1.5 Product Information: REZN TABLETS

1.5.1 Prescribing information (Summary of products characteristics):

1. Name of the Medicinal Product: REZN TABLETS

Strength:
Zinc sulfate monohydrate equivalent to elemental zinc 20mg
Pharmaceutical form: Dispersible Tablet

2. Qualitative and Quantitative composition:

Qualitative composition:

Sr. No.	Ingredient	Specification	Uses
1	Zinc Sulfate Monohydrate	BP	Active
2	Microcrystalline Cellulose (PH102)	BP	Diluent
3	Aspartame	BP	Sweetener
4	Sodium Starch Glycollate	BP	Disintegrant
5	Crospovidone	BP	Disintegrant
6	Colloidal Silicon Dioxide	USP/BP	Glidant
7	Maize Starch	BP	Diluent
8	Vanilla Powder	INH	Flavor
9	Magnesium Stearate	BP	Lubricant

Quantitative composition:

Sr. No.	Ingredient	Specification	Quantity mg per tablet
1	Zinc Sulfate Monohydrate	BP	54.90
2	Microcrystalline Cellulose (PH102)	BP	125.00
3	Aspartame	BP	90.00
4	Sodium Starch Glycollate	BP	20.00
5	Crospovidone	BP	35.00
6	Colloidal Silicon Dioxide	USP/BP	10.00
7	Maize Starch	BP	8.10
8	Vanilla Powder	INH	5.00
9	Magnesium Stearate	BP	2.00

3.Pharmaceutical form: Dispersible Tablet

4. Clinical particular's:

4.1 Therapeutic indication:
Acute and persistent diarrhea, Lower respiratory tract infections,
Acrodermatitisenteropathica (It is rare genetic disorder caused due to malabsorption of zinc through the intestinal cells characterized by diarrhea, an inflammatory rash around the mouth and/or anus, and hair loss)

4.2 Posology and method of administration:
For infants between 2 and 6 months of age: 1/2 a tablet (10mg elemental zinc) to be administered every day for 10 consecutive days (even if diarrhoea episode has stopped).
For children between 6months and 5 years of age: one full tablet (20mg elemental zinc) to be administered every day for 10 consecutive days (even if diarrhoea episode has stopped). In case of vomiting within 1/2 hour following the intake of tablet, give another one
Method of Administration: Oral route.

4.3 Contraindication:
Precautions:In the treatment of diarrhoea, use Rezn Tablets in connection with O.R.S.

AdverseEffects:The most frequent adverse effects of zinc salts (the gluconate and sulfate) administered by mouth are gastrointestinal and include abdominal pain, dyspepsia, nausea, vomiting, diarrhoea, gastric irritation, and gastritis. These are particularly common if zinc salts are taken on an empty stomach, and may be reduced by Administration with meals.

Interactions:The absorption of zinc may be reduced by iron supplements, penicillamine, phosphorus-containing preparations, and tetracyclines. Zinc supplements reduce the absorption of copper, fluoroquinolones, iron, penicillamine, and tetracyclines

4.4 Special warning and precaution for use:
Store in a dry place below 30°C. Protect from light. Keep all medicines out of the reach of children.

Drugs which may inhibit zinc absorption, such as penicillamine, sodium valproate and ethambutol, should not be co administredwith Rezn 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 interactions:

Tetracycline Antibacterials:
Zinc may reduce the absorption of concurrently administered tetracyclines, also the absorption of zinc may be reduced by tetracyclines; when both are being given an interval of at least three hours should be allowed.
Quinolone Antibacterials:
Zinc may reduce the absorption of quinolones; ciprofloxacin, levofloxacin, moxifloxacin, norfloxacin and ofloxacin.
Calcium Salts:
The absorption of zinc may be reduced by calcium salts.
Iron:
The absorption of zinc may be reduced by oral iron, also the absorption of oral iron may be reduced by zinc.
Penicillamine:
The absorption of zinc may be reduced by penicillamine, also the absorption of penicillamine may be reduced by zinc.
Trientine:
The absorption of zinc may be reduced by trientine, also the absorption of trientine may be reduced by zinc.

Additional information on special populations:
Not Applicable

Paediatric population:
Not Applicable

4.6 Fertility, pregnancy and lactation:
The safety of this product in human pregnancy has not been established. Zinc crosses the placenta and is present in breast milk.

4.7 Effects on ability to drive and use machines:
There is no evidence regarding the effect of zinc on the ability to drive or use machines, however Rezn Tablets is not expected to have any effect 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.

4.9 Overdose and Treatment:

Zinc sulfate is corrosive in overdosage. Symptoms are corrosion and inflammation of the mucous membrane of the mouth and stomach; ulceration of the stomach followed by perforation may occur. Gastric lavage and emesis should be avoided. Demulcents such as milk should be given. Chelating agents such as sodium calcium edetate may be useful.

5. Pharmacological Properties:

5.1 Pharmacodynamic properties:

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:

No further relevant information.

6. Pharmaceutical Particulars:

6.1 List of excipients

Rezn tablet contains the following excipients:

Microcrystalline cellulose PH 102, crospovidone, Sodium Starch Glycolate, aspartame, vanilla flavor, magnesium stearate, maize starch and colloidal silicon dioxide.

6.2 Incompatibilities

None known

6.3 Shelf life

24 months

6.4Special precaution for storage

Store in cool & dry place. Below 30°C.

6.5 Nature and contents of container

10 tablets are packed in Aluminium/PVDC blister; such tenblistersare packed in a unit carton along with literature insert.

6.6Special precautions for disposal

No special precaution.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESSES:

Marketing Authorization Holder:
Rene Industries Ltd
Address : PO Box 6034, Plot No.680, Kamuli, Kireka, Kampala, Uganda.

Manufactured by:
Rene Industries Ltd
Address : PO Box 6034, Plot No.680, Kamuli, Kireka, Kampala, Uganda.

8. MARKETING AUTHORISATION NUMBER:

Not Applicable

9. DATE OF FIRST REGISTRATION/RENEWAL OF THE REGISTRATION:

Not Applicable

10. DATE OF REVISION OF THE TEXT:

Not Applicable

11. DOSIMETRY (IF APPLICABLE):

Not Applicable

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE):

Not Applicable