Summary of Product Characteristics

KOFGON RED

(Chlorphenamine Maleate / Diphenhydramine Hydrochloride / Ammonium Chloride / Sodium Citrate / Menthol Oral Syrup)

1 Name of the medicinal product

Kofgon Red – Chlorphenamine Maleate, Diphenhydramine Hydrochloride, Ammonium Chloride, Sodium Citrate and Menthol Oral Syrup

2 Qualitative and quantitative composition

Each 5 ml of syrup contains:

- Chlorphenamine maleate 2 mg
- Diphenhydramine hydrochloride 5 mg
- Ammonium chloride 50 mg
- Sodium citrate 30 mg
- Menthol 0.25 mg

Excipient(s) with known effect

Ponceau 4R (E124), sodium benzoate (E211), and sodium (from sodium citrate and sodium-containing excipients). See section 4.4.

For the full list of excipients, see section 6.1.

3 Pharmaceutical form

Syrup.

A red-coloured, sweet, flavoured syrup.

4 Clinical particulars

4.1 Therapeutic indications

Kofgon Red is indicated for the symptomatic relief of cough and its associated upper respiratory symptoms, including chesty (productive) cough with associated nasal congestion, runny nose and sneezing, associated with the common cold and other upper respiratory tract conditions. The antihistamines (chlorphenamine and diphenhydramine) relieve associated rhinitis and allergic symptoms; the expectorants (ammonium chloride and sodium citrate) help to loosen and clear bronchial secretions; and menthol provides a soothing, cooling effect on the throat.

4.2 Posology and method of administration

Posology

Children under 6 years

Not recommended. Cough and cold preparations containing sedating antihistamines should not be used in children under 6 years of age (see section 4.4).

Children 6 to 12 years
5 ml (one 5 ml spoonful) every 4 hours as required, on the advice of a physician or pharmacist. Not more than 30 ml (six 5 ml spoonfuls) in 24 hours.

Adults and children over 12 years
10 ml (two 5 ml spoonfuls) every 4 hours as required. Not more than 60 ml (twelve 5 ml spoonfuls) in 24 hours.

The preparation should not be used for longer than 4 to 5 days without medical advice. A physician should be consulted if the cough persists or worsens, or is accompanied by fever, rash or persistent headache, and by patients who are pregnant or breast-feeding, have a chronic medical condition, or are taking other medicines.

Elderly
The elderly are more likely to experience the anticholinergic and neurological effects; use with caution and consider a reduced dose (see section 4.4).

Method of administration
For oral use. The dose should be measured with a suitable measuring device.

4.3 Contraindications

- Hypersensitivity to antihistamines, to any of the active substances, or to any of the excipients listed in section 6.1.
- Patients who have been treated with monoamine oxidase inhibitors (MAOIs) within the previous 14 days (see section 4.5).
- Acute asthma attack.
- Neonates and premature infants.
- Children under 2 years of age.
- Breast-feeding (see section 4.6).

4.4 Special warnings and precautions for use

In common with other medicines having anticholinergic effects, this product should be used with caution in patients with epilepsy; raised intra-ocular pressure, including glaucoma; prostatic hypertrophy, urinary retention or bladder-neck obstruction; severe hypertension or cardiovascular disease; bronchitis, bronchiectasis and asthma; hepatic impairment; renal impairment; hyperthyroidism; and stenosing peptic ulcer.

Children and the elderly are more likely to experience the neurological anticholinergic effects and paradoxical central nervous system stimulation (for example increased energy, restlessness, nervousness and excitability). Use should be avoided in elderly patients with confusion. Cough and cold preparations containing sedating antihistamines are not recommended in children under 6 years of age.

This medicine may cause marked drowsiness. The sedative effect is enhanced by alcohol and by other central nervous system depressants (see section 4.5).

Patients should not take other antihistamine-containing preparations concurrently, including products applied to the skin that contain diphenhydramine.

The stated dose should not be exceeded. Medical advice should be sought if the cough persists for more than 4 to 5 days, or is accompanied by high fever, skin rash or persistent headache.

