

Summary of products characteristics (SmPC):

1. Name of the Medicinal Product: REZN TABLETS

2. Qualitative and Quantitative composition:

Each dispersible tablet contains Zinc Sulfate Monohydrate equivalent to zinc 20 mg.

For the full list of excipients, See section 6.1

3. Pharmaceutical form: Dispersible Tablet

Off white coloured round flat shaped tablet with break line on one side and plain on another side

4. Clinical particular's:

4.1 Therapeutic indication:

Rezn Tablets contains zinc. In the body, a small quantity of zinc (a so-called 'trace element') is essential for many different processes e.g. the ability to fight off infection. Zinc also prevents the growth of bacteria that can cause diarrhoea.

Rezn Tablets is used for treating acute and persistent diarrhoea in infants and children aged up to 5 years.

This product is intended for use in children. Safety information on its use in adults is also provided.

4.2 Posology and method of administration:

Always give Rezn Tablets exactly as your doctor or healthcare provider has told you.

Ask your doctor, healthcare provider or pharmacist if you have any questions about this medicine.

How much to give

Children less than 6 months old: ½ tablet daily for 10 to 14 days

Children 6 months to 5 years old: 1 tablet daily for 10 to 14 days

Giving Rezn Tablets

- It is recommended you give the doses between meals.
- Fill a teaspoon (5 ml) with either breast milk or boiled and cooled water. Place the tablet (or half tablet) in the liquid. As soon as the tablet has dispersed completely get the child to swallow all the mixture.
- If the child vomits within 30 minutes of taking the dose, give another dose. If in doubt, talk to your doctor or healthcare provider.

Method of Administration: Oral route.

4.3 Contraindication:

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

Adverse Effects: 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:

Do not store above 30°C. Protect from light. Keep out of the reach of children.

Drugs which may inhibit zinc absorption, such as penicillamine, sodium valproate and ethambutol, should not be co administered with 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:

Pharmacotherapeutic group: Vitamins / Micro nutrients; 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:

No further relevant information.

6. Pharmaceutical Particulars:

6.1 List of excipients

Rezn tablet contains the following excipients:

Microcrystalline cellulose 102, Aspartame granules, Sodium Starch Glycolate (Type A), Cross povidone, Colloidal silicon dioxide, Maize starch, Vanilla powder, Magnesium stearate.

6.2 Incompatibilities

None known

6.3 Shelf life

24 months

6.4 Special precaution for storage

Do not store above 30°C. Protect from light. Keep out of reach of Children.

6.5 Nature and contents of container

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

6.6 Special 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