1. NAME OF THE MEDICINAL PRODUCT

Alben Zinc Sulphate Tablet 50mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated tablet contains:
Zinc Sulphate BP……50mg

Excipients with known effect:

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

- White Circular, uncoated tablet, plain on one side and "ALBEN" on other side.

4. Clinical Particulars

4.1 Therapeutic indications

Zinc sulphate is a source of zinc which is an essential trace element and involved in a number of body enzyme systems.

Alben Zinc Tablet is indicated in adults and children for the treatment of zinc deficiency.

4.2 Posology and method of administration

Method of Administration: oral

Adults: One tablet, once to three times daily after meals.

Children: More than 30kg: One tablet, once to three times daily after meals.

10-30kg: ½ tablets, once to three times daily after meals.

4.3 Contraindications

- Hypersensitivity to the active substance or any of the excipients.
- Copper deficiency

4.4 Special warnings and precaution for use

Drugs which may inhibit zinc absorption, such as penicillamine, sodium valproate and ethambutol, should not be co-administered with Zinc Sulphate Tablets, unless the risks of discontinuation of the drug are judged to outweigh the benefit of zinc in treatment of the child's diarrhoea.

4.5 Interactions with other medicinal products and other forms of interaction

Antibiotics When taken together, zinc may reduce the absorption of tetracyclines (but not doxycycline), and quinolone antibiotics. In addition, zinc may also interfere with the absorption of cephalexin or ceftibuten. An interval of at least three hours should be allowed between administration of zinc and any of these medicines**.**

4.6 Pregnancy and Lactation
Pregnancy: The safety of Zinc Sulfate Tablet in pregnancy has not been established. Lactation: Zinc crosses the placenta and is present in breast milk. The safety of Zinc Sulfate Tablet in lactation has not been established.

4.7 Effects on ability to drive and use machines
No influence on the ability to drive and use machines.

4.8 Undesirable effects
Zinc salts may cause abdominal pain, dyspepsia, nausea, vomiting, diarrhoea, gastric irritation and gastritis. There have also been cases of irritability, headache and lethargy observed.

Zinc may interfere with the absorption of copper, leading to reduced copper levels, and potentially copper deficiency. The risk of copper deficiency may be greater with long-term treatment (e.g. if zinc deficiency is no longer present) and/or with higher doses of zinc.

4.9 Overdose

Symptoms: High doses of zinc cause emesis. In addition, zinc sulfate is corrosive at high doses, and may cause irritation and corrosion of the gastrointestinal tract, including ulceration of the stomach and possible perforation. Over dosage with zinc has also been associated with acute renal tubular necrosis and interstitial nephritis. Prolonged high dose zinc supplementation may result in copper deficiency.

5. Pharmacological properties:

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Mineral Supplement, ATC Code: A12CB01
Zinc is an essential trace element involved in many enzyme systems. Severe deficiency causes skin lesion, alopecia, diarrhoea, increased susceptibility to infections and failure to thrive in children. Symptoms of less severe deficiency include distorted or absent perceptions of taste and smell and poor wound healing.

5.2 Pharmacokinetic properties

Zinc is absorbed from the gastrointestinal tract and distributed throughout the body. The highest concentrations occur in hair, eyes, male reproductive organs and bone. Lower levels are present in liver, kidney and muscle. In blood 80% is found in erythrocytes. Plasma zinc levels range from 70 to 110µg/dL and about 50% of this is loosely bound to albumin. About 7% is amino-acid bound and the rest is tightly bound to alpha 2-macroglobulins and other proteins.

5.3 Preclinical safety data
None Stated

6. Pharmaceutical particulars

6.1 List of excipients

- Starch
- Microcrystalline Cellulose
- Sodium Propyl Paraben
- Ethylcellulose
- Magnesium stearate
- Aerosil
- Croscarmellose Sodium
- Aspartame
- Orange flavour

6.2 Incompactibilities

- None relevant known.

6.3 Shelf life

- 36 Months

6.4 Special precautions for storage

- Do not store above 30°C
- Store in a cool dry place protected from light and out of reach of children.

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

Plastic container of 60 tablets.

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.