NEW ZEALAND DATA SHEET

1. PRODUCT NAME

DBL™ Zinc Chloride Injection 10.6 mg/ 2 mL Solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

DBL™ Zinc Chloride Injection contains 10.6 mg Zinc Chloride equivalent to 5.1 mg Zinc in 2 mL. (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).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection

DBL™ Zinc Chloride Injection is a clear, colourless solution.

The pH of the solution ranges between 4.0 and 5.5.

4. CLINICAL PARTICULARS

4.1 Therapeutic 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.

4.2 Dose and method of administration

Dose

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.

Dose Adjustments

Paediatric population

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.

Method of Administration

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.

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.

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

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.

4.5 Interaction with other medicines and other forms of interaction

No Data available.

4.6 Fertility, pregnancy and lactation

Fertility

No data available

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.

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 machinery

No data available

4.8 Undesirable 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.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/.

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 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.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic properties

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.

5.3 Preclinical safety data

Genotoxicity

No data available

Carcinogenicity

No data available

Reproductive and developmental toxicity

No data available

6. PHARMACEUTICAL PARTICUALRS

6.1 List of excipients

Water for injections

6.2 Incompatibilities

No data available

6.3 Shelf life

60 months from date of manufacture stored at or below 25°C

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Strength	Pack
10.6 mg Zinc Chloride equivalent to 5.1 mg Zinc in 2 mL	5 x 2 mL Ampoules

6.6 Special precautions for disposal and other handling

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

Any unused medicine or waste material should be disposed of in accordance with local requirements.

7. MEDICINE SCHEDULE

General Sale Medicine

8. SPONSOR

Pfizer New Zealand Limited
P O Box 3998
Auckland, New Zealand

Toll Free Number: 0800 736 363

9. DATE OF FIRST APPROVAL

13 December 1984

10. DATE OF REVISION OF THE TEXT

14 February 2019

Summary table of changes

Section changed	Summary of new information
All	Reformat to MedSafe Data Sheet guidance