

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Zinc gluconate 20 mg/5 ml oral solution.

Jink

2. Qualitative and quantitative composition

Each 5 ml of syrup contains 20 mg zinc gluconate.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Solution

A light pink coloured clear solution.

4. Clinical particulars

4.1 Therapeutic indications

Zinc gluconate solution is indicated for the treatment of acute and persistent diarrhoea in infants and children up to 5 years of age.

4.2 Posology and method of administration

Posology

For acute and persistent diarrhoea:

For children less than 6 months of age: 2.5 ml (10 mg) once daily for 10-14 days.

For children 6 months of age to 5 years of age: 5 ml (20 mg) once daily for 10-14 days.

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

Hypersensitivity to any of the components of the formulation.

4.4 Special warnings and precautions for use

Warnings

Consumption of fiber containing food inhibits absorption of zinc. Take the solution an hour before, or two hours after, food high in fibre.

Renal impairment: Accumulation of zinc may occur in cases of renal failure

4.5 Interaction with other medicinal products and other forms of interaction

Penicillamine: Zinc might decrease the effectiveness of penicillamine.

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 Fertility, pregnancy, and lactation

Pregnancy and lactation: The safety of Zinc gluconate 20 mg oral solution in pregnancy has not been established. Zinc crosses the placenta and is present in breast milk. The safety of Zinc gluconate 20 mg oral solution in lactation has not been established.

4.7 Effects on ability to drive and use machines

Not known.

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.

Symptoms: High doses of zinc cause emesis. 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

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the e-PV desktop applications

(https://drive.google.com/file/d/16hwTz0587ZWtSWadbBAMwQPOD_KSExZP/view) or search for e-PV Mobile applications on the Google Play or Apple App Store.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacological Classification: 16.6 Antidiarrhoeals.

5.2 Pharmacokinetic properties

Absorption

No available data.

Distribution

No available data.

Metabolism

No available data.

Elimination

Zinc is excreted in the faeces with only traces appearing in the urine since the kidneys have only little or no role in regulating the zinc content of the body.

5.3 Preclinical safety data

Not applicable.

6. Pharmaceutical particulars

6.1 List of excipients

Liquid Sorbitol (Non-Crystallising) BP
Sodium Methyl Hydroxybenzoate BP
Sodium Propyl Hydroxybenzoate BP
Sucralose BP
Anhydrous Citric Acid BP
Colour Ponceau 4R (Supra) IHS
Ess. Rose white IHS
Ess. Honey supreme (Firmenich) IHS
Sodium Citrate BP
Purified water BP

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store below 30°C. Protect from Light. Do not freeze.

6.5 Nature and contents of container

A light pink coloured clear solution filled in 60 ml amber pet bottle with LPL printed 25 mm aluminium PP cap & 10 ml measuring cup, such 1 bottle is packed in a printed carton with packaging insert.

6.6 Special precautions for disposal and other handling

Not applicable.

7. Applicant

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8. Manufacturer

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9. Registration details

Zimbabwe registration number: 2023/16.6/6365.

Zimbabwe category for distribution: Pharmacy Medicines (P.).

10. Date of revision of the text

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