SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Ozinc-DT TABLET

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated dispersible tablet contains:

Zinc sulfate monohydrate USP
(54.9 mg) equivalent to elemental
zinc……20 mg

Each uncoated dispersible tablet contains 46.43 mg of aspartame.
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

White to off white, round, flat faced bevel edge, uncoated dispersible tablets with break line on one side and debossed with 'C 70' on other side. The tablet can be divided into equal halves.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Ozinc-DT is indicated for the treatment of acute and persistent diarrhoea in infants and children up to 5 years of age.

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.

4.3 Contraindications

Not Applicable

4.4 Special warnings and precautions for use

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

Excipients
Ozinc-DT contain aspartame, a source of phenylalanine. This should be considered when prescribing the product to patients with phenylketonuria.

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.

4.6 Pregnancy and Lactation

Pregnancy
The safety of Ozinc-DT in pregnancy has not been established.

Lactation
Zinc crosses the placenta and is present in breast milk. The safety of Ozinc-DT in lactation has not been established.

4.7 Effects on ability to drive and use machines

There is no evidence regarding the effect of zinc on the ability to drive or use machines, however Ozinc-DT is not expected to have any effect on the ability to drive and use machines.

4.8 Undesirable effects

- In clinical trials in children, administration of Ozinc-DT was associated with vomiting or regurgitation. In one study vomiting attributed to the tablet was reported very commonly (≥ 10%), i.e. in 14% and regurgitation was reported commonly (≥ 1% to <10%), i.e. in 5.2% of the children, respectively. In most cases vomiting or regurgitation occurred shortly after administration of the first dose (within 10 minutes) and was not recurrent. Zinc salts may also cause abdominal pain and dyspepsia (frequency unknown).
- Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org'

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.

5.2 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 from Ozinc-DT 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 Ozinc-DT (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

Microcrystalline
Cellulose
Crospovidone
Aspartame
Sucralose
Orange Dry Flavour DC 116

Colloidal Silicon Dioxide
Magnesium stearate

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

PVDC/PVC - Alu Blister -24 months Alu-Alu Blister - 36 months

6.4 Special precautions for storage

Store below 30°C, protect from moisture.

6.5 Nature and contents of container

The tablets are packed in PVDC/PVC – Alu Blister and Alu-Alu Blister. Each blister pack contains 10 tablets.

Presentation:

1) PVDC/PVC – Alu blister of 10 tablets in a printed show box along with a leaflet.

2) 3 PVDC/PVC – Alu blister of 10 tablets in a printed show box along with a leaflet.

3) 10 PVDC/PVC – Alu blister of 10 tablets in a printed carton along with a leaflet.

4) Alu-Alu blister of 10 tablets in a printed show box along with leaflet.

5) 3 Alu-Alu blisters of 10 tablets in a printed show box along with leaflet.

6) 10 Alu-Alu blisters of 10 tablets in a printed carton along with leaflet.

6.6 Special precautions for disposal

No special requirement

7. APPLICANT/SUPPLIER

Ipca Laboratories Limited 48,

Kandivli Industrial Estate
Kandivli (W),
Mumbai 400067 India

8. MARKET AUTHORISATION NUMBER

CTD9125/19768

9. DATE OF 1st AUTHORISATION

04-02-2026

10. DATE OF REVISION OF THE TEXT

04-02-2026