SUMMARY OF PRODUCT CHARACTERISTICS

Ped Zinc®

1.0 NAME OF THE MEDICINAL PRODUCT : Zinc Sulfate Tablets USP 20mg

2.0 QUALITATIVE AND QUANTITATIVE COMPOSITION :

Each tablet contains :
Zinc Sulfate Monohydrate USP 54.9mg equivalent to elemental Zinc 20mg

3.0 PHARMACEUTICAL FORM :

3.1 Pharmaceutical dosage form : Tablets

3.2 Description :- White, circular, flat tablets with "S/L" engraving on one side and plain other side.

4.0 CLINICAL PARTICULARS :

4.1 Therapeutic indiacations :- Zinc Sulfate 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 Sulfate Tablets are indicated in the treatment of diarrhoea, always in connection with Oral Rehydration Salts (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 :- As directed by the Physician or
Acute Diarrhoea : 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 : 25-50 mg elemental zinc two to three times daily
Sickle cell anaemia : 10-15 mg elemental zinc daily
Acrodermatitis enteropathica : 1-2 mg elemental zinc per kg of body weight daily.
Ped Zinc Tablet 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 brest milk. Let the tablet disperse (around 45 seconds). Give the entire spoonful to the child.

4.3 **Contraindications :-** Zinc Sulfate 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 special 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.

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

4.6 **Pregnancy and lactation :-** Problems in humans have not been documented with intake of normal daily recommended amounts. Use extreme caution during pregnancy

4.7 **Effects on ability to drive and use machines :-** Effects on ability to drive and use machines have not been documented.

4.8 **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 Sulfate Tablets can be taken with food, but foods high in calcium, phosphorous and phytates must be avoided.

4.9 **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.

5.0 PHARMACOLOGICAL PROPERTIES :

5.1 Pharmacodynamic properties :-

Pharmacotherapeutic group – Anti-diarrhoeal for children (Mineral Supplement).

ATC code – A12CB01

Mechanism of action – Zinc sulphate is a zinc salt used for the treatment of zinc deficiency. Zinc sulphate contains 23 percentage of elemental zinc.
Zinc sulphate 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 the tissues.
Normal growth and tissue repair depend upon adequate zinc. Zinc acts as an integral part of several enzymes important to protein and carbohydrate 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.
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 intakes of zinc shorten the duration of respiratory tract infections including common cold.

5.2 Pharmacokinetic properties :-

Zinc is incompletely absorbed from the gastrointestinal tract and the 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 20-30%. Zinc is distributed throughout the body with the highest concentration found in muscle, bone, skin and prostatic fluids. It is primarily excreted in the faeces. Small amounts are lost in urine and perspiration.

6.0 PHARMACEUTICAL PARTICULARS :

6.1 List of excipients :- Microcrystalline Cellulose, Colloidal Anhydrous Silica, Maize Starch, Aspartame, Croscarmellose Sodium, Raspberry Flavour, Sodium Starch Glycolate, Magnesium Stearate.

6.2 Incompatibilities :- Zinc Sulfate Tablets are incompatable with 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.

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

6.3 Shelf life :- 2 years when stored under recommanded 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 :- Blister pack of 10 Tablets in an inner box along with a leaflet. 10 such inner boxes in an outer box.

6.6 Instructions for use and handling :- Any unused product or waste material should be disposed of in accordance with local requirement.

7.0 MARKETING AUTHORISATION HOLDER :

Shelys Pharmaceuticals Limited,
New Bagamoyo Road, Mwenge,
P.O. Box 3016, Dar Es Salaam, Tanzania.

8.0 MARKETING AUTHORISATION NUMBER :

08285/07915/REN/2021

9.0 DATE OF FIRST AUTHORIZATION OF THE AUTHORIZATION :

Jun 11, 2021

10.0 DATE OF REVISION OF THE TEXT :

5th February, 2010