

apex	apex laboratories private limited Plant-I	Date : 14.02.2024
Title:	Ascazin Capsules (Leaflet) Malaysia	AWC : B3PMS324/00

REVISION HISTORY		
Sl. No.	From	To
1.	B3PMS105/00	B3PMS324/00
2.	Manufactured by: apex laboratories private limited B-23, SIDCO Pharmaceutical Complex, Alathur-603110, Tamil Nadu, INDIA.	Manufactured by: apex laboratories private limited B-23 (Plant 1), SIDCO Pharmaceutical Complex, Alathur-603110, Kancheepuram District, India.
3.	Imported by: Unimed Sdn Bhd No. 53, Jalan Tembaga SD 5/2B, Bandar Sri Damansara, 52200 Kuala Lumpur, Malaysia.	Product Registration Holder: Unimed Sdn Bhd 53, Jalan Tembaga SD 5/2B, Bandar Sri Damansara 52200, Kuala Lumpur, Malaysia.

Size: 160 x 190 mm

LEAFLET

For the use of Registered Medical Practitioner or a Hospital or a Laboratory only.

Ascazin

Capsules
(Zinc 50.96 mg)
ZINC SULFATE CAPSULES

DESCRIPTION:
Black / Orange coloured '0' size hard gelatin capsules containing white powder.

COMPOSITION:
Each hard gelatin capsule contains:
Zinc Sulfate Monohydrate USP 140 mg
Equivalent to Elemental Zinc 50.96 mg
Excipients.
Approved colours used for capsule shell.

PHARMACODYNAMICS:
Zinc is an essential trace element involved in many enzyme systems.
Mechanism of Action / Effect: Zinc is necessary for the proper functioning of over 200 metalloenzymes, including carbonic anhydrase, caroxypeptidase A, alcohol dehydrogenase, alkaline phosphatase, and RNA polymerase. It is also required to maintain structure in nucleic acids, proteins, and cell membranes. Physiological functions that are zinc dependent include cell growth and division, sexual maturation and reproduction, dark adaptation and night vision, wound-healing, host immunity, taste acuity, and possibly olfactory acuity.

PHARMACOKINETICS:
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.
Elimination: Primarily fecal (approximately 90%); to a lesser extent in the urine and in perspiration.

INDICATION:
Zinc sulfate is a source of zinc which is an essential trace element and involved in a number of body enzyme systems.
Indications: For the treatment of zinc deficiency.

RECOMMENDED DOSE:
Adults: One Capsule, once to three times daily after meals.
Children: More than 30kg: One Capsule, once to three times daily after meals.

MODE OF ADMINISTRATION:
For oral administration.

CONTRAINDICATION:
Zinc is contraindicated in those who are hypersensitive to any component of a zinc-containing product.

WARNING AND PRECAUTIONS:
Accumulation of zinc may occur in cases of renal failure.

INTERACTIONS WITH OTHER MEDICAMENTS:
The absorption of zinc may be reduced by iron supplements, penicillamine, phosphorus-containing preparations, and tetracyclines. Zinc supplements reduce the absorption of copper, fluoroquinolones, iron, penicillamine, and tetracyclines.

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.

SIDE EFFECTS:
The most common adverse reactions are gastrointestinal and include nausea, vomiting and gastrointestinal discomfort. Other adverse reactions include a metallic taste, headache and drowsiness. Chronic intake of high doses of zinc can lead to copper deficiency and hypochromic, microcytic anemia secondary to zinc-induced copper deficiency.

SYMPTOMS AND TREATMENT OF 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.

STORAGE CONDITION:
Store in a dry place below 30°C, and protect from light.

SHELF LIFE:
36 months from date of manufacture.

PRESENTATION:
Ascazin capsule is available 10 x 10 capsules in Blister pack in an attractive carton.

apex
Manufactured by:
apex laboratories private limited
B-23 (Plant 1), SIDCO Pharmaceutical Complex, Alathur - 603110,
Kancheepuram District, India.
Revised on Date: Jan. 2024

Product Registration Holder:
Unimed Sdn Bhd
53, Jalan Tembaga SD 5/2B, Bandar Sri Damansara 52200,
Kuala Lumpur, Malaysia.

B3PMS324/00

Dimension	4 Color/ Pantone	Type of board	Type of varnish	Embossing	Unvarnished Zone	GSM	Type of Fold
W:160 x L:190 mm	BLACK	MAPLITHO	—	—	—	60 Gsm	2 Fold 40 mm x 190 mm
Initiated by		Reviewed by					Approved by
Product Manager	Design	RA	R&D	Production	QC	QA	Head - QA
Name :							
Date :							