SUMMARY OFPRODUCTCHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICALPRODUCT

Zinc Sulfate Dispersible Tablets 20mg (MEDOZINC DT)

2. QUALITATIVE AND QUANTITATIVECOMPOSITION:

Each Dispersible tablets contain:

Zinc Sulfate USP (as monohydrate)

Equivalent to elemental zinc 20 mg

For a full list of excipients, see section 6.1

3. PHARMACEUTICALFORM

White to off-white , circular , flat dispersible tablet with beveled edges , having breakline on one face and plain on other face of the tablet with pleasant odour.

4. Clinicalparticulars

4.1 Therapeuticindications

Zinc sulfate is a source of zinc which is an essential trace element and involved in a number of body enzyme systems.

Zinc sulfate is indicated in adults and children for the treatment of zinc deficiency.

This product is intended for use in children. Nonetheless, safety information is provided with respect to adult health issues such as liver disease, pregnancy and lactation, to allow full access to all relevant information.

4.2 Posology and method of administration

For acute and persistent diarrhoea

For children less than 6 months of age: ½ tablet once daily for 10-14 days.

For children 6 months of age to 5 years of age: 1 tablet once daily for 10-14 days.

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

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.

Method of Administration

For oral administration.

4.3 Contraindications

Not Applicable

4.4 Special warnings and precautions for use

Accumulation of zinc may occur in cases of renal failure.

This product contains sorbitol (E420), therefore patients with rare hereditary problems of fructose intolerance should not take this medicine.

This medicinal product contains 106mg sodium per tablet, equivalent to 5.3% of the WHO recommended maximum daily intake of 2g sodium for an adult.

4.5 Interaction with other medicinal products and other forms of interaction

Antibiotics

When taken together, zinc may reduce the absorption of tetracyclines (but not doxycycline), and quinolone antibiotics. In addition, zinc may also interfere with the absorption of cephalexin or ceftibuten. An interval of at least three hours should be allowed between administration of zinc and any of these medicines.

Copper:

Zinc may inhibit the absorption of copper.

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 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

Quinine may cause visual disturbances and vertigo, hence patients should be advised that if affected they should not drive or operate machinery.

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.

Zinc may interfere with the absorption of copper, leading to reduced copper levels, and potentially copper deficiency. The risk of copper deficiency may be greater with long- term treatment (e.g. if zinc deficiency is no longer present) and/or with higher doses of zinc.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinalproduct is important. It allows continued monitoring of the benefit/risk balanceof the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme(www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in theGooglePlay or Apple App Store.

4.9 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.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group:Other mineral supplements

ATC code:A12CB01.

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.

5.2Pharmacokineticproperties

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 from ZinCfant® tablets 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 ZinCfant® 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.

5.3 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Anhydrous calcium hydrogen phosphateBP
- Microcrystalline cellulose PH 102BP
- Aspartame BP
- Maize starchBP
- Orange dry powder (Trusil orange SPL)INH
- Sodium starch glycolate BP
- Colloidal silicon dioxideNF
- Magnesium stearateBP

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

6.4 Special precautions for storage

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

6.5 Nature and contents ofcontainer

Presentation: Zinc sulfate dispersible tablets BP 20 mg (MEDO ZINC DT) is available as10 x 10’s, 100 x 10's PVDC Blister pack.

Primary Container (s):

Zinc sulfate dispersible tablets BP 20 mg (MEDO ZINC DT) is available as PVDC Blister pack.

10x10's& 100x 10’s - Each blister contains 10 tablets

Description and composition of primary packaging materials:

Blister pack:

- Printed blister Foil
- PVDC Film clear

Secondary packing:

Such blisters are packed in cartons of GSM 300, made of ITC cyber XL board with aqua varnish.Carton is printed in Multicolor.

Leaflet: leaflet made with 70 GSM Map Lithopaper.

Outer Container:

Such cartons are packed in Export Worthy 5/7 Ply Shippers. These shippers are labelled with product name and relevant batch details and sealed with BOPP tape. Shippers are then strapped with Polypropylene tapes.

Transportation: Should be transported with precautions.

The Cautions Like- This Side Up

- Not For Loose Handling
- Protect from Water
- Avoid Vigorous Transportation Not all pack sizes may be marketed.

6.6 Special precautions for disposal and otherhandling

None

7. MARKETING AUTHORIZATIONHOLDER

Name and Permanent address of the Marketing authorization holder:

Medopharm

"MEDO HOUSE"

25, Puliyur II Main road, Trustpuram, Chennai-600 024, Tamil Nadu, India.

PH: +91 44-30149992/30149955

Fax: 260211 286283

Manufacturing Site address:

MEDOPHARM
34-B Industrial Area,

Malur-563160, Kolar District,

KarnatakaIndia

8. NUMBER (S) IN THE NATIONAL REGISTER OF FINISHED PHARMACEUTICAL PRODUCTS

08487/10239/NMR/2022

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION:

21.03.2023

10. DATE OF REVISION OF THE TEXT

13.07.2023