SUMMARY OF PRODUCT CHARACTERISTICS ZINCOS 20 MG DISPERSIBLE TABLET

1. **Name of the Medicinal Product**

   Zincos 20 mg dispersible Tablets

2. **Qualitative and Quantitative Composition**

   Each dispersible tablet contains 20 mg of Elemental Zinc.

3. **Pharmaceutical Form**

   Dispersible Tablet

4. **Clinical Particulars**

4.1 Therapeutic Indications

For the treatment of acute diarrhoea

It is recommended in cases of severe acute diarrhoea in young children, and is used in association with oral rehydration salts (ORS).

It reduces the severity and duration of episodes of diarrhoea, regenerates the body's reserves of zinc and has a preventive effect up to three months after the end of the treatment.

4.2 Posology and Method of administration

Method of Administration: oral after dissolution in water.

Adults: One tablet, dissolved in water, once to three times daily after meals.

Children: More than 30kg: One tablet, dissolved in water, once to three times daily after meals.

10-30kg: ½ tablet, dissolved in water, once to three times daily after meals.

Less than 10kg: ½ tablet, dissolved in water, once daily after meals.

4.3 Contraindications

None

4.4 Special warnings and precautions for use

None

4.5 Interaction with other medicinal products and other forms of interaction

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.

4.6 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

None.

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.

5 Overdose

Symptoms High doses of zinc cause emesis. In addition, zinc sulfate is corrosive at high doses, and may cause irritation and corrosion of the gastrointestinal tract, including ulceration of the stomach and possible perforation. Overdosage with zinc has also been associated with acute renal tubular necrosis and interstitial nephritis. Prolonged high dose zinc supplementation may result in copper deficiency.

Treatment

In cases of acute zinc overdose, treatment is primarily supportive, however induced emesis, gastric lavage, or activated charcoal may be useful in cases of substantial ingestions of zinc tablets. Chelating agents such as calcium disodium EDTA may be useful.

6 Pharmacological Properties

6.1 Pharmacodynamic Properties

Zinc sulfate is a zinc salt used for the treatment of acute and persistent diarrhoea in children. Zinc is an essential trace element which is present in a wide range of foods. It is found in all tissues. Normal growth and tissue repair depend upon adequate zinc levels. Zinc acts as an integral part of several enzymes important to protein and carbohydrate metabolism. . Severe zinc deficiency is associated with growth retardation, primary hypogonadism, skin disease, disturbances of taste and smell, and impaired immunity, with increased susceptibility to infection. Zinc supplementation has been shown to reduce the duration and severity of diarrhea in populations of children with a high incidence of zinc deficiency, and also to reduce the frequency of recurrences in the subsequent 2-3 months. The beneficial effects of zinc are likely associated with reconstitution of the immune response, however direct inhibitory effects of zinc on enteric pathogens have also been reported.

6.2 Pharmacokinetic Properties

Absorption

Zinc is incompletely absorbed from the small bowel, with between 10 and 40% of an ingested dose absorbed. Numerous dietary components can interfere with zinc absorption, particularly phytates and fibre, which bind to zinc, resulting in poorly absorbed zinc complexes. The absorption of zinc was examined in 10 healthy, zinc replete, adult male volunteers (baseline mean plasma zinc level ±SD of 15.1 ±3.5 mmol/L). Absorption of zinc from 1½ ZIncos tablets (i.e. a 30 mg dose) was rapid, with a maximal increase in mean plasma zinc level (±SD) of 11.6 (±6.0) mmol/L observed within approximately 2 hours of administration.

Distribution Approximately 60% of circulating zinc is bound to albumin and roughly 30% is bound to macroglobulin. The majority of zinc is stored in the liver and kidney, chiefly intracellularly,and bound to metalloproteins.

Elimination

In adults, it has been estimated that approximately 0.5 to 1.0 mg/day is secreted in the biliary tract and excreted in the stool, while 0.5 to 0.8 mg/day is excreted in the urine.

6.3 Preclinical safety data

Non-clinical data have not revealed significant hazards for humans, based on standard studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, and reproductive toxicity. Effects in non-clinical studies were observed only at exposures sufficiently in excess of the maximum human exposure to be of little clinical relevance.

Pharmaceutical Particulars

6.4 List of Excipients

Microcrystalline Cellulose BP

Maize starch BP

Aerosil BP

Croscarmellose sodium BP

Sodium starch glycolate BP

Sodium lauryl sulphate BP

Vanilla powder flavour

Aspartame powder

Magnesium stearate BP

7.2 Incompatibilities

None

7.3 Shelf life

3 Years

7.4 Special precautions for storage

Store in a dry place below 30ºC.

7.5 Nature and contents of container

PVC/ALU blister packing

7.6 Instructions for use, handling and disposal

No special requirements

8 Registrant

Cosmos Limited

9 Manufacturer

Cosmos Limited

Rangwe Road; Off Lunga Lunga, Industrial Area

P.O Box 41433, GPO 00100-Nairobi

Kenya

Telephone: + (254-20) 2519603/4/5, 020 8042200/2/3/4/5

Telefax: +254-020-8096280/1

E-mail: admin@cosmos-pharm.com