

## **1. NAME OF THE MEDICINAL PRODUCT**

Ped Zinc Tablets 20mg.

## **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each dispersible tablet contains Zinc Sulphate Monohydrate USP 54.9mg equivalent to elemental Zinc 20mg.

For the full list of excipients, see section 6.1.

## **3. PHARMACEUTICAL FORM**

A white, circular, beveled-edged flat tablets with a score line and debossing with letters "S" and "L" on one side and plain on other side.

## **4. CLINICAL PARTICULARS**

### **4.1 Therapeutic indications**

Zinc Sulphate Monohydrate Tablets are indicated in children suffering from acute and persistent diarrhea, respiratory tract infections, common cold, malaria, acrodermatitis enteropathica, sickle cell anaemia and Wilson's disease.

Zinc Sulphate Monohydrate Tablets are indicated in the treatment of diarrhoeal, always in connection with Oral Rehydration Salt (ORS) of the WHO by giving Zinc as soon as diarrhea starts, at the same time as ORS. By continuing Zinc supplementation after diarrhea stops, the Zinc lost in the stools will be replaced. The risk of the child having new episodes of diarrhea in the following 2 to 3 months is reduced.

### **4.2 Posology and method of administration**

**Posology:** As directed by the physician or

Acute diarrhea: For children below 6 months: 10mg elemental Zinc daily for 10-14 days. For children above 6 months: 20mg elemental Zinc daily for 10-14 days.

Wilson's disease: 25-50mg elemental zinc two to three times daily.

Sickle cell anaemia: 10-15mg elemental zinc daily

Acrodermatitis enteropanthonica: 1-2mg elemental zinc per kg of body weight daily.

Ped Zinc Tablets should be taken between meals but if GI upset occurs, it can be taken with food. In case of vomiting within half an hour following the intake of tablet, give another tablet.

**Method of administration:** - Place the tablet in a teaspoon/tablespoon. Add about 5ml water or breast milk. Let the tablet disperse (around 45 seconds). Give the entire spoonful to the child

#### **4.3 Contraindications**

Zinc Sulphate Monohydrate Tablets are contraindicated as co-prescription with certain drugs like penicillamine, sodium valproate and ethambutol which inhibit zinc absorption. It is contraindicated to patients with hypersensitivity to the active substances or to any of the excipients.

#### **4.4 Special Warnings and Precautions for Use**

Problems in human beings and especially for pediatrics have not been documented with intake of normal daily recommended amounts of Zinc. Keep the medicine out of reach of children.

#### **4.5 Interaction with other medicinal products and other forms of interaction :**

Combinations containing any of the following, depending on the amount present, may interact with zinc.

**Diuretics:** Thiazide diuretics have been found to increase urinary zinc excretion. Fiber, found in bran, whole-grain breads and cereals or Phosphorus-containing foods, with zinc supplements may reduce zinc absorption by formation of non-absorbable complexes.

**Folic Acid :** Some studies have found that folate can decrease the absorption of zinc.

**Tetracyclines :** Oral Zinc Salts may decrease the absorption of tetracycline by forming insoluble chelates.

#### **4.6 Fertility, pregnancy and lactation :**

Problems in humans have not been documented with intake of normal daily recommended amounts. Use with extreme caution during pregnancy.

#### **4.7 Additional information on special populations**

The contraindications, special warnings and precautions and interaction with other medicinal products of Ped Zinc Tablets do not affect any special populations.

#### **4.8 Effects on ability to drive and use machines**

Zinc sulphate dispersible tablets 20mg effects on ability to drive and use machines have not been performed.

#### **4.9 Undesirable effects**

Adverse reactions are rare but if excessive doses of Zinc are used it may cause copper deficiency. Nausea and vomiting may occur. If GI upset occurs, Zinc Sulphate

Monohydrate Tablets can be taken with food, but foods high in calcium, phosphorus and phytates must be avoided.

#### **4.10 Overdose:**

Symptoms: Overdosage includes dizziness or fainting, yellow eyes or skin, chest pain or shortness of breath, Vomiting etc.

Treatment: Dilute with milk or water. For specific treatment intramuscular or intravenous Edetate Calcium Disodium at a dose of 50 to 75 mg per kg (mg/kg) of body weight per day, in 3 to 6 divided doses, for up to 5 days shall be given.

## **5 PHARMACOLOGICAL PROPERTIES.**

### **5.1 Pharmacological Properties**

#### **Pharmacotherapeutic group and ATC Code**

Pharmacotherapeutic group: **Anti - diarrhoeal for children**

ATC Code: **A12CB01**

**Pharmacodynamic Properties** - Zinc Sulphate Monohydrate is a Zinc salt used for the treatment of Zinc deficiency. Zinc Sulphate Monohydrate contains 23 percentage of elemental Zinc. Zinc Sulphate Monohydrate is absorbed over a broad pH range and may cause mild GI irritation. 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.

Normal growth and tissue repair depend upon adequate Zinc. Zinc acts as an integral part of several enzymes important to protein and carbohydrates metabolism. Features of zinc deficiency include growth retardation and defects of rapidly dividing tissues such as the skin and the intestinal mucosa. Zinc facilitates wound healing and helps maintain normal growth rates, normal skin hydration and senses of taste and smell.

**Mechanism of Action** – Zinc improves absorption of water electrolytes. Zinc supplements prevent subsequent episodes of diarrhea. WHO and UNICEF recommend daily zinc supplements for children with acute diarrhea to curtail the severity of the episode and prevent further occurrences in the ensuing 2-3 months. Zinc deficiency in humans alters several aspects of immune function. Immune defects associated with zinc deficiency include impaired function of lymphocytes, natural killer cells and neutrophils. Zinc deficiency has also been hypothesized to exacerbate malaria and other diseases (infection with human immunodeficiency virus and tuberculosis) that rely on macrophage killing of infected cells. Adequate intake of zinc shorten the duration of respiratory tract infections including common cold.

## 5.2 Pharmacokinetic Properties

**Absorption:** Zinc is incompletely absorbed from the gastrointestinal tract and the absorption is reduced in the presence of some dietary constituents such as phytates.

**Distribution:** Zinc is distributed throughout the body with the highest concentration found in muscle, bone, skin and prostatic fluids

**Metabolism:** Bioavailability of dietary Zinc varies widely between different sources but is about 20-30%.

**Excretion:** It is primarily excreted in the faeces. Small amounts are lost in urine and perspiration.

### Special populations

The contraindications, special warnings and precautions and interaction with other medicinal products of Ped Zinc Tablets do not affect any special populations.

## 5.3 Preclinical safety data

There is no preclinical data of relevance to the prescriber in addition to that included in other sections of the summary of product characteristics.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Microcrystalline cellulose  
Colloidal Anhydrous Silica  
Maize Starch  
Aspartame  
Croscarmellose Sodium  
Raspberry Flavor  
Sodium Starch Glycolate  
Magnesium Stearate.

### 6.2 Incompatibilities.

None known.

### **6.3 Shelf-life.**

36 months (about 3 years) when stored under recommended conditions.

### **6.4 Special precautions for storage**

Store in a dry place below 30°C. Protect from light.

### **6.5 Nature and contents of container.**

Ped Zinc Tablets are packed in blister packs of 10 tablets in 10 inner boxes (dispenser cartons) along with leaflets then packed in an outer box (dispenser carton) made of chipboard material.

### **6.6 Special precautions for disposal/and other handling**

Any unused product or waste material should be disposed of in accordance with local requirements.

## **7 MANUFACTURER**

### **SHELYS PHARMACEUTICALS LTD.,**

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