

1. Name of the medicinal product

Avro-Z 50mg Tablet

2. Qualitative and quantitative composition

Each tablet contains 50mg of elemental Zinc (as zinc sulphate)

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Tablet.

Each tablet is white and round with the marking on one side and plain on the reverse side.

4. Clinical particulars

4.1 Therapeutic indications

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

Avro-Z is indicated as a mineral supplement for immune system support and for prevention and treatment of zinc deficiency states.

4.2 Posology and method of administration

Method of administration

Oral.

Posology

Adult and Children 18 years and above: 1 Tablet daily with food.

Tablet should be swallowed whole.

Not recommended for children below 18 years old.

Do not exceed the recommended dose.

4.3 Contraindications

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

Copper deficiency. (See section 4.5)

Pregnancy and breast feeding.

4.4 Special warnings and precautions for use

Accumulation of zinc may occur in cases of renal failure.

If you are pregnant, nursing or taking other medications or have a known medical condition, consult a physician before using this product

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

Avro-Z has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Zinc salts may cause abdominal pain, dyspepsia, nausea, vomiting, diarrhea, 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 zinc deficiency is no longer present) and/or with higher doses of zinc.

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, diarrhea, 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. Pharmaceutical particulars

6.1 List of excipients

Dicalcium Phosphate
Microcrystalline Cellulose
Colloidal Silicon Dioxide
Povidone
Magnesium Stearate

6.2 Incompatibilities

None.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30°C.
Store in the original package to protect from moisture.

6.5 Nature and contents of container

Polypropylene containers with polyethylene caps and packed in cartons. Each tablet container contains 100 tablets.

6.6 Special precautions for disposal and other handling

None.

7. Applicant/Manufacturer

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