Excipients
This medicine contains Ponceau 4R (E124), which may cause allergic reactions. It contains sodium benzoate (E211), which is a mild irritant to the skin, eyes and mucous membranes. It also contains sodium (from sodium citrate and sodium-containing excipients); this should be taken into account by patients on a controlled-sodium diet.

4.5 Interaction with other medicinal products and other forms of interaction

The anticholinergic properties of the antihistamines are intensified by monoamine oxidase inhibitors (MAOIs); concurrent use, or use within 14 days of MAOI therapy, is contraindicated (see section 4.3).

Concurrent use with alcohol and with other central nervous system depressants – including hypnotics, sedatives, anxiolytics, opioid analgesics, antipsychotics and tricyclic antidepressants – may potentiate sedation and central nervous system depression.

Additive antimuscarinic (anticholinergic) effects may occur with other medicines having anticholinergic activity, such as atropine and tricyclic antidepressants.

Chlorphenamine may inhibit the metabolism of phenytoin, which can lead to phenytoin toxicity.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no adequate data from the use of these active substances in pregnant women, and the potential risk for humans is unknown. Use during the third trimester may result in reactions in the newborn or premature neonate. The product is not recommended during pregnancy and should be used only if considered essential by a physician.

Breast-feeding
Chlorphenamine, diphenhydramine and other antihistamines are excreted in breast milk, may inhibit lactation, and may cause effects (such as sedation or irritability) in the breast-fed infant. The product should not be used during breast-feeding.

Fertility
No data on the effect of the product on fertility are available.

4.7 Effects on ability to drive and use machines

This medicine may cause drowsiness, dizziness, blurred vision and psychomotor impairment, which can seriously impair the ability to drive and use machines. Patients who are affected should not drive or operate machinery. These effects are enhanced by alcohol.

4.8 Undesirable effects

Summary of the safety profile

The most commonly reported adverse reactions are those expected of sedating (first-generation) antihistamines and include sedation, somnolence, dizziness, incoordination and antimuscarinic effects such as dry mouth. Drowsiness usually diminishes after a few days of treatment.

Tabulated list of adverse reactions

Adverse reactions are listed below by System Organ Class (MedDRA) and frequency. Frequencies are defined as: very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000), very rare (< 1/10,000) and not known (cannot be estimated from the available data).

System Organ Class	Frequency	Adverse reaction
Blood and lymphatic system disorders	Rare	Blood dyscrasias
	Not known	Haemolytic anaemia, thrombocytopenia, agranulocytosis
Immune system disorders	Rare	Hypersensitivity reactions
	Not known	Angioedema, anaphylactic reaction
Metabolism and nutrition disorders	Not known	Increased appetite, anorexia
Psychiatric disorders	Rare	Confusion, depression, sleep disturbance
	Not known	Paradoxical excitation (especially in children), restlessness, nervousness, irritability, insomnia, hallucinations
Nervous system disorders	Common	Sedation, somnolence, dizziness, headache, disturbed attention, incoordination
	Rare	Convulsions, tremor, extrapyramidal effects
	Not known	Paraesthesia, dyskinesia, psychomotor impairment
Eye disorders	Not known	Blurred vision, dry eyes, diplopia
Ear and labyrinth disorders	Not known	Tinnitus, vertigo
Cardiac disorders	Rare	Palpitations, arrhythmia
	Not known	Tachycardia, extrasystoles, chest tightness
Vascular disorders	Rare	Hypotension
Respiratory, thoracic and mediastinal disorders	Not known	Thickening of bronchial secretions, dryness of the nose and throat, nasal stuffiness, wheezing
Gastrointestinal disorders	Common	Dry mouth

System Organ Class	Frequency	Adverse reaction
	Not known	Nausea, vomiting, constipation, diarrhoea, dyspepsia, epigastric distress
Hepatobiliary disorders	Rare	Hepatic dysfunction
Skin and subcutaneous tissue disorders	Not known	Rash, urticaria, erythema, pruritus, photosensitivity, increased sweating
Renal and urinary disorders	Not known	Urinary retention or difficulty, dysuria
General disorders and administration site conditions	Common	Fatigue
	Not known	Asthenia

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to the National Regulatory Authority.

