1.5 Product Information

1.5.1 Prescribing information (Summary of Product Characteristics):

Enclosed herewith

Summary of product characteristics.

1. Name of the medicinal product

Dacold Syrup.

2. Qualitative and quantitative composition

Each 5ml contains: Paracetamol BP 120mg, Pseudoephedrine HCl BP 10mg and Chlorphenamine Maleate BP 2mg.

3.0 Pharmaceutical form:

Syrup for oral administration.
Pink –red syrup, free from visible evidence of contamination.

4.0 Clinical particulars

4.1 Therapeutic indications

Dacold is indicated for the relief of cough and cold symptoms, symptomatic relief of nasal congestion, Allergic rhinitis, Hay fever, and sinus headache.

4.2 Posology and method of administration:

Dosage: Dacold syrup is administered orally by mouth.

Children under 2 years: Not recommended except on Physician's advice.

Dosage: To be taken orally 3 -4 times a Day.	
Children over 10 years (Above 32kgs)	Two 5ml spoonfuls
Children 6 – 10years (20-31kgs)	One – Two 5 ml spoonfuls
Children 2 – 5 years (12-20 kgs)	Half – one 5 ml spoonfuls
Children under Two years (Below 11kgs)	Not Recommended

4.3 Contraindications

Dacold is contraindicated in-patients with known hypersensitivity to any of the components of the preparation. Administer the preparation cautiously to patients with anemia, hepatic or renal disease, to patients with a history of gastrointestinal disease, increased risk of gastrointestinal bleeding, decreased renal function, in symptomatic cardiac arrhythmias or palpitations, after acute myocardial infarction and a history of peptic ulcer disease. Should not be used in diabetic patients.

4.4 Special warnings and precautions for use

Administer the preparation cautiously to patients with anemia, hepatic or renal disease, to patients with a history of gastrointestinal disease, increased risk of gastrointestinal bleeding, decreased renal function, in symptomatic cardiac arrhythmias or palpitations, after acute myocardial infarction and a history of peptic ulcer disease. Should not be used in diabetic patients.

4.5 Interaction with other medicinal products and other forms of interaction

May enhance the sedative effects of CNS depressants.
May have an additive muscarinic action with other drugs.
Not to be used in patients taking MAOIs or within 14 days of stopping treatment Moclobemide:
risk of hypertensive crisis
Antihypertensive: may block the hypotensive effects. Cardiac glycosides: increased risk of dysrhythmias
Ergot alkaloids (ergotamine & methysergide): increased risk of ergotism
Appetite suppressants and amphetamine-like psychostimulants: risk of hypertension
Oxytocin – risk of hypertension.
Enhances effects of anticholinergic drugs (such as TCAs).

4.6. **Pregnancy and lactation**
The active ingredients in Dacold syrup have not been conclusively associated with adverse effects on the developing fetus; but as with all drugs, care should be exercised in use of the product, particularly during the first trimester. Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol used in the recommended dosage, but patients should follow the advice of their doctor regarding its use. All of the actives are excreted into breast milk, although few adverse effects have been reported as a result of ingestion, cautious use of Dacold syrup is advised during lactation. Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data do not contraindicate breast feeding.

4.7 Effects on ability to drive and use machines:
Patients should be advised that if they feel drowsy they should not drive or operate a machine.

4.8 Undesirable effects
The most common adverse reactions include:
- Nausea, vomiting, diarrhea, abdominal cramps, abdominal pain, loss of appetite.
- Rash, urticaria, itching, unusual bruising, erythema
- Hypotension, muscular weakness, drowsiness, tinnitus, and euphoria and occasionally headache.
- Tachycardia, anxiety, restlessness, and insomnia; skin rashes and urinary retention.

4.9 Overdose.
Signs and symptoms include; convulsion, palpitation, hypertension, tremors, hyperpyresia, restlessness, abdominal pain, anoresia and anticholinergic effect. Treatment is symptomatic and supportive. Due to paracetamol, N-acetylcysteine is used. Gastric lavage is also applied due to pseudoephedrine.

5.0 Pharmacological properties
Pharmacodynamic properties.
ATC Code: R05X
Pharmacotherapeutic group –Cough and cold preparations
Pharmacology: Paracetamol is believed to exert its antipyretic effect by direct action on the hypothalamic heat-regulating center to block the effects of endogenous pyrogens. This results in increased heat dissipation through sweating and vasodilation. Its analgesic effect may be related to an elevation of the pain threshold probably by inhibition of prostaglandin synthesis in the CNS.
Chlorphenamine competes with histamine for histamine H1-receptor sites on smooth muscle of the bronchi, gastrointestinal tract, uterus, and large blood vessels; it binds to cellular receptors, preventing access of histamine, thereby suppressing histamine-induced allergic symptoms. It does not directly alter histamine or its release. Pseudoephedrine is a direct- and indirect-acting sympathomimetic. It is a stereoisomer of ephedrine and has a similar action, but has been stated to have less pressor activity and fewer CNS effects. It facilitates the vasodilation of bronchial smooth muscles, an action that causes relief of lung congestion.

5.1 Pharmacokinetic properties
Paracetamol is completely and rapidly absorbed via gastrointestinal tract after oral administration with a peak serum levels occurring in 15 – 45 minutes with a bioavailability of 96% ± 10%. It is 25% protein-bound. Plasma concentrations do not correlate well with analgesic effect, but do correlate with toxicity. Approximately 90% to 95% is metabolized by hepatic microsomal enzymes. It is excreted in the urine. The average elimination half-life ranges from 1 to 4hours.
Chlorphenamine is rapidly and well absorbed from the gastrointestinal tract; action begins within 10 to 30 minutes, and peaks in 2 to 6 hours. It is distributed extensively into the body fluids; drug is about 72% protein-bound. The drug is metabolized largely in the mucosal cells and liver. Chlorpheniramine half-life is 12 to 43 hours in adults and 10 to 13 hours in children; drug and metabolites are excreted in urine.
Pseudoephedrine is readily absorbed from the gastrointestinal tract. It is largely excreted unchanged in the urine together with small amounts of its hepatic metabolites. It has a half-life of about 5 to 8 hours; elimination is enhanced and half-life accordingly shorter in acid urine. Small amounts are distributed into breast milk.

5.1 Preclinical safety data No additional data of relevance.

6. Pharmaceutical particulars

6.1 List of excipients

Sodium Saccharin,
Sodium methyl paraben,
Sodium propyl paraben,
Natrosol, Bronopol,
Propylene glycol,
Neutral spirit,
Citric acid,
Sodium citrate,
Ponceau 4R colour,
Strawberry flavour liquid
Purified water.

6.2 Incompatibilities: None known**.**

6.3 Shelf life

36 months from the date of manufacture. (3 years).

6.4 Special precautions for storage

Store in a dry place, below 30°C.

Protect from light.

Keep all medicines out of reach of children

6.5 Nature and contents of container

100 mL pack in PET bottle in a unit box along with a literature insert.

6.6 Special precautions for disposal and other handling

None applicable.

7.0 **Marketing authorization holder/Registrant**.

Dawa limited
Plot No.7879/8, Baba Dogo Road, Ruaraka,
P.O Box 16633-00620, Nairobi –Kenya

8.0 **Manufacturer**

Dawa Limited
Plot No.7879/8, Baba Dogo Road, Ruaraka
P.O.BOX 16633-00620 Nairobi, Kenya.

9. Date of revision of the text:

March 2020