

1. Name of the medicinal product

Gee-Kuf Expectorant Syrup with Liquorice

2. Qualitative and Quantitative Composition

Each 5 mL (one teaspoonful) contains:

Chlorphenamine Maleate.....2mg

Ammonium Chloride.....150mg

Menthol.....2mg

Liquorice Root Extract0.25ml

3. Dosage Form and Strength

Syrup

4. Clinical Particulars

4.1 Therapeutic Indications

For symptomatic treatment of cough.

4.2 Posology and Method of Administration

Oral

Recommended Dosage

Do not exceed the stated dose or frequency of dosing.

3 Months – 1 Year

2.5ml mark on the dosing cup three times daily

1-5 Years:

5ml mark on the dosing cup three times daily

6-12 years

7.5ml mark on the dosing cup three times daily

Adult

15ml mark on the dosing cup three times daily

Or as directed by the physician

Special Populations

Elderly

The elderly are more likely to experience neurological anticholinergic effects of Chlorpheniramine maleate. Consideration should be given to using a lower daily dose. 10ml every 8hour.

Hepatic or Renal Impairment

Contraindicated in the presence of impaired hepatic or renal function.

4.3 Contraindications

Gee-Kuf Expectorant Syrup with Liquorice is contraindicated in patients who are:

- hypersensitive to antihistamines or dextromethorphan or to any of the inactive ingredients in the formulation (see List of Excipients, 4.8 Undesirable Effects).
- taking monoamine oxidase inhibitors (MAOIs) or in patients who have been treated with MAOIs within the last fourteen days.
- Impaired hepatic or renal function.
- Children under the age of 12 years

4.4 Special Warnings and Precautions for Use

Gee-Kuf Expectorant Syrup with Liquorice contains chlorphenamine, and hence should be used with caution in epilepsy; raised intra-ocular pressure including glaucoma; prostatic hypertrophy; severe hypertension or cardiovascular disease; bronchitis, bronchiectasis and asthma; urinary retention. Children and the elderly are more likely to experience the neurological anticholinergic effects and paradoxical excitation (e.g. increased energy, restlessness, nervousness). Avoid use in elderly patients with confusion.

The anticholinergic properties of chlorphenamine in Gee-Kuf Expectorant Syrup with Liquorice may cause drowsiness, dizziness, blurred vision and psychomotor impairment in some patients which may seriously affect ability to drive and use machinery.

Should not be used with other antihistamine containing products, including antihistamine containing cough and cold medicines.

Concurrent use with drugs which cause sedation such as anxiolytics and hypnotics may cause an increase in sedative effects, therefore medical advice should be sought before taking chlorphenamine concurrently with these medicines.

The effects of alcohol may be increased and therefore concurrent use should be avoided.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

Gee-Kuf Expectorant Syrup with Liquorice 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.

Keep out of the reach and sight of children.

4.5 Drug Interactions

Concurrent use of chlorpheniramine and hypnotics or anxiolytics may cause an increase in sedative effects. Concurrent use of alcohol may have a similar effect.

Chlorpheniramine inhibits phenytoin metabolism and can lead to phenytoin toxicity.

The anticholinergic effects of chlorpheniramine are intensified by MAOIs. Not to be used in patients taking MAOIs or within 14 days of stopping treatment as there is a risk of serotonin syndrome (see 4.3 Contraindications).

Other adrenoceptor stimulants: Concurrent use of ephedrine with theophylline may result in increased nausea, nervousness, and insomnia.

Anaesthetics: There may be an increased risk of arrhythmias when used with volatile liquid anaesthetics.

4.6 Use in Special Population

Pregnancy

The potential risk for humans is unknown. Use during the third trimester may result in reactions in the newborn or premature neonates.

Gee-Kuf Expectorant Syrup with Liquorice should not be used during pregnancy unless considered essential by a physician.

Lactation

Chlorpheniramine maleate may inhibit lactation and may be secreted in breast milk.

Not to be used during lactation unless considered essential by a physician.

4.7 Effects on Ability to Drive and Use Machines

Gee-Kuf Expectorant Syrup with Liquorice may cause drowsiness, dizziness, blurred vision and psychomotor impairment, which can seriously hamper the patients' ability to drive and use machinery.

Refer to 4.4 Special Warnings and Precautions For Use

4.8 Undesirable Effects

In absence of availability of adverse event data on the fixed dose combination of chlorpheniramine, ammonium chloride, and methol, adverse event data of the individual ingredients (where available) is presented below.

The following convention has been utilised for the classification of the frequency of adverse reactions: very common ($>1/10$), common ($>1/100$ to $<1/10$), uncommon ($>1/1000$ to $<1/100$), rare ($>1/10,000$ to $<1/1000$) and very rare ($<1/10,000$), not known (cannot be estimated from available data).

