Summary of Product Characteristics

1. Name of the medicinal product

Junior Zinc tablets

2. Qualitative and quantitative composition

Each dispersible tablet contains Zinc Sulfate Monohydrate USP equivalent to Zinc 20mg

3. Pharmaceutical form

Oral tablets

White coloured; circular, bevel edged tablets, with a break line on one side and plain on the other

4.0 Clinical particulars

4.1 Therapeutic indications

Junior Zinc tablets is indicated for the treatment of acute and persistent diarrhoea in infants and children aged up to 5 years

4.2 Posology and method of administration:

Route of administration: Oral administration.

Dosage

For acute and persistent diarrhoea

For children less than 6 months of age:

Half tablet (10mg) once daily for 10-14 days.

For children 6 months of age to 5 years of age:

One tablet (20mg) 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.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients.

Do not give simultaneously with ferrous salts, administer at least 2 hours apart

4.4 Special warnings and precautions for use

Drugs which may inhibit zinc absorption, such as penicillamine, sodium valproate and ethambutol, should not be co-administred with Junior Zinc 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 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

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.

Co-administration of Zinc with Drugs, such as penicillamine, sodium valproate and ethambutol, should may inhibit zinc absorption

4.6 Pregnancy and lactation

Pregnancy: The safety of zinc Tablet in pregnancy has not been established.

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

4.7 Effects on ability to drive and use machines
No effect on ability to drive and use machines.

4.8 Undesirable effects
In clinical trials in children, administration of Zinc Tablets was associated with vomiting or regurgitation. In one study vomiting attributed to the tablet was reported very commonly (≥ 10%),
i.e. in 14% and regurgitation was reported commonly (≥ 1% to <10%), 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. Overdosage with zinc has also been associated with acute renal tubular necrosis and interstitial nephritis. Prolonged high dose zinc supplementation may result in copper deficiency.
Treatment: In cases of acute zinc overdose, treatment is primarily supportive, however induced emesis, gastric lavage, or activated charcoal may be useful in cases of substantial ingestions of zinc tablets. Chelating agents such as calcium disodium EDTA may be useful

5. Pharmacological properties
5.1 Pharmacodynamic properties
Pharmacology
Pharmacotherapeutic group: Other mineral supplements, ATC code: A12CB01
Zinc sulfate is a zinc salt used for the treatment of acute and persistent diarrhoea in children.
Zinc is an essential trace element which is present in a wide range of foods. It is found in all tissues.
Normal growth and tissue repair depend upon adequate zinc levels. Zinc acts as an integral part of several enzymes important to protein and carbohydrate metabolism. . Severe zinc deficiency is associated with growth retardation, primary hypogonadism, skin disease, disturbances of taste and smell, and impaired immunity, with increased susceptibility to infection.
Zinc supplementation has been shown to reduce the duration and severity of diarrhea in populations of children with a high incidence of zinc deficiency, and also to reduce the frequency of recurrences in the subsequent 2-3 months. The beneficial effects of zinc are likely associated with reconstitution of the immune response, however direct inhibitory effects of zinc on enteric pathogens have also been reported.

5.2 Pharmacokinetic properties
Absorption: Zinc is incompletely absorbed from the small bowel, with between 10 and 40% of an ingested dose absorbed. Numerous dietary components can interfere with zinc absorption, particularly phytates and fibre, which bind to zinc, resulting in poorly absorbed zinc complexes.
The absorption of zinc from Zinc tablets was examined in 10 healthy, zinc replete, adult male volunteers (baseline mean plasma zinc level ±SD of 15.1 ±3.5 mmol/L). Absorption of zinc from 1½ ZinC tablets (i.e. a 30 mg dose) was rapid, with a maximal increase in mean plasma zinc level (±SD) of 11.6 (±6.0) mmol/L observed within approximately 2 hours of administration.
Distribution: Approximately 60% of circulating zinc is bound to albumin and roughly 30% is bound to macroglobulin. The majority of zinc is stored in the liver and kidney, chiefly intracellularly,and bound to metalloproteins.
Elimination: In adults, it has been estimated that approximately 0.5 to 1.0 mg/day is secreted in the biliary tract and excreted in the stool, while 0.5 to 0.8 mg/day is excreted in the urine.

5.3 Preclinical safety data
Not applicable.

6. Pharmaceutical particulars
6.1 List of excipients
Microcrystalline cellulose pH 102
Maize starch
Aerosil 200
Magnesium stearate
Vanilla flavour powder
Croscarmellose sodium
Aspartame
Kollidon CL

6.2 Incompatibilities:
Not applicable

6.3 Shelf life : 3 years

6.4 Special precautions for storage
Store in a cool dry place, below 30°C.Protect from direct sunlight.
Keep all medicines out of reach of children.

6.5 Nature and contents of container
Blister pack of 10x10's in a unit carton with a literature insert

7. Manufacture.
Dawa limited,
Plot No: 7879/8, Baba Dogo road, Ruaraka,
P.O Box 16633-00620,
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8. Marketing authorization holder
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9. Legal category : GSL

10. Date of revision of the text
June 2019