination.

4. Clinical particulars
4.1 Therapeutic indications
Dacof Paediatric Syrup is indicated for treatment of chesty productive coughs in children.
4.2 Posology and method of administration
Oral administration only
Dosage and Administration:
Children: 6 - 12years:10ml three to four times a day
Children: 2 - 5 years: 5ml three to four times a day

4.3 Contra-indications.
Its use is contraindicated in acute asthmatic attack and epilepsy.
Not to be administered to children below 2 years of age.

4.4 Special warning and precautions for use.
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.

4.5 Interaction with other medicinal products and other forms of interaction.
Drug-drug. Antihistamines, opioids, sedative-hypnotics: additive CNS depression.
Disopyramide, quinidine, tricyclic antidepressants: increased anticholinergic effects.
MAO inhibitors: intensified and prolonged anticholinergic effects.
Hemoglobin, platelets: decreased values.
Drug-herbs. Angel's trumpet, jimson weed, scopolia: increased anticholinergic effects.
Chamomile, hops, kava, and skullcap, valerian: increased CNS depression.
Drug-behaviors. Alcohol use: increased CNS depression.

4.6 Pregnancy and lactation.
Diphenhydramine HCI is not recommended for pregnant & breast feeding mothers since is known to cross the placenta and has also been detected in breast milk

4.7 Effects on ability to drive and use machines.
This product may cause drowsiness hence patients receiving it should refrain from driving or operating machinery.

4.8 Undesirable 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, and 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.

4.9 Overdose.
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.

5. Pharmacological properties.
5.1 Pharmacodynamic properties.
Antihistamines Combinations with expectorants - R05C
ATC CODE: 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 nerve

5.2 Pharmacokinetic properties:
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.

5.3 Preclinical safety data.
No additional data of relevance.

6. Pharmaceutical particulars.
6.1 List of excipients
Sodium methyl paraben, Sodium propyl paraben, Sodium saccharin, Sugar, Glycerine, Alcohol, Citric acid, Natrosol, Ponceau, Strawberry flavour and purified water.

6.2 Incompatibilities
None known

6.3 Shelf life.
36 months from the date of manufacture.

6.4 Special precautions for storage:
Store in cool dry place below 30°C out of direct sunlight.
Keep all medicines out of reach of children.

6.5 Nature and contents of container.
100ml amber coloured PET bottle contained in a unit box

6.6 Special precautions for disposal and other handling
No special requirements.

7. Marketing authorization holder.
Dawa limited,
Plot No: 7879/8, Baba Dogo road, Ruaraka,
P.O Box 16633-00620, Nairobi –Kenya.

8. Registration number(s)
Kenya, License No. H2007/454

9. Legal category: Prescription only medicine, (POM)
10. Date of revision of the text.
May 2018.