

DBL™ ZINC CHLORIDE INJECTION

Name of medicine

Zinc chloride

CAS Registry number 7646-85-7

Presentation

DBL™ Zinc Chloride Injection is equivalent to Zinc 5.1 mg in 2 mL, and is a clear, colourless solution containing 10.6 mg of zinc chloride and water for injection in each 2 mL ampoule. (The zinc component of each ampoule is 0.078 mmol (5.1 mg) and the chloride component of each ampoule is 0.156 mmol (5.5 mg). The pH of the solution ranges between 4.0 and 5.5.

Uses

Actions

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.

Pharmacokinetics

Zinc is distributed widely throughout the body and 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. 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.

Indications

DBL™ Zinc Chloride Injection 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.

Dosage and administration

Adults

The suggested IV dosage is 2.5 to 4 mg zinc per day. An additional 2 mg zinc/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.

DBL™ Zinc Chloride Injection should be given via intravenous infusion by diluting each 2 mL ampoule 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 3kg 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: DBL™ Zinc Chloride Injection should be filtered through asbestos or sintered glass, since they dissolve paper and cotton wool. DBL™ Zinc Chloride Injection should be diluted before use. It contains no preservative; therefore any unused portions should be discarded.

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.

Warnings and precautions

Do not use unless solution is clear and seal is intact.

Zinc should be used in conjunction with a pharmacy directed admixture program using aseptic technique in a laminar flow environment. The injection contains no preservatives; therefore any unused portion should be discarded.

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.

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

Avoid contact of DBL™ Zinc Chloride Injection 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.

Pregnancy and Lactation

Use in pregnancy

Animal reproduction studies have not been conducted with zinc chloride. It is not known whether zinc can cause foetal harm when administered to a pregnant woman, or whether it can affect reproductive capacity. Therefore, DBL™ Zinc Chloride Injection 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.

Adverse effects

Direct IM or IV injection may cause considerable tissue irritation and is therefore not recommended.

Chronic zinc toxicity in man 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.

Overdosage

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

In case of overdose, immediately contact the Poisons Information Centre for advice on management. (In New Zealand call 0800 764 766.)

Pharmaceutical precautions

Special Precautions for Storage

Store below 25°C.

Medicine classification

General Sale Medicine

Package quantities

Strength

10.6 mg Zinc Chloride equivalent to 5.1 mg Zinc in 2 mL

Pack

5 x 2 mL Ampoules

Further information

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

Name and address

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Date of preparation

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