



Bharat Parenterals Limited

Registered Office & Works:
Vill. Haripura, Ta. Savli, Dist. Vadodara - 391520 (Guj.) India.
Tele Fax : (02667)-251679, 251680, 251669, 99099 28332.
E-mail: bplbrd@bplindia.in, info@bplindia.in, Web.: www.bplindia.in
CIN NO: U24231GJ1992PLC018237

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. Name of the medicinal product

1.1. Name of the medicinal product:

Generic Name/INN Name: Zinc Sulfate Dispersible tablets 10mg

Trade Name: Health gate Zinc 10mg tablets

1.2 Strength:

Each dispersible uncoated tablet contains:

Zinc Sulfate Monohydrate BP

Eq. to Elemental Zinc 10mg

Excipients q.s.

1.3 Pharmaceutical form:

Solid Oral Dosage form – Tablets





Bharat Parenterals Limited

Registered Office & Works:
Vill. Harijura, Ta. Savli, Dist. Vadodara - 391520 (Guj.) India.
Tele Fax : (02667)-251679, 251680, 251689, 99099 28332.
E-mail: bplbrd@bplindia.in, info@bplindia.in, Web: www.bplindia.in
CIN NO: U24231GJ1992PLC018237

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

2. Qualitative and Quantitative composition:

Sr. No.	Ingredients	Specification	Label Claim (mg)	Std. Qty. /Tablet (mg)	Function
Mixing					
1.	Zinc sulphate monohydrate	BP	27.442 mg eq. to 10.00 mg	27.442	Active
2.	Microcrystalline cellulose pH102	BP	--	196.558	Diluent
3.	Pregelatinized maize starch	BP	--	15.000	Binder and Disintegrant
4.	Aspartame	BP	--	15.000	Sweetener
5.	Colloidal Anhydrous Silicon	BP	--	5.000	Glidant
6.	Flav. Mango dry flavor Strdm 60484	BP	--	5.000	Flavouring agent
7.	Cross Povidone	BP	--	15.000	Superdisintegrant
8.	Magnesium Stearate	BP	--	3.000	Lubricant
Total weight of uncoated tablets				282.00	

3. Pharmaceutical form:

Dosage Form: Solid Oral Dosage form - Tablets

Visual & Physical characteristics of the product:

A white coloured round shape biconvex uncoated dispersible tablets, having "Z" embossed on one side and "10" embossed on other side of the tablets.





Bharat Parenterals Limited

Registered Office & Works:
Vil. Haripura, Ta. Savli, Dist. Vadodara - 391520 (Guj.) India.
Tele Fax : (02667)-251679, 251680, 251689, 99099 28332.
E-mail: bplbrd@bplindia.in, info@bplindia.in, Web.: www.bplindia.in
CIN NO: U24231GJ1992PLC018237

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

4. Clinical particulars

4.1. Therapeutic indications:

Zinc sulfate is a source of zinc which is an essential trace element and involved in a number of body enzyme systems. Health gate Zinc 10 is indicated in adults and children for the treatment of zinc deficiency.

4.2. Posology and method of administration:

Method of Administration: oral after dissolution in water.

Adults: One tablet, dissolved in water, once to three times daily after meals.

Children: More than 30kg: One tablet, dissolved in water, once to three times daily after meals.

10-30kg: ½ tablet, dissolved in water, once to three times daily after meals.

Less than 10kg: ½ tablet, dissolved in water, once daily after meals.

4.3. Contraindications:

Hypersensitivity to the active substance or any of the excipients.

4.4. Special warnings and precautions for use:

Accumulation of zinc may occur in cases of renal failure.

4.5. Interaction with other medicinal products and other forms of interaction:

Copper:

Zinc may inhibit the absorption of copper.

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.





Bharat Parenterals Limited

Registered Office & Works:
Vill. Haripura, Ta. Savli, Dist. Vadodara - 391520 (Guj.) India.
Tele Fax : (02667)-251679, 251680, 251669, 99099 28332.
E-mail: bplbrd@bplindia.in, info@bplindia.in, Web.: www.bplindia.in
CIN NO: U24231GJ1992PLC018237

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

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. 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:

Health gate Zinc 10 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.

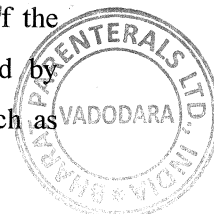
Zinc may interfere with the absorption of copper, leading to reduced copper levels, and potentially copper deficiency. The risk of copper deficiency may be greater with long-term treatment (e.g. if zinc deficiency is no longer present) and/or with higher doses of zinc.

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.

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.





Bharat Parenterals Limited

Registered Office & Works:
Vill. Haripura, Ta. Savli, Dist. Vadodara - 391520 (Guj.) India.
Tele Fax : (02667)-251679, 251680, 251689, 99099 28332.
E-mail: bplbrd@bplindia.in, info@bplindia.in, Web : www.bplindia.in
CIN NO: U24231GJ1992PLC018237

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

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.

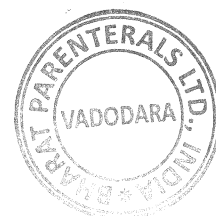
5.3. Preclinical safety data

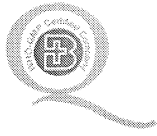
Non-clinical data have not revealed significant hazards for humans, based on standard studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, and reproductive toxicity. Effects in non-clinical studies were observed only at exposures sufficiently in excess of the maximum human exposure to be of little clinical relevance.

6. Pharmaceutical particulars:

6.1. List of Excipients:

Microcrystalline cellulose pH102
Partially Pregelatinized maize starch
Aspartame
Colloidal Anhydrous Silicon
Flav. Mango dry flavor Strdm 60484
Cross Povidone
Magnesium Stearate





Bharat Parenterals Limited

Registered Office & Works:
Vill. Haripura, Ta. Savli, Dist. Vadodara - 391520 (Guj.) India.
Tele Fax : (02667)-251679, 251680, 251689, 99099 28332.
E-mail: bplbrd@bplindia.in, info@bplindia.in, Web: www.bplindia.in
CIN NO: U24231GJ1992PLC018237

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

6.2. Incompatibilities:

Not applicable

6.3. Shelf life:

36 months

6.4. Special precautions for storage:

Store below 30°C. Protect from sunlight and moisture.

6.5. Nature and contents of container:

Primary Packing: 10 tablets packed in a Alu- PVC blister pack.

Secondary Packing: Such a 10 Alu-PVC blister packed in a monocarton.

6.6. Special precautions for disposal:

No special requirements.

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

7. Applicant:

Name and Address of Applicant

M/s. Chanrai Health Care Limited

Plot 122-132, Oshodi Apapa

Expressway, Isolo, Lagos, Nigeria.

Name and Address of manufacturer:

M/s. Bharat Parenterals Limited

Survey No. 144 &146, Jarod Samlaya Road,

Village: Haripura, Ta. Savli, Dist. Vadodara – 391520

Gujarat, INDIA.

Tel.91-2667-251680

Fax: 91-2667-251679

E-mail: ra@bplindia.in

