Summary of Product Characteristics.

1.Name of the medicinal product.
Dawa-CPM syrup
2.Qualitative and quantitative composition
Each 5ml contains: Chlorphenamine Maleate BP 2mg
For more information on excipients see section 6.1
3.Pharmaceutical form
An Orange coloured, syrup liquid with sweet taste free from visible evidence of contamination
4Clinical particulars
4.1Therapeutic indications
Dawa-CPM syrup is indicated for symptomatic control of all allergic conditions responsive to antihistamines, including hay fever, vasomotor rhinitis, urticaria, angioneurotic oedema, food allergy, drug and serum reactions, insect bites.
Also indicated for the symptomatic relief of itch associated with chickenpox.
4.2Posology and method of administration
Oral administration only Dosage and Administration: Adults: 10ml every 4 - 6 hours
Children: 1 - 2 years: 2.5ml twice Daily, Maximum daily dose: 5ml (2mg) in any 24 hours. Children: 2 - 5 years: 2.5ml every 4 - 6 hours, Maximum daily dose: 15ml (6mg) in any 24 hours. Children: 6 - 12 years: 5ml every 4 - 6 Hours, Maximum daily dose: 30ml (12mg) in any 24 hours. Not recommended for children below 1 year
4.3Contra-indications.
Dawa-CPM syrup is contra-indicated in patients who are hypersensitive to antihistamines or to any of the syrup ingredients.
The anticholinergic properties of chlorphenamine are intensified by monoamine oxidase inhibitors (MAOIs). Piriton Syrup is therefore contra-indicated in patients who have been treated with MAOIs within the last fourteen days.
4.4Special warning and precautions for use.
Chlorphenamine, in common with other drugs having anticholinergic effects, should be used with caution in epilepsy; raised intra-ocular pressure including glaucoma; prostatic hypertrophy; severe hypertension or cardiovascular disease; bronchitis, bronchiectasis or asthma; hepatic impairment; renal impairment. Children and the elderly are more likely to experience the neurological anticholinergic effects and paradoxical excitation (eg. Increased energy, restlessness, nervousness).
The anticholinergic properties of chlorphenamine may cause drowsiness, dizziness, blurred vision and psychomotor impairment in some patients which may seriously affect ability to drive and use machinery.
The effects of alcohol may be increased and therefore concurrent use should be avoided.
Should not be used with other antihistamine containing products, including antihistamine containing cough and cold medicines.
Harmful for those suffering from alcoholism. To be taken into account in pregnant and breast feeding women, children and high risk groups such as patients with liver disease or epilepsy.
Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.
Syrup contains sucrose this should be taken into account in patients with diabetes mellitus.
Long term use increases the risk of dental caries and it is essential that adequate dental hygiene is maintained.

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

Concurrent use of chlorphenamine and hypnotics or anxiolytics may cause an increase in sedative effects, therefore medical advice should be sought before taking chlorphenamine concurrently with these medicines.

Chlorphenamine inhibits phenytoin metabolism and can lead to phenytoin toxicity. The anticholinergic effects of chlorphenamine are intensified by MAOIs

4.6 Pregnancy and lactation.

Pregnancy: There are no adequate data from the use of chlorphenamine in pregnant women. The potential risk for humans is unknown; Use during the third trimester may result in reactions in the newborn or premature neonates. Not to be used during pregnancy unless considered essential by a physician.

Lactation: Chlorphenamine maleate and other antihistamines may inhibit lactation and may be secreted in breast milk. Not to be used during lactation unless considered essential by a physician

4.7Effects on ability to drive and use machines.

