SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Zinc Sulfate 220 mg Capsules.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 220 mg Zinc Sulfate BP.

Excipients with known effect:

Lactose,

Brilliant black BN (E151)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Hard capsule.

4.1 Therapeutic indications

For the treatment of zinc deficiency which can occur in individuals on an inadequate diet, in malabsorption with increased tissue loss due to trauma, burns, and protein-losing conditions and during intravenous feeding.
Zinc sulfate is a source of zinc which is an essential trace element and involved in a number of body enzyme systems.
Zinc Sulfate Capsules is indicated in adults, elderly and children over 12 years.

4.2 Posology and method of administration

Posology

One capsule to be taken three times a day an hour before food or two hours after meals.

Paediatric population

The safety and efficacy of Zinc Sulfate Capsules in children under the age of 12 years have not yet been established. Currently available data are described in section 5.1 and 5.2 but no recommendation on a posology can be made.

Method of administration

Oral use.

4.3 Contraindications

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

Copper deficiency (see section 4.5).

4.4 Special warnings and precautions for use

Therapy should continue until clinical improvement occurs and be replaced by dietary measures unless there is severe malabsorption, metabolic disease or continuing zinc loss. Continued long-term treatment with Zinc sulfate capsule if zinc deficiency is no longer present may lead to copper deficiency (see section 4.8).
Zinc capsules should be taken two hours before eating fibre containing foods and should not be taken within two hours of iron, copper or phosphorous supplements.
Zinc levels may accumulate in acute renal failure.
Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Copper:

Large doses of zinc inhibit the absorption of copper in the intestine (see section 4.3).

Tetracycline antibacterials:

Zinc decreases the absorption of tetracyclines by the formation of an insoluble chelate. 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.

Penicillamine:

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

Calcium salts:

The absorption of zinc may be reduced by calcium salts.

Food:

The absorption of zinc is reduced when it is taken concurrently with phytates (found in bran, whole grain breads), fibre containing foods or phosphorus containing medicinal products and foods (milk or poultry).

Iron:

The absorption of zinc may be reduced by oral iron, also the absorption of oral iron 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 Fertility, pregnancy and lactation

Problems in humans have not been documented with intake of normal daily requirements.

The safety of this product in human pregnancy has not been established. Zinc crosses the placenta and is present in breast milk. Therefore, like other drug preparations caution should be exercised in administering this product during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

Zinc Sulfate Capsules has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Gastro-intestinal disturbances such as abdominal pain, dyspepsia, epigastric pain, gastric irritation, gastritis, nausea, vomiting, diarrhoea, leukopenia (fever, chills or sore throat) and neutropenia (continuing ulcers and sores in mouths), headache, lethargy, irritation.

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; see Section 4.4) and/or with higher doses of zinc.

Signs of copper deficiency can include neurological symptoms e.g. polyneuropathy (symptoms of which can include gait disturbances, ataxia and paraesthesia and/or hypoaesthesia) and haematological symptoms e.g. anaemia, neutropenia, leucopenia and pancytopenia.

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 the Yellow Card Scheme at website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms:

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.

Prolonged use of large doses may interfere with the absorption of iron and copper, leading to deficiency in these minerals, causing nausea, vomiting, headache, fever, malaise and abdominal pain.

Management:

Excess intake may be treated with withdrawal of zinc and symptomatic therapy. The level of zinc can be diluted by drinking plenty of demulcents such as milk and water or administration of intramuscular or intravenous chelating agents such as edetate calcium disodium at a dose of 50 to 75 mg per kg (mg/kg) of bodyweight per day, in 3 to 6 divided doses, for up to 5 days.

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Alimentary Tract and Metabolism, Mineral Supplements, ATC code: A12CB01

Zinc is an essential trace element involved in the activities of over 100 enzymes including carbonic anhydrase, alcoholic dehydrogenase, alkaline phosphatise and RNA polymerase. It is also required to maintain structure in nucleic acids, protein and cell membranes and is involved in the function of the hormone insulin in the utilisation of carbohydrates. It is necessary for normal rate of growth, development of the reproductive organs, normal function of the prostate gland and the healing of wounds and burns.

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

Absorption

Zinc is absorbed from the gastrointestinal tract and distributed throughout the body. Approximately 20 to 30% of dietary zinc is absorbed primarily from the duodenum and ileum. The amount absorbed depends on the bioavailability of the food. Zinc is the most bioavailable from red meat and oysters.

Distribution

After absorption zinc is bound in the intestine to the protein metallothionein. 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 110 µg/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.

Elimination

Zinc is primarily eliminated (approximately 40%) in the faeces and to lesser extent in the urine and perspiration.

5.3 Preclinical safety data

None Stated

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose BP

Maize starch pre-gelatinised BP

Talc BP

Colloidal silicon dioxide BP

Capsule shell component

Cap

Patent blue V (E131)

Brilliant black BN (E151)

Gelatin USP

Body

Titanium dioxide (E171)

Gelatin USP

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years- Opaque containers.

2 years - Blister packs.

6.4 Special precautions for storage

Store below 25 ºC.

Keep the container or the blister in the outer carton in order to protect from light and moisture.

6.5 Nature and contents of container

1. Opaque plastic containers composed of polypropylene tubes and polyethylene made tamper evident closures for packs sizes of 28, 30, 42, 50, 56, 60, 84, 90, 100, 112, 250, 500 and 1000.

2. Opaque plastic containers composed of either high density polypropylene or high density polyethylene with a tamper evident or child resistant tamper evident closure composed of high density polyethylene in all pack sizes (28, 30, 42, 50, 56, 60, 84, 90, 100, 112, 250, 500 and 1000), packing inclusion of standard polyether foam or polyethylene or polypropylene made filler.

3. Blister packs of aluminium/opaque PVC. It is subsequently packed in printed boxboard cartons in pack sizes of 28, 30, 56, 60, 84, 90 and 112.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements for disposal

7 MARKETING AUTHORISATION HOLDER

Crescent Pharma Ltd.,
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8 MARKETING AUTHORISATION NUMBER(S)

PL 20416/0231

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28 June 2004

10 DATE OF REVISION OF THE TEXT

16/12/2024