

Zincogut Drops

1. Generic Names

Zinc Sulphate monohydrate

2. Qualitative and Quantitative Composition

Each ml contains

Zinc Sulphate monohydrate equivalent to elemental Zinc 20mg

3. Dosage form and strength

Oral drops containing zinc 20mg.

4. Clinical particulars

4.1 Therapeutic indication

Zincogut drops is indicated in patients with:

- Acute Infective Diarrhoea
- Persistent Diarrhoea

4.2 Posology and method of administration

Age Group	Orally, once daily during an acute diarrhoea episode. Take for 10-14 days even when diarrhoea has already stopped.
Under 6 months old	0.5 ml of Zincogut drops
6 months and older	1 ml of Zincogut drops

4.3 Contraindication

Zincogut drops is contraindicated in patients:

- Hypersensitive to components of the formulation.
- Infected with Human Immuno Deficiency Virus (HIV)



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4.4 Special warnings and precautions for use

- Infants and children: Zinc is likely safe when taken by mouth appropriately in the recommended amounts.
- Diabetes: Large doses of zinc can lower blood sugar in people with diabetes.

4.5 Drug interactions

- Antibiotics (Quinolone antibiotics) interacts with ZINC: Zinc might decrease how much antibiotic the body absorbs. Taking zinc along with some antibiotics might decrease the effectiveness of some antibiotics. To avoid this interaction take zinc supplements at least 1 hour after antibiotics.
- Antibiotics (Tetracycline antibiotics) interacts with ZINC: Zinc can attach to tetracycline in the stomach. This decreases the amount of tetracycline that can be absorbed. Taking zinc with tetracycline might decrease the effectiveness of tetracycline.
- Cisplatin (Platinol-AQ) interacts with ZINC
- Penicillamine interacts with ZINC.

4.6 Use in special population

- Pediatric: Safe in children.
- Geriatric: Problems in older adults have not been reported with intake of normal daily recommended amounts.
- Liver impairment: No data available.
- Renal failure: No data available.
- Pregnancy and lactation: Although there appears to be no harmful effects of zinc supplementation in pregnancy and lactation, consultation with doctor is recommended.

4.7 Effects on ability to drive and use machine

No data available.

4.8 Undesirable effects

- Metallic taste
- Abdominal pain
- Diarrhoea
- Vomiting
- Interferes with iron absorption causing Anaemia.
- Zinc can interfere with Copper absorption

4.9 Overdose

There is limited experience of overdose with Zincogut drops. Initiate general symptomatic and supportive measures in all cases of over dosages where necessary.

5. Pharmacological properties

5.1 Mechanism of action

Zinc helps in diarrhoea by causing:

- ✓ Improved absorption of water and electrolytes by the intestine and increased levels of enterocyte brush border enzymes.
- ✓ Zinc reduces stool volume and duration of diarrhoea.
- ✓ Action on intestinal mucosa: Zinc reduces fluid secretion in the intestine by indirectly inhibiting cAMP dependent Cl transport across the mucosa through an action on the basolateral membrane K⁺.
- ✓ In terms of Immune Response: Zinc strengthens the immune response and helps in regeneration of intestinal epithelium.

5.2 Pharmacodynamics properties

- Zinc is an important mineral found in almost every cell in the human body. It promotes the activity of about 100 enzymes. Zinc deficiency is often associated with an increased risk of infection. When they are used to treat the common cold, zinc



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supplements may interfere with rhinovirus cleavage or adhesion and may play a role in protecting plasma membranes from microbial toxins and complement.

5.3 Pharmacokinetic properties

- Zinc is absorbed in the small intestine by a carrier-mediated mechanism. More recent studies have determined different absorption rates for various populations based on their type of diet and phytate to zinc molar ratio. Zinc-deprived humans absorb this element with increased efficiency, whereas humans on a high-zinc diet show a reduced efficiency of absorption. Approximately 60-70% of the zinc in circulation is bound to albumin. Any condition that alters serum albumin concentration may have a secondary effect on serum zinc levels. Considerable amounts of zinc are secreted through both biliary and intestinal secretions, however most is reabsorbed.

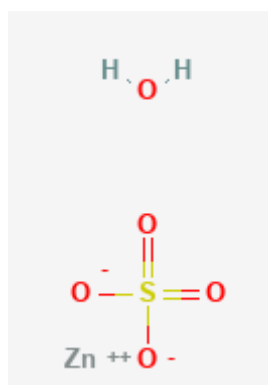
6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

NA.

7. Description

Zinc sulfate monohydrate is a nutritional supplement for the purpose of providing zinc. The molecular formula and weight is $\text{H}_2\text{O}_5\text{SZn}$ and 179.5 g/mol.



8. Pharmaceutical particulars

8.1 Incompatibilities

There are no known incompatibilities.

8.2 Shelf-life

24 months

8.3 Packaging Information

Zincogut drops is presented as 20ml Bottle.

8.4 Storage and handling instructions

Store at 25°C in cool and dry place.

9. Patient Counselling Information

9.1 Adverse Reactions

Refer part 4.8

9.2 Drug Interactions

Refer part 4.5

9.3 Dosage

Refer part 4.2

9.4 Storage

Refer part 8.4

9.5 Risk Factors

Refer part 4.4

9.6 Self-monitoring information

NA



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9.7 Information on when to contact a health care provider or seek emergency help

Patient is advised to be alert for the emergence or worsening of the adverse reactions and contact the prescribing physician.

9.8 Contraindications

Refer part 4.3

10. Manufactured by SWISS GARNIER LIFE SCIENCES

11. Details of permission or license number with date

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