ZINC CHLORIDE
(zinc chloride) 10.6 mg in 2 mL Concentrated Injection for Infusion

1 NAME OF THE MEDICINE

Zinc chloride

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 mL of Zinc Chloride Concentrated Injection for Infusion contains:

- 10.6 mg zinc chloride.
- Equivalent to 5.1 mg of Zinc and 5.5 mg of Chloride.
- Equivalent to 0.078 mmoles of Zinc and 0.156 mmoles of Chloride.
- Equivalent to 0.156 mEq of Zinc and 0.156 mEq of Chloride.

For the full list of excipients, see Section 6.1 List of Excipients.

3 PHARMACEUTICAL FORM

Zinc Chloride Concentrated Injection for Infusion is a clear, colourless to faint straw coloured, sterile solution for injection.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Zinc Chloride Concentrated Injection for Infusion is intended for use as an additive to compatible intravenous fluids or total parenteral nutrition solutions. It is indicated for the prevention and treatment of zinc deficiency, which may be characterised by growth deterioration, skin lesions, alopecia, impaired reproductive development and function, and delayed or inhibited wound healing.

4.2 DOSE AND METHOD OF ADMINISTRATION

Adults: The suggested IV dosage is 2.5 to 4 mg zinc per day. An additional 2 mg zinc per day is suggested for acute catabolic states. If there is fluid loss from the small intestines, an additional 12.2 mg of zinc per litre of small intestinal fluid lost, or an additional 17.1 mg of zinc per kg of stool or ileostomy output is suggested. Blood levels of zinc should be frequently monitored to ensure proper dosage.

Zinc Chloride Concentrated Injection for Infusion should be given via intravenous infusion by diluting each 2 mL vial in 1 litre infusion solution (glucose 5% injection or sodium chloride 0.9% injection) and administering over 8 to 24 hours.

Children: For premature infants (up to 3 kg in body weight) 300 microgram of zinc/kg/day is suggested. For full-term infants and children up to 5 years of age, 100 microgram of zinc/kg/day is recommended. For children over 5 years of age, the dose is the same as that recommended for adults; up to a maximum of 4 mg/day.

Note: Zinc Chloride Concentrated Injection for Infusion should be filtered through asbestos or sintered glass, since they dissolve paper and cotton wool. Zinc Chloride Concentrated Injection for Infusion should be diluted before use. It contains no preservatives, therefore any unused portions should be discarded.

Compatibilities

Zinc Chloride Concentrated Injection for Infusion is reported to be compatible with glucose 5% injection or sodium chloride 0.9% injection.

4.3 CONTRAINDICATIONS

Direct intramuscular (IM) or intravenous (IV) injection is contraindicated as the acidic pH of the injection may cause considerable tissue irritation. It is contraindicated in individuals hypersensitive to any of the ingredients in the preparation.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

The injection should NOT be given undiluted by direct injection into a peripheral vein because of the likelihood of infusion phlebitis and the potential for increased excretory loss of zinc from a bolus injection. Administration of zinc in the absence of copper may cause a decrease in serum copper levels. Periodic determinations of serum copper as well as zinc are suggested as a guideline for subsequent zinc administration.

Avoid contact of Zinc Chloride Concentrated Injection for Infusion with the eyes and skin. Wash with copious amount of water if contamination of the skin and eyes occurs. Zinc chloride is a caustic agent and, therefore, should not be given orally.

Copper uptake, liver biopsy and clinical observations are all useful procedures to check the dose and compliance.

Warnings

Do not use unless solution is clear and seal is intact. Single use injection - **do not** multidose. Discard after use and discard any unused portion. Do not store or re-sterilise.

Use in renal impairment

There is a possible risk of zinc accumulation in patients with renal failure.

Use in the elderly

No data available.

Paediatric use

See Section 4.2 Dose and Method of Administration.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

No data available.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available.

Use in pregnancy

Animal reproduction studies have not been conducted with zinc chloride. It is not known whether zinc can cause fetal harm when administered to a pregnant woman, or whether it can affect reproductive capacity. Therefore, Zinc Chloride Concentrated Injection for Infusion should be administered to pregnant women only if clearly indicated.

Use in lactation

Zinc is excreted in breast milk. The baby may be at risk of zinc-induced copper deficiency. However, the amount of zinc in the milk may not be sufficient to induce copper deficiency in infants. Therefore, the potential hazards of zinc to the infant must be weighed against the potential benefits to the mother before zinc is administered to mothers who are breast feeding.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Direct IM or IV injection may cause considerable tissue irritation and is therefore not recommended. Chronic zinc toxicity in humans has not been identified with certainty. Prolonged use of zinc may lead to copper deficiency and anaemia which has responded to withdrawal of zinc and symptomatic therapy.

Increased serum levels of amylase, lipase and alkaline phosphatase which may indicate pancreatic damage, are commonly reported during zinc therapy. However, insufficient evidence was found for pancreatic damage on either humans or rat studies.

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration 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 at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

Symptoms of zinc poisoning include hypotension, pulmonary oedema, diarrhoea, vomiting, jaundice and oliguria.

Treatment of overdosage: Symptomatic and supportive measures should be given as required in the event of overdosage.

Administration of sodium calcium edetate by mouth and intravenously has been suggested. To relieve pain, analgesics may be given. The electrolyte imbalance should be corrected.

For information on the management of overdose, contact the Poisons Information Centre on 131126 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Zinc is an essential trace element in nutrition. It is a constituent of many enzymatic systems, including alkaline phosphatase, carbonic anhydrase, carboxypeptidase and alcohol dehydrogenase. It is also present with insulin in the pancreas. Zinc is involved in DNA and protein synthesis and facilitates wound healing, helping to maintain normal growth rates. It is essential for immune function and development of the reproductive organs and normal functioning of the prostate gland. It is also involved in certain enzymatic reactions necessary for the normal functioning of the skin's oil glands. Zinc is required for the mobilisation of vitamin A from the liver into plasma. It also helps to maintain the senses of taste and smell.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

Absorption

No data available.

Distribution

Zinc is distributed widely throughout the body. Approximately 70% of zinc is loosely bound to albumin and other proteins. The normal concentration of zinc in plasma and serum ranges from 0.7 to 1.5 mg/L.

Metabolism

No data available.

Excretion

Zinc is excreted in the faeces. Only traces appear in the urine since the kidneys play only a minor role in regulating the content of zinc within the body.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Zinc Chloride Concentrated Injection for Infusion contains water for injections. The solution also contains hydrochloric acid for pH adjustment. It contains no preservatives.

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG)[1]. The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C.

6.5 NATURE AND CONTENTS OF CONTAINER

Zinc Chloride Concentrated Injection for Infusion is presented as:

2 mL in a 2 mL glass vial, as a pack of 10 vials.

Phebra product code – INJ062

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

6.7 PHYSICOCHEMICAL PROPERTIES

Chemical structure

The chemical formula for zinc chloride is: $ZnCl_2$.

The molecular weight of the compound is 136.3.

[1] AUST R 22876

CAS number

7646-85-7

7 MEDICINE SCHEDULE (POISONS STANDARD)

Not scheduled.

8 SPONSOR

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9 DATE OF FIRST APPROVAL

14 Oct 1991

10 DATE OF REVISION

23 Dec 2019

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
All	PI reformatted to align with new form Minor editorial changes to improve readability
All	Changed the name of dosage form

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