Chlorpheniramine Maleate

Adverse reactions identified during post-marketing use with chlorphenamine are listed below. As these reactions are reported voluntarily from a population of uncertain size, the frequency of some reactions is unknown but likely to be rare or very rare:

Gee-Kuf Expectorant Syrup with Liquorice**Document 1.3.1 Summary Of Product Characterization (SMPC)**

System organ class	Adverse Reaction	Frequency
Nervous system disorders*	Sedation, somnolence	Very common
	Disturbance in attention, abnormal coordination, dizziness, headache	Common
Eye disorders	Blurred vision	Common
Gastrointestinal disorders	Nausea, dry mouth	Common
	Vomiting, abdominal pain, diarrhoea, dyspepsia	Unknown
General disorders and administration site conditions	Fatigue	Common
	Chest tightness	Unknown
Immune system disorders	Allergic reactions, angioedema, anaphylactic reactions	Unknown
Metabolism and nutritional disorders	Anorexia	Unknown
Blood and lymphatic system disorders	Haemolytic anaemia, blood dyscrasias	Unknown
Musculoskeletal and connective tissue disorders	Muscle twitching, muscle weakness	Unknown
Psychiatric disorders	Confusion*, excitation*, irritability*, nightmares*, depression	Unknown
Renal and urinary disorders:	Urinary retention	Unknown
Skin and subcutaneous disorders	Exfoliative dermatitis, rash, urticaria, photosensitivity	Unknown
Respiratory, thoracic and mediastinal disorders	Thickening of bronchial secretions	Unknown
Vascular disorders	Hypotension	Unknown
Hepatobiliary disorders	Hepatitis, including jaundice	Unknown
Ear and labyrinth disorders	Tinnitus	Unknown
Cardiac disorders	Palpitations, tachycardia, arrhythmias	Unknown
General Disorders and administration site conditions	Fatigue	Common
	Chest tightness	Unknown

*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. Large doses of ammonium chloride may cause nausea, vomiting, thirst, headache, hyperventilation and progressive drowsiness and lead to profound acidosis and hypokalaemia.

The symptoms of overdose are normally seen as nausea, vomiting, hypertension, fever, palpitations, tachycardia, restlessness, respiratory depression and convulsions. Paranoid psychosis, delusions and hallucinations may also follow ephedrine overdosage.

Treatment

Management should be as clinically indicated or as recommended by the national poisons centers where available. Symptomatic and supportive measures should be provided with special attention to cardiac, respiratory, renal and hepatic functions and fluid and electrolyte balance. If over dosage 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.

Ammonium Chloride

Large doses of ammonium chloride may cause nausea, vomiting, thirst, headache, hyperventilation and progressive drowsiness and lead to profound acidosis and hypokalaemia.

5. PHARMACOLOGICAL PROPERTIES

5.1 Mechanism of Action/Pharmacodynamics Effects

Chlorpheniramine maleate

Chlorphenamine is a potent antihistamine (H1-antagonist).

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

Antihistamines act to prevent the release of histamine, prostaglandins and leukotrienes and have been shown to prevent the migration of inflammatory mediators. The actions of chlorphenamine include inhibition of histamine on smooth muscle, capillary permeability and hence reduction of oedema and wheal in hypersensitivity reactions such as allergy and anaphylaxis.

Ammonium chloride

Ammonium chloride has an irritant effect on the gastric mucous membrane.

Menthol

Menthol dilates the blood vessels causing a sensation of coldness followed by analgesic effect. It is used to relieve the symptoms of bronchitis, sinusitis and similar conditions.

Liquorice

Liquorice is a demulcent and mild expectorant.

5.2 Pharmacokinetic Properties

Chlorpheniramine maleate

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 metabolized to the monodesmethyl and didesmethyl derivatives. About 22% of an oral dose is excreted unchanged in the urine.

Ammonium Chloride

Ammonium chloride is effectively absorbed from the gastrointestinal tract. The ammonium ion is converted into urea in the liver. The anion liberated into the bloodstream and extracellular fluid causes a metabolic acidosis and decreases the pH of the urine. This is followed by transient diuresis.

Menthol

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

6. Pharmaceutical Particulars

6.1 List of Excipients

Sucrose,
Sodium Benzoate,
Sodium Saccharin,
Citric Acid Monohydrate,
Propylene Glycol, Menthol,
Colour Sunset Yellow
Methyl Paraben
Propyl Paraben

6.2 Incompatibilities

There are no relevant data available.

6.3 Shelf Life

3 years

6.4 Special precautions for storage

Store in a well-closed container at temperature not exceeding 30°C, protected from direct sunlight.

Keep out of reach of children.

It is dangerous to take this preparation except under medical supervision.

6.5 Nature and contents of container

100ml amber colour glass bottle with ropp cap

6.6 Special precautions for disposal and other handling

Gee-Kuf Expectorant Syrup with Liquorice

Document 1.3.1 Summary Of Product Characterization (SMPC)

No special requirements.

7. Marketing authorization holder

Distributed by

Greenvine Pharmaceuticals Ltd.

30, Adekitan Street, Off Palm Avenue,
Mushin, Lagos.

Manufactured by

Jehyson Healthcare Limited,

Jehyson crescent, km 78, lagos-Abeokuta
Expressway, Apamu, Ewekoro LGA, Ogun
State