NEW ZEALAND DATA SHEET

1 PRODUCT NAME

ZINCAPS zinc 50 mg capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains zinc sulfate monohydrate equivalent to 50 mg of elemental zinc.

3 PHARMACEUTICAL FORM

Capsules.

The capsule cannot be divided into equal doses.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

ZINCAPS is indicated in adults as a zinc supplement.

4.2 Dose and method of administration

Dose

1 Capsule a day with food. ZINCAPS should always be taken immediately after a meal and not on an empty stomach.

Paediatric population

No data available.

Method of administration

For oral use only.

4.3 Contraindications

Hypersensitivity to the active substance.

Copper deficiency (see section 4.4)

4.4 Special warnings and precautions for use

Accumulation of zinc may occur in cases of renal failure.

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.

4.5 Interaction with other medicines and other forms of interaction

Copper: zinc may inhibit the absorption of copper (see sections 4.3 and 4.4)

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

Pregnancy

ZINCAPS should be used with extreme caution during pregnancy. Zinc crosses the placenta.

Breastfeeding

Use with extreme caution in breastfeeding women. Zinc is present in breast milk.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Zinc supplementation can cause a copper deficiency.

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. Mild discomfort or nausea reported rarely, resolved if capsules taken with food.

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/

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.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

No data available.

5.2 Pharmacokinetic properties

No data available.

5.3 Preclinical safety data

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

n/a

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months from date of manufacture.

6.4 Special precautions for storage

Store below 25^{o}C. Protect from light.

6.5 Nature and contents of container

Bottle of 100 capsules.

6.6 Special precautions for disposal

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

7 MEDICINE SCHEDULE

Prescription medicine.

8 SPONSOR

Arrotex Pharmaceuticals (NZ) Limited:

Address: C/o Quigg Partners

Level 7, The Bayleys Building

36 Brandon Street,

Wellington 6011, New Zealand

DISTRIBUTOR

Pharmacy Retailing (NZ) Ltd trading as Healthcare Logistics

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9 DATE OF FIRST APPROVAL

30 June 1977

10 DATE OF REVISION OF THE TEXT

09 February 2023

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
4.3	Added copper deficiency
4.4	Included precautions for copper deficiency and renal failure
4.5	Added interactions with copper, tetracycline antibacterials, quinolone antibacterials, calcium salts, iron, penicillamine and trientine
4.6	Expanded pregnancy and breastfeeding
4.8	Added adverse effects
4.9	Included information on overdosage