Summary of Product Characteristics

Summary of Product Characteristics

1.0 Name of the medicinal product

Zinc Sulfate tablets USP 20 mg

2.0 Qualitative and Quantitative Composition

Each uncoated tablet contains:

Zinc Sulfate USP (As Monohydrate)…… 54.89 mg

Eq. to Elemental Zinc …….20 mg

3.0 Pharmaceutical Form

Tablet

White to off white, round, flat, uncoated tablets with beveled edges having score line on one side.

4.0 Clinical particulars

4.1 Therapeutic Indications

Zinc sulfate is a source of zinc which is an essential trace element and involved in a number of Body enzyme systems. Zinc sulfate is indicated in adults and children for the treatment of zinc deficiency.

4.2 Posology and method of Administration

Method of Administration: oral after dissolution in water.

Adults: One tablet, dissolved in water, once to three times daily after meals.

Children: More than 30kg: One tablet, dissolved in water, once to three times daily after meals.

10-30kg: ½ tablet, dissolved in water, once to three times daily after meals.

Less than 10kg: ½ tablet, dissolved in water, once daily after meals.

4.3 Contraindications

Hypersensitivity to the active substance or any of the excipients. Copper deficiency

4.4 Special warnings and precautions for use

Accumulation of zinc may occur in cases of renal failure.

This product contains sorbitol (E420), therefore patients with rare hereditary problems of fructose intolerance should not take this medicine.

This product contains sodium. This should be taken into consideration by patients on a controlled sodium diet.

4.5 Interaction with other medicinal products and other forms of interact.

Copper:

Zinc may inhibit the absorption of copper

Tetracycline Antibacterials:

Zinc may reduce the absorption of concurrently administered tetracyclines, also the absorption of zinc may be reduced by tetracyclines; when both are being given an interval of at least three hours should be allowed.

Quinolone Antibacterials:

Zinc may reduce the absorption of quinolones; ciprofloxacin, levofloxacin, moxifloxacin, norfloxacin and ofloxacin.

Calcium Salts:

The absorption of zinc may be reduced by calcium salts.

Iron:

The absorption of zinc may be reduced by oral iron, also the absorption of oral iron may be reduced by zinc.

Penicillamine:

The absorption of zinc may be reduced by penicillamine, also the absorption of penicillamine may be reduced by zinc.

Trientine:

The absorption of zinc may be reduced by trientine, also the absorption of trientine may be reduced by zinc.

4.6 Pregnancy and Lactation

The safety of this product in human pregnancy has not been established. Zinc crosses the placenta and is present in breast milk.

4.7 Effects on ability to drive and use machines

Zinc sulfate has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Zinc salts may cause abdominal pain, dyspepsia, nausea, vomiting, diarrhoea, gastric irritation and gastritis. There have also been cases of irritability, headache and lethargy observed.

Zinc may interfere with the absorption of copper, leading to reduced copper levels, and potentially copper deficiency. The risk of copper deficiency may be greater with long-term treatment (e.g. if zinc deficiency is no longer present) and/or with higher doses of zinc.

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 EFDA yellow Card Scheme, online at https://primaryreporting.who-umc.org/ET or toll free call 8482 to Ethiopian food and drug authority (EFDA).

4.9 Overdose

Zinc sulfate is corrosive in overdosage. Symptoms are corrosion and inflammation of the mucous membrane of the mouth and stomach; ulceration of the stomach followed by

perforation may occur. Gastric lavage and emesis should be avoided. Demulcents such as milk should be given. Chelating agents such as sodium calcium edetate may be useful.

5.0 Pharmacological Properties

5.1 Pharmacodynamic Properties

Pharmacotherapeutic Group: Mineral Supplement, ATC Code: A12CB01

Zinc is an essential trace element involved in many enzyme systems. Severe deficiency causes skin lesion, alopecia, diarrhoea, increased susceptibility to infections and failure to thrive in children. Symptoms of less severe deficiency include distorted or absent perceptions of taste and smell and poor wound healing.

5.2 Pharmacokinetic Properties

Zinc is absorbed from the gastrointestinal tract and distributed throughout the body. The highest concentrations occur in hair, eyes, male reproductive organs and bone. Lower levels are present in liver, kidney and muscle. In blood 80% is found in erythrocytes. Plasma zinc levels range from 70 to 110µg/dL and about 50% of this is loosely bound to albumin. About 7% is amino-acid bound and the rest is tightly bound to alpha 2-macroglobulins and other proteins.

5.3 Preclinical Safety Data

None stated.

6.0 Pharmaceutical Particulars

6.1 List of Excipients

Maize Starch, Microcrystalline Cellulose, Calcium Hydrogen Phosphate, Purified Talc, Calcium Hydrogen Phosphate, Purified Talc, Magnesium Stearate, Sodium Starch Glycolate (Type A), Cross Povidone XL 10, Vanilla Flavour (Dry), Aspartame, Colloidal Anhydrous Silica, Microcrystalline Cellulose (pH102)

6.2 Incompatibilities

Not known

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store at temperature not exceeding 30^0C in a dry place. Protect from light**.** Keep out of reach of children.

6.5 Nature and contents of container

Zinc Sulfate Tablets USP 20mg is packed in Blister pack of 10x10 tablets packed in carton along with pack insert.

6.6 Special precautions for disposal

No special requirements

7.0 Marketing Authorization holder

Medicamen Biotech Limited
SP-1192 A & B, Phase-IV,
Industrial Area, Bhiwadi-301019,
Distt Alwar, Rajasthan
INDIA
Tel: +91-1493-221291, 221292
Fax: +91-1493-22194

8.0 Marketing Authorization Number

Registration No; 07967/09047/NMR/2021

9.0 Date of first registration/renewable of registration

Approval date; 21-10-2022

10.0 Date of revision of the text

July 2024