1. NAME OF THE MEDICINAL PRODUCT

Alkum Cough Expectorant (Non-Drowsy)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml of syrup contains:

Cetirizine HCl B.P..... 2.5mg

Ammonium Chloride B.P..... 100mg

Menthol B.P..... 2mg

Sodium Citrate B.P..... 40mg

Excipients with known effect:

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

- Oral Liquid/Syrups.
- A Green viscous syrup.

4. Clinical Particulars

4.1 Therapeutic indications

Symptomatic relief of cough, cold and other allergic conditions.

4.2 Posology and method of administration

For oral use only.

Adults: 10ml every 8hours.

Children (6-12years): 5ml every 8hours.

4.3 Contraindications

Hypersensitivity to the active substance, to any of the excipients listed in section 6.1, to hydroxyzine or to any piperazine derivatives.
Alkum Cough Expectorant is also contraindicated in patients with severe renal impairment at less than 10 ml/min creatinine clearance.

4.4 Special warnings and precaution for use

(See also section 4.7 Effects on Ability to Drive and Use Machines).
Dosage adjustment is necessary in patients with moderate or severe renal impairment (see section 4.2 Posology and Method of Administration).
Caution should be taken in patients with predisposition factors of urinary retention (e.g. spinal cord lesion, prostatic hyperplasia) as cetirizine may increase the risk of urinary retention.

Caution in epileptic patients and patients at risk of convulsion is recommended.
Pruritus and/or urticaria may occur when cetirizine is stopped, even if those symptoms were not present before treatment initiation. In some cases, the symptoms may be intense and may require treatment to be restarted. The symptoms should resolve when the treatment is restarted.
Paediatric population
Due to the amount of some excipients in the formulation, the use of the product is not recommended in children aged less than 2 years.

4.5 Interactions with other medicinal products and other forms of interaction

Due to the pharmacokinetic, pharmacodynamic and tolerance profile of cetirizine, no interactions are expected with this antihistamine. Actually, neither pharmacodynamic nor significant pharmacokinetic interaction was reported in drug-drug interactions studies performed, notably with pseudoephedrine or theophylline (400 mg/day).
The extent of absorption of cetirizine is not reduced with food, although the rate of absorption is decreased.
In sensitive patients, the concurrent use of alcohol or other CNS depressants may cause additional reductions in alertness and impairment of performance although cetirizine does not potentiate the effect of alcohol (0.5 g/l blood levels).

4.6 Pregnancy and Lactation

Pregnancy
For cetirizine, very rare clinical data on exposed pregnancies are available. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development. Caution should be exercised when prescribing to pregnant women.
Breast-feeding
Cetirizine is excreted in human milk at concentrations representing 25% to 90% of those measured in plasma, depending on sampling time after administration. Cetirizine passes into breast milk. A risk of side effects in breastfed infants cannot be excluded. Caution therefore should be exercised when prescribing cetirizine to lactating women.

4.7 Effects on ability to drive and use machines

Objective measurements of driving ability, sleep latency and assembly line performance have not demonstrated any clinically relevant effects at the recommended dose of 10 mg. However, patients who experience somnolence should refrain from driving, engaging in potentially hazardous activities or operating machinery. They should not exceed the recommended dose and should take their response to the medicinal product into account.
In sensitive patients, concurrent use with alcohol or other CNS depressants may cause additional reductions in alertness and impairment of performance.

4.8 Undesirable effects

Clinical studies have shown that cetirizine at the recommended dosage has minor adverse effects on the CNS, including somnolence, fatigue, dizziness and headache. In some cases, paradoxical CNS stimulation has been reported.
Although cetirizine is a selective antagonist of peripheral H_1-receptors and is relatively free of anticholinergic activity, isolated cases of micturition difficulty, eye accommodation disorders and dry mouth have been reported. Affected patients may divide their daily dose, i.e. take as 5 mg in the morning and 5 mg in the evening.
Instances of abnormal hepatic function with elevated hepatic enzymes accompanied by elevated bilirubin have been reported. Mostly this resolves upon discontinuation of the treatment with cetirizine hydrochloride.

4.9 Overdose

Symptoms
Symptoms observed after an overdose of cetirizine are mainly associated with CNS effects or with effects that could suggest an anticholinergic effect.
Adverse events reported after an intake of at least 5 times the recommended daily dose are: confusion, diarrhoea, dizziness, fatigue, headache, malaise, mydriasis, pruritus, restlessness, sedation, somnolence, stupor, tachycardia, tremor and urinary retention.
Management
There is no known specific antidote to cetirizine.
Should overdose occur, symptomatic or supportive treatment is recommended. Gastric lavage should be considered following ingestion of a short occurrence. In addition active charcoal should be considered if cetirizine has been ingested within 1 hour.
Cetirizine is not effectively removed by dialysis.

5. Pharmacological properties:

5.1 Pharmacodynamic properties

Cetirizine, a human metabolite of hydroxyzine, is a potent antihistamine, selective H1 receptor antagonist. The histamine-mediated 'early' phase of the allergic reaction is inhibited by cetirizine, which also reduces the migration of inflammatory cells and the release of mediators associated with the 'late' allergic responses. Effects on other receptors are negligible and consequently cetirizine is unlikely to cause undesirable anti-cholinergic and anti-serotonin effects.
Ammonium chloride is an expectorant that helps loosen phlegm and catarrh.
Levomenthol relieves the discomfort of congestion and also provides a cooling effect.

5.2 Pharmacokinetic properties

Cetirizine is rapidly absorbed from the gastrointestinal tract; absorption is not reduced by food, though the rate may be decreased slightly. Peak blood levels in the order of 0.3 micrograms/ml are attained between 30 and 60 minutes following administration of a 10 mg oral dose of cetirizine. Apparent plasma clearance is greater in children than in adults: the terminal elimination half-life in healthy adult volunteers ranges between 6.7 – 10.7 hours; in children 6.1 – 7.1 hours; and in children aged under 4 years 5.55 hours. Cetirizine is mainly excreted unchanged in the urine (approximately 70% over 5 days compared with 10% in the faeces). The half-life is increased in renal dysfunction: half lives of 19 and 21 hours in patients with mild to moderate renal impairment respectively have been reported. This may have implications for elderly patients. Cetirizine binds strongly to plasma proteins.

Ammonium chloride is completely absorbed within 3–6 h. Ammonium ion is converted to urea in the liver; chloride ion replaces bicarbonate. Route of elimination is urine.

5.3 Preclinical safety data

- None Known.

6. Pharmaceutical particulars

6.1 List of excipients

- Carboxymethylcellulose Sodium
- Ethanol
- Propyl Parabenl
- Methyl paraben
- Citric Acid
- Sugar
- Sorbitol
- Glycerin
- Neelicol Grass Colour
- Purified Water

6.2 Incompactibilities

- Not Applicable.

6.3 Shelf life

36 Months

6.4 Special precautions for storage

- Store in a cool dry place below 30°C protected from light and out of reach of children.

6.5 Nature and contents of container<and special equipment for use, administration or implantation>

Each cardboard box contains one bottle of 100ml PET bottle with metallic screw cap.

6.6 Special precautions for disposal<and other handling>

- None.

7. Applicant/Manufacturer

- Name: Alben Healthcare Industries Limited.
- Address: Km 15 Old Onitsha-Awka Road Ogidi, Anambra State, Nigeria.
- Phone No: 08068056661.
- Email Address:albenng@rocketmail.com.