

**CTD MODULE 1**  
**ADMINISTRATIVE INFORMATION AND**  
**PRODUCT INFORMATION**

<b>Product Name :</b>	<b>REZN TABLETS</b> <b>Zinc Sulfate Monohydrate equivalent to elemental Zinc 20mg</b>
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**Pack Insert:**

## ReZn TABLETS 20MG

**COMPOSITION:**

**Each Dispersible tablet contains:**

Zinc Sulfate Monohydrate BP (54.89mg) equivalent to 20mg elemental Zinc.

**CLINICAL PHARMACOLOGY:**

Zinc is an essential element of nutrition and traces are present in a wide range of foods. It is a constituent of many enzyme systems and is present in all tissues. Adequate zinc intake is crucial for health. Zinc deficiency affects cells of the immune system. It causes a reduction in the number of B lymphocytes and T lymphocytes (CD4 lymphocytes in particular) through increased apoptosis and also reduces their functional capacity. The functions of the macrophage, another key immunological cell that engulfs and destroys bacteria, are also compromised. The production and potency of several cytokines, the central messengers of the immune system, are also perturbed by zinc deficiency. Many of these changes occur even in the early stages of deficiency. Zinc plays a part in the maintenance of epithelial and tissue integrity through promoting cell growth and suppressing apoptosis and through its role as an antioxidant, protecting against free radical damage during inflammatory responses. Thus, in the case of diarrhoea, multiple functions of zinc may help to maintain the integrity of the gut mucosa to reduce or prevent fluid loss. Notably, these responses can occur within 48 hours, much more rapidly than the direct effects of zinc on cellular development.

**USES:**

Zinc supplementation has been shown to be an effective treatment for acute, persistent, and dysenteric diarrhoea in children under five. ReZn tablets are used to reduce morbidity and mortality in children under five with acute, persistent and dysenteric diarrhoea.

**DOSAGE AND ADMINISTRATION:**

For infants between 2 and 6 months of age: 1/2 a tablet (10mg elemental zinc) to be administered once daily for 10 consecutive days (even if diarrhoea episode has stopped).

For children between 6 months to 5 years of age: one full tablet (20mg elemental zinc) to be administered once daily for 10 consecutive days (even if diarrhoea episode has stopped). In case of vomiting within 30 minutes following the intake of tablet, give another one.

It is recommended that doses be administered between meals and a repeat dose be given if vomiting occurs within 30 minutes.

For missed doses, the missing dose can be taken as soon as possible, unless there is less than 6 hours until the next dose.

In the treatment of diarrhoea, use ReZn 20mg tablets co-prescribed with O.R.S.

**Directions for use:**

The tablet (or half tablet) should be dispersed completely in 1 teaspoon (5ml) of clean water or breast milk and the entire amount administered orally to the infant or child.

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**CONTRA-INDICATIONS AND WARNINGS:**

**Precautions:**

Drugs which may inhibit zinc absorption, such as penicillamine, sodium valproate and ethambutol, should not be co-administered with ReZn 20mg Tablets, unless the risks of discontinuation of the drug are judged to outweigh the benefit of zinc in treatment of the child's diarrhoea.

ReZn 20mg Tablets contain aspartame, a source of phenylalanine. This should be considered when prescribing the product to patients with phenylketonuria.

**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.

**Pharmacokinetics:**

Zinc is incompletely absorbed from the gastrointestinal tract, and absorption is reduced in the presence of some dietary constituents such as phytates. Bioavailability of dietary zinc varies widely between different sources, but is about 20 to 30%. Zinc is distributed throughout the body with the highest concentrations found in muscle, bone, skin, and prostatic fluids. It is primarily excreted in the faeces, and regulation of faecal losses is important in zinc homeostasis. Small amounts are lost in urine and perspiration.

**Storage Conditions:**

Store in a dry place, below 25°C. Protect from light.

**KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN**

**Presentation:**

Blister Pack of 10x10's Tablets

**MANUFACTURED BY**  
**RENE INDUSTRIES LIMITED**  
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*A Milestone to Golden Health*