National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) TEMPLATE

1. NAME OF THE MEDICINAL PRODUCT

Maydon Zinc Sulfate Tablet
(Zinc Sulfate Tablets USP 20 Mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sr. No.	Ingredients	Specification	Category	Qty. per Tablets (unit) mg	Std. Qty. (in kg)
1	Zinc Sulfate	USP	API	54.90	5.490
2	MCC PH -112	BP	Binder	240.100	24.010
3	Co-povidone (povidone VA-65)	IH	Disintegrant	12.00	1.200
4	Cross povidone	IP	Disintegrant	11.00	1.1
5	Colloidal silicon dioxide	IH	Binder	4.000	0.400
6	Purified talc	BP	Lubricant	4.000	0.400
7	Magnesium stearate	BP	Lubricant	4.000	0.400
			Total wt. of Tablet	330.00	33.000

Label Claim: 54.9 mg
Zinc Sulfate USP (As Monohydrate).....54.9 mg
Equivalent to Elemental Zinc.....20 mg
Flavour: Vanilla

3. PHARMACEUTICAL FORM

Oral Tablets

Description: White Circular, dispersible uncoated tablet, plain on one side and having a break line on one side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Zinc Sulfate Tablet is indicated for the treatment of acute and persistent diarrhoea in infants and children up to 5 years of age. This product is intended for use in children. Nonetheless, safety information is provided with respect to adult health issues such as liver disease, pregnancy and lactation, to allow full access to all relevant information.

Maydon Zinc Sulfate tablets are indicated in adults and children for the treatment of zinc deficiency

4.2 Posology and method of administration

For acute and persistent diarrhoea

For children less than6 months of age: Half tablet once daily for 10-14 days.

For children 6 months of age to 5 years of age: 1 tablet once daily for 10-14 days.

The tablet (or half tablet) should be dispersed completely in 1 teaspoon (5 ml) of clean water or breast milk and the entire amount administered orally to the infant or child. It is recommended that doses be administered between meals and a repeat dose be given if vomiting occurs within 30 minutes. For

missed doses, the missing dose can be taken as soon as possible, unless there is less than 6 hours until the next dose or as directed by physician

4.3 Contraindications

Not applicable

4.4 Special warnings and precautions for use

Drugs which may inhibit zinc absorption, such as penicillamine, sodium valproate and ethambutol, should not be coadministred with Zinc Sulfate Tablets, unless the risks of discontinuation of the drug are judged to outweigh the benefit of zinc in treatment of the child's diarrhoea. Zinc Sulfate Tablets contain aspartame, a source of phenylalanine. This should be considered when prescribing the product to patients with phenylketonuria.

4.5 Interaction with other medicinal products and other forms of interaction

Antibiotics When taken together, zinc may reduce the absorption of tetracyclines (but not doxycycline), and quinolone antibiotics. In addition, zinc may also interfere with the absorption of cephalexin or ceftibuten. An interval of at least three hours should be allowed between administration of zinc and any of these medicines.

4.6 Pregnancy and lactation:

***Pregnancy*:** The safety of Zinc Sulfate Tablet in pregnancy has not been established.

Lactation: Zinc crosses the placenta and is present in breast milk. The safety of Zinc Sulfate Tablet in lactation has not been established.

4.7 Effects on ability to drive and use machines

No influence on the ability to drive and use machines.

4.8 Undesirable effects:

In clinical trials in children, administration of Zinc Sulfate Tablets was associated with vomiting or regurgitation. In one study vomiting attributed to the tablet was reported very commonly i.e. in 14% and regurgitation was reported commonly i.e. in 5.2% of the children, respectively. In most cases vomiting or regurgitation occurred shortly after administration of the first dose (within 10 minutes) and was not recurrent. Zinc salts may also cause abdominal pain and dyspepsia (frequency unknown).

4.9 Overdose

Symptoms: High doses of zinc cause emesis. In addition, zinc sulfate is corrosive at high doses, and may cause irritation and corrosion of the gastrointestinal tract, including ulceration of the stomach and possible perforation. Over dosage with zinc has also been associated with acute renal tubular necrosis and interstitial nephritis. Prolonged high dose zinc supplementation may result in copper deficiency.

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 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

Raw Materials	**Pharmacopoeia Reference**
MCC PH -112	BP
Co-povidone (povidone VA-65)	IH
Cross povidone	IP
Colloidal silicon dioxide	IH
Purified talc	BP
Magnesium stearate	BP

6.2. Incompatibilities
None

6.3. Shelf life

3 Years

6.4 Special precautions for storage

Store below 30^{o}C, protect from light.

6.5. Nature and contents of container

10 tablets packed in Alu-PVC Blister.

6.6. Special Precaution for Disposal
None

7. Applicant of Manufacturer.

NAFDAC Reg. No.
MAXHEAL LABORATORIES PVT LTD.
2-7/80-85, SURSEZ Sachin, Surat,
Gujarat-394230, India.