The anticholinergic properties of chlorphenamine may cause drowsiness, dizziness, blurred vision and psychomotor impairment, which can seriously hamper the patients' ability to drive and use machinery

4.8 Undesirable effects.

Unknown: haemolytic anaemia, blood dyscrasias, allergic reaction, angioedema, anaphylactic reactions, anorexia, confusion*, excitation*, irritability*, nightmares* , depression, tinnitus, palpitations, tachycardia, arrhythmias, thickening of bronchial secretions, vomiting, abdominal pain, diarrhoea, dyspepsia, hepatitis including jaundice, exfoliative dermatitis, rash, urticaria, photosensitivity, muscular twitching, muscle weakness, Urinary retention and chest tightness **Very common:** sedation, somnolence, Hypotension

Common: disturbance in attention, abnormal coordination, dizziness, headache, blurred vision, Ear and labyrinth disorders nausea, dry mouth, fatigue,

Children and the elderly are more susceptible to neurological anticholinergic effects and paradoxical excitation (eg increased energy, restlessness, nervousness)

4.9 Overdose.

Symptoms and signs: The estimated lethal dose of chlorphenamine is 25 to 50mg/kg body weight. Symptoms and signs include sedation, paradoxical excitation of the CNS, toxic psychosis, convulsions, apnoea, anticholinergic effects, dystonic reactions and cardiovascular collapse including arrhythmias.

Treatment : Symptomatic and supportive measures should be provided with special attention to cardiac, respiratory, renal and hepatic functions and fluid and electrolyte balance. If overdosage is by the oral route, treatment with activated charcoal should be considered provided there are no contraindications for use and the overdose has been taken recently (treatment is most effective if given within an hour of ingestion.) Treat hypotension and arrhythmias vigorously. CNS convulsions may be treated with i.v. diazepam. Haemoperfusion may be used in severe cases.

5.0 Pharmacological properties

5.1Pharmacodynamic properties.

ATC Code R06AB0: Chlorphenamine is a potent antihistamine (H1-antagonist).

Antihistamines diminish or abolish the actions of histamine in the body by competative reversible blockade of histamine H1-receptor sites on tissues. Chlorphenamine also has anticholinergic activity.

Antihistamines act to prevent the release of histamine, prostaglandins and leukotrines and have been shown to prevent the migration of inflammatory mediators. The actions of chlorphenmine include inhibition of histamine on smooth muscle, cappillary permeability and hence reduction of oedma and wheal in hypersneitivity reactions such as allergy and anaphylaxis.

5.2 Pharmacokinetic properties:

Chlorphenamine is well absorbed from the gastro-intestinal tract, following oral administration. The effects develop within 30 minutes, are maximal within 1 to 2 hours and last 4 to 6 hours. The plasma half-life has been estimated to be 12 to 15 hours.Chlorphenamine is metabolised to the monodesmethyl and didesmethyl derivatives. About 22% of an oral dose is excreted unchanged in the urine.

5.3Preclinical safety data
No additional data of relevance.
6.Pharmaceutical particulars.
List of excipients
Sodium CMC
Sodium Saccharin
Sodium Methyl Paraben
Sodium Propyl Paraben
Sodium Benzoate Tartrazine
Yellow Colour Bronopol
Ponceau 4R Orange flavour
Citric Acid
Purified water
6.2Incompatibilities
None known
6.3 Shelf life.
36 months from the date of manufacture.
6.4 Special precautions for storage:
Store in dry place below 30°C protected from light.
Keep all medicines out of reach of children.
6.5 Nature and contents of container.
60ml or 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.
7.1 Local Technical Representative.
Reddy's Pharma Ltd
PLOT NO.479, 1st Floor, Zahara & Arcade Tower, Mindu Street, Upanga Area Dar-es-Salaam.
P.O.BOX NO.38328, Tanzania.
8. Registration number(s)
Kenya, License No. H2007/454
Malawi, License No PMPB/PL12/80
Rwanda, License No N°20/1948/DGCS/PH/2017 **Uganda,**
License No 8773/03/14
Mozambique, License No R5308
9. Legal category: Pharmacy Only Medicines (POM)
10. Date of revision of the text/ renewal of the authorization
August 2023.