

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Zinc 1mg/ml concentrate for solution for infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of solution contains 6.97 mg of zinc gluconate, equivalent to 1 mg of zinc (i.e 15.29 micromoles).
Each vial of 10 ml contains 69.7 mg of zinc gluconate equivalent to 10 mg of zinc (i.e 152.9 micromoles).

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Concentrate for solution for infusion. Clear colourless solution.

Osmolarity: between 25 and 45 mosmol/l.

Osmolality: between 25 and 45 mosmol/kg.

Density: 1.006 g/cm³ (at 25°C)

pH: between 5.0 and 7.0

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Supplementation solution in prolonged parenteral nutrition and in situations where a pronounced deficiency may occur: e.g. severe malnutrition, hypercatabolism, digestive fistula, chronic diarrhoea.

4.2 Posology and method of administration

Posology

The dosage must be adapted to each patient, taking into account losses and zinc status.

The solution is a supplementation additive for parenteral nutrition intended to be used in mixtures for parenteral nutrition or diluted in isotonic solutions.

Recommended basal requirements by intravenous route are the following. Higher doses may be needed to compensate abnormally high losses.

Adults:

- 2.5 to 5 mg/day

Paediatric population:

- premature: 0.45 to 0.50 mg/kg/day,
- infants younger than 3 months: 0.25 mg/kg/day,
- infants older than 3 months: 0.1 mg/kg/day,
- children: 0.05 mg/kg/day to a maximum of 5 mg/day.

Method of administration

Recommended administration: intravenous route after dilution with a slow infusion rate.

For instructions on dilution of the medicinal product before administration, see section 6.6.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Warning

This product must not be given undiluted.

Precaution for use:

In complex parenteral nutrition protocols, special precaution is required to avoid incompatibilities among the added medications.

4.5 Interaction with other medicinal products and other forms of interaction

Large doses of oral zinc inhibit copper absorption. Clinical significance of this interaction for intravenous zinc remains unclear.

4.6 Fertility, pregnancy and lactation

Pregnancy

Animal studies conducted with different zinc salts do not indicate direct or indirect harmful effects with respect to pregnancy, embryonic/fetal development, parturition or postnatal development with standard doses (see section 5.3). According to available data, use in women who are pregnant is possible.

Breast-feeding

According to available data, use in women who are breastfeeding is possible.

Fertility

No fertility data are available.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Summary of the safety profile

Undesirable effects are mainly observed at high doses (see section 4.9).

Tabulated list of adverse reactions

General disorders and administration site conditions:

Infusion site inflammation (frequency not known).

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Hyperamylasaemia without evidence of acute pancreatitis, nausea, vomiting, fever, anaemia, hypotension, pulmonary oedema, diarrhoea, jaundice, oliguria, cardiac arrhythmias and thrombocytopenia have been reported in patients with overdose. Other manifestations of toxicity may include profuse sweating, blurred vision, decreased consciousness and hypothermia.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: MINERAL SUPPLEMENTS; ATC code: A12CB02

Zinc has three main biological roles: catalytic, structural and regulatory.

Zinc is a component of many metalloenzymes including carbonic anhydrase, alkaline phosphatase, carboxypeptidase, oxidoreductases, transferases, ligases, hydrolases, isomerases and alcohol dehydrogenase.

Zinc is also involved in the structure and stabilisation of some enzymes, such as the antioxidant superoxide dismutase.

It also plays a role in the synthesis of RNA and DNA and in regulating the catabolism of RNA. Apoptosis is potentiated by zinc deficiency.

Zinc affects multiple aspects of the immune system.

Zinc is involved in some hormonal metabolisms (such as insulin, gustin, thymulin), and in the metabolism of carbohydrates, lipids and proteins.

It has an important place in the growth of premature babies, infants and children with increased requirements.

Zinc has an effect on tissue integrity and can improve the sense of taste in depleted patients.

Considering all its potential biochemical activities, zinc is necessary for growth and cellular multiplication, in bone metabolism, immunity, reproduction. It contributes in protection against free radicals, inflammation and intervenes in cerebral functions. All these physiological actions can be modified by zinc deficiency.

5.2 Pharmacokinetic properties

Zinc is widely distributed in the body and is bound to albumin and metallothioneins. Zinc is mainly eliminated via the faecal route, resulting in increased elimination in chronic diarrhoea. Faecal excretion includes both unabsorbed dietary zinc and endogenous faecal zinc excretion.

Amino acids like histidine, threonine and lysine can bind zinc and promote its elimination via the kidneys.

5.3 Preclinical safety data

No specific information on I.V toxicity of zinc gluconate is available; however the toxicity of orally administered zinc has been well studied using different salts.

Long-term feeding to rodents of very large amounts of zinc salts resulted in growth retardation, anaemia and metabolic effect.

The weight of evidence, from in vitro and in vivo tests, suggests that zinc is apparently neither a mutagen nor a carcinogen.

Reproduction toxicology studies showed no clinically relevant evidence of embryotoxicity, fetotoxicity or teratogenicity with standard doses.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections.

6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.

6.3 Shelf life

30 months.

After dilution, chemical and physical in-use stability has been demonstrated for 24 hours at room temperature. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

6.4 Special precautions for storage

Do not freeze.

For storage conditions after dilution of the medicinal product, see section 6.3

6.5 Nature and contents of container

10 ml solution in glass vial with an elastomer (bromobutyl) stopper fitted with an aluminium cover and crimped. Box of 10 vials.

6.6 Special precautions for disposal and other handling

The recommended administration is by intravenous route after dilution with a slow infusion rate.

The solution can be diluted in parenteral nutrition mixes or in an isotonic solution (such as sodium chloride 0.9% or glucose 5%).

When removing a volume using a syringe, do not use a needle with a diameter greater than 0.8 mm.

For single use only. Do not store partly used containers and discard all equipment after use

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

7 MARKETING AUTHORISATION HOLDER

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1 Rue Alexander Fleming
69007 LYON
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8 MARKETING AUTHORISATION NUMBER

PA1968/008/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 9th October 2015

10 DATE OF REVISION OF THE TEXT

December 2015