4.9 Overdose

The effects of antihistamine overdose are variable. In children, central nervous system stimulation predominates, with excitation, hallucinations, ataxia, incoordination and convulsions, together with fixed dilated pupils, a flushed face, hyperpyrexia and antimuscarinic effects. In adults, central nervous system depression with drowsiness, progressing to coma, is more usual, and may be preceded by a phase of excitation; convulsions and cardiorespiratory collapse may occur. Antimuscarinic effects (dry mouth, urinary retention, tachycardia) and cardiac arrhythmias may also be seen.

Management is symptomatic and supportive, with attention to cardiac, respiratory, renal and hepatic function and to fluid and electrolyte balance. If a substantial oral overdose has been taken recently (within about one hour), activated charcoal may be considered where there is no contraindication. Hypotension and arrhythmias should be treated vigorously, and convulsions may be controlled with intravenous diazepam. There is no specific antidote.

5 Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Cough and cold preparations; expectorants, combinations.

ATC code: R05CA10

Kofgon Red is a fixed-dose combination of two sedating (first-generation) antihistamines, two expectorants and menthol, formulated for the symptomatic relief of cough and associated upper respiratory symptoms.

Chlorphenamine maleate

Chlorphenamine is an alkylamine first-generation antihistamine that competitively antagonises histamine at H1 receptors on smooth muscle of the bronchi, gastrointestinal tract and blood vessels, thereby suppressing histamine-induced allergic symptoms such as rhinorrhoea, sneezing and itching. It also possesses antimuscarinic and sedative properties.

Diphenhydramine hydrochloride
Diphenhydramine is an ethanolamine first-generation antihistamine with marked sedative, antimuscarinic and antitussive properties. It competitively inhibits the histamine H1 receptor, alleviating the effects of endogenous histamine on bronchial, capillary and gastrointestinal smooth muscle.

Ammonium chloride and sodium citrate
Ammonium chloride and sodium citrate act as expectorants. By a mild irritant action on the gastric mucosa they reflexly increase the volume, and reduce the viscosity, of respiratory tract secretions, thereby assisting expectoration of retained secretions.

Menthol
Menthol acts as a counter-irritant with a mild local anaesthetic action, producing a sensation of coolness that provides subjective relief of throat irritation and a soothing effect.

5.2 Pharmacokinetic properties

Chlorphenamine
Chlorphenamine is well absorbed after oral administration. It is metabolised to the monodesmethyl and didesmethyl derivatives, and about 22% of an oral dose is excreted unchanged in the urine. It has a relatively long elimination half-life.

Diphenhydramine
Diphenhydramine is well absorbed after oral administration but undergoes significant first-pass metabolism. The mean volume of distribution is approximately 17 l/kg in adults (higher in children), and plasma protein binding is high (approximately 98–99%). It is extensively metabolised in the liver by N-demethylation, principally via CYP2D6 with minor contributions from CYP1A2, CYP2C9 and CYP2C19, and is excreted in the urine as metabolites and unchanged drug. Peak serum concentrations are reached at about 2 hours. The elimination half-life is approximately 9 hours in adults, shorter in children (about 4–7 hours) and longer in the elderly.

Ammonium chloride, sodium citrate and menthol
Ammonium chloride and sodium citrate are absorbed and enter the body's normal metabolic and electrolyte pools, being handled by the usual homeostatic mechanisms. Menthol is absorbed and metabolised in the liver, principally by glucuronide conjugation, and excreted in the urine and bile.

5.3 Preclinical safety data

The active substances are well established, with extensive clinical use over many decades. Non-clinical data reveal no special hazard for humans of relevance to the prescriber at the recommended doses beyond that already included in other sections of this Summary of Product Characteristics.

6 Pharmaceutical particulars

6.1 List of excipients

- Sodium carboxymethylcellulose
- Sodium benzoate
- Potassium sorbate
- Citric acid
- Saccharin sodium
- Ponceau 4R (colour)
- Raspberry essence (flavour)
- Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Do not store above 30°C. Protect from light.

6.5 Nature and contents of container

Amber-coloured PET bottles containing 60 ml or 100 ml of syrup, packed in a unit carton with a package insert.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 Marketing authorisation holder

Zain Pharma Ltd

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8 Marketing authorisation number

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9 Date of first authorisation/renewal of the authorisation

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10 Date of revision of the text

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