Zincol Enteric Coated Tablets

Summary of Product Characteristics

1. Name of the medicinal product

Zincol enteric coated tablets.

2. Qualitative and quantitative composition

Each tablet contains 50 mg of zinc (as sulphate) (equivalent to 137 mg of zinc monohydrate, equivalent to 220 mg of zinc heptahydrate).

Excipient with known effect: each tablet contains 170 mg of lactose. For the full list of the excipients, see section 6.1.

3. Pharmaceutical form

Enteric coated tablets.

4. Clinical particulars

4.1 Therapeutic indications

Zincol is indicated as zinc supplement.

Zinc sulphate is a source of zinc which is an essential trace element and involved in a number of body enzyme systems.

4.2 Posology and method of administration

Method of Administration: oral.
The usual dose is 1 tablet a day.
Patients should take the medicine1 hour before or 2 hours after the meal. Patients should wait at least 2 hours between taking the medicine and products containing bran, foods containing copper, iron and phosphorus such as dairy products, chicken and turkey.

4.3 Contraindications

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

Copper deficiency (see section 4.5).

4.4 Special warnings and precautions for use

Accumulation of zinc may occur in cases of renal failure.

This product contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Copper:

Zinc may inhibit the absorption of copper (see section 4.3).

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 Fertility, 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

Zincol 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.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form https://sideeffects.health.gov.il/

4.9 Overdose

Zinc sulphate 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. 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 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.

5.3 Preclinical safety data

None stated.

6. Pharmaceutical particulars

6.1 List of excipients

Zincol contains the following excipients:

Core: lactose, cellulose powdered, corn starch, povidone, sodium starch glycolate, magnesium stearate, colloidal silicon dioxide

Coating: Eudragit L, talc, castor oil, dibutyl phthalate, titanium dioxide, quinoline yellow AL lake, magnesium stearate

6.2 Incompatibilities

None.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

PVC/aluminium blisters of 10 tabs each, packed in carton. Each pack contains 30/90/1000 tablets.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

None.

7. Manufacturer and marketing authorisation holder

SAM-ON Ltd., 25 Haavoda st. Bat-Yam, Israel

8. Marketing authorisation number

010-61-24158-00

Revised/Approved in 01/2021