Brand Name : **DT-ZINC TABLETS** **Generic Name** : Zinc Sulphate Dispersible Tablets 10 mg		2021
Module 1 **1.5**	Administrative Information and Product Information Product Information	**Confidential**

1.5 PRODUCT INFORMATION

1.5.1 Prescribing information (Summary of products characteristics)

SUMMARY PRODUCT CHARACTERISTICS

1. Name of drug product:

DT-ZINC TABLETS (Zinc Sulphate Dispersible Tablets 10 mg)

2. Qualitative and Quantitative Composition:

Each dispersible tablets contains: Zinc Sulphate Monohydrate BP EQ. To Elemental Zinc 10 mg

3. Pharmaceutical form:

Yellow coloured, round, Dispersible tablets having breakline on one side and other side is plain of each tablet.

4. Clinical particulars:

4.1 Therapeutic Indications:

DT-ZINC Tablet is indicated for the treatment of acute and persistent diarrhoea in infants and children from 2 months to 5 years of age in connection with Oral Rehydration Salts (ORS).

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 the treatment of acute and persistent *diarrhoea*
For children less than 6 months of age: 1 tablet once daily for 10-14 days.
For children between 6 months of age to 5 years of age: 2 tablet once daily for 10-14 days.
The 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:

It is contraindicated in patients with hypersensitivity to Zinc.

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 DT-ZINC Tablets, unless the risks of discontinuation of the drug are judged to outweigh the benefit of zinc in treatment of the child's diarrhoea.
Excipients
DT-ZINC Tablets contain aspartame, a source of phenylalanine. This should be considered when prescribing the product to patients with phenylketonuria.

4.5 Interactions 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 DT-ZINC Tablet in pregnancy has not been established.

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

4.7 Effects on ability to drive and use of machines

There is no evidence regarding the effect of zinc on the ability to drive or use machines, however DT-ZINC Tablet 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 DT-ZINC Tablets 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).

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 Pharmacodynemic 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 DT-ZINC 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 DT-ZINC 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 intracellular, and bound to metalloproteinase.

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. Pharmaceutical particulars:

6.1 List of Excipients:

Lactose	BP
Maize starch	BP
Aspartame	BP
Colour Tartrazine Supra	INH
Methyl Paraben Sodium	BP
Propyl Paraben Sodium	BP
Talcum	BP
Magnesium Stearate	BP
Colloidal silicon dioxide	BP
Polyplasdone XL-10 (Cross Povidone)	USP
Micro Crystalline Cellulose Powder DC Grade 102# 20-24# Mesh	BP
Essence Orange Powder	INH

6.2 Incompatibilities:
None Reported

6.3 Shelf-Life:
36 months from the date of manufacture.

6.4 Special Precautions for Storage:
Store in a cool, dry and dark place. Protect from light store below 25°C.

6.5 Nature and Contents of Container:

White PVC/PVDC with Printed Aluminum foil is used as primary packaging material for packing the DT-ZINC TABLETS. 10 tablets packed in one blister. Such 10 blister packed in 1 unit printed duplex board carton along with its package insert. Such cartons packed in export worthy shipper. Shippers are sealed with BOPP tape. Each shipper is labelled with shipping marks.

6.6 Special precautions for disposal:
None reported.

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7. Registrant:

AGOG PHARMA LTD.
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8. Manufacturer:

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9. Date of revision of the text :