FOR THE USE OF REGISTERED MEDICAL PRACTITIONER, OR A HOSPITAL OR A LABORATORY

Zinc chloride Injection IP

AMERICAN
ZINRIDE
Injection

Composition :
Each ml contains :
Zinc chloride IP 2.09 mg
(eq. to 1 mg elemental zinc)
Sodium Chloride IP 9 mg
Water for Injections IP q.s.

Pharmaceutical Form
Sterile solution for injection.

Clinical Particulars
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 characterized by growth deterioration, skin lesions, alopecia, impaired reproductive development and function, and delayed or inhibited wound healing.

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.

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

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.

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-dose vial. Discard any unused portion. Discard after use and discard any unused portion. Do not store or re-sterilize.

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

Use in the elderly
No data available.

Interactions with other medicines and other forms of interactions
No data available.

Fertility, pregnancy and lactation
Effects on fertility
No data available.
Use in pregnancy
Animal reproduction studies have not been conducted with zinc chloride. There are no adequate and well-controlled studies in pregnant women 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.

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.

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 anemia 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.

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.

PHARMACOLOGICAL PROPERTIES
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 mobilization of vitamin A from the liver into plasma. It also helps to maintain the senses of taste and smell.

Pharmacokinetic properties
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.

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.

PHARMACEUTICAL PARTICULARS
Incompatibilities
NA

Shelf life
As printed on carton.

Special precautions for storage
Storage: Store in a cool, dry place. Protect from light. Do not allow to freeze.

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