SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Zinc (as sulfate) Dispersible Tablets 20 mg*

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dispersible tablet contains 54.89 mg zinc sulfate monohydrate equivalent to 20 mg of zinc.

Each dispersible tablet contains 15 mg of aspartame. For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Dispersible tablets

White to off-white, circular flat, bevelled, uncoated, flavoured tablet with break-line on one side and plain surface on the other side.

The tablet can be divided into two equal halves.

4. CLINICAL PARTICULARS

4.1 Therapeutic indication

Zinc (as sulfate) Dispersible Tablets 20 mg is indicated for the treatment of acute and persistent diarrhoea in infants and children aged up to 5 years.

This product is intended for use in children. Nonetheless, safety information is provided for adult health issues such as pregnancy and lactation, to allow full access to all relevant information.

4.2 Posology and method of administration

For acute and persistent diarrhoea

Children aged less than 6 months: ½ tablet once daily for 10–14 days.

Children aged 6 months–5 years: 1 tablet once daily for 10–14 days.

The tablet (or half tablet) should be dispersed completely in 1 teaspoon (5 ml) clean water or breast milk and the entire amount administered orally.

It is recommended that doses are given between meals and the dose repeated if the child vomits within 30 minutes.

For missed doses, the missing dose can be taken as soon as possible, unless the next dose is due within 6 hours.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

Excipients

Zinc (as sulfate) Dispersible Tablets 20 mg contains aspartame, a source of phenylalanine. This should be considered when prescribing the product to patients with phenylketonuria.

* Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

4.5 Interactions with other medicinal products and other forms of interaction

When taken together, zinc may reduce the absorption of tetracyclines (but not doxycycline), and quinolone antibacterials. 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.

Drugs which reduce the absorption of zinc such as pencillamine should not be taken together. An interval of at lest three hours should be allowed between administation of zinc and drugs such as penicillamine.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are few data on the use of zinc sulfate in pregnant women.

Animal studies do not indicate reproductive toxicity at the human therapeutic dose (see section 5.3).

The use of Zinc (as sulfate) Dispersible Tablets 20 mg may be considered during pregnancy, if necessary.

Lactation

Zinc appears in human milk, but at therapeutic doses of Zinc (as sulfate) Dispersible Tablets 20 mg no effects on the breastfed infant are anticipated.

Fertility

No data on the effect of zinc on fertility are available.

4.7 Effects on ability to drive and use machines

Zinc (as sulfate) Dispersible Tablets 20 mg is not expected to have any effect on the 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 i.e. in 14% and regurgitation was reported commonly i.e. in 5.2% of the children. In most cases vomiting or regurgitation occurred within 10 minutes of the first dose 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. Overdose 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

For acute zinc overdose, treatment is primarily supportive, but giving milk or alkali carbonates and activated charcoal may be useful in cases of substantial ingestions of zinc tablets. Chelating agents such as sodium calcium edetate may be useful.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other mineral supplements, ATC code: A12CB01.

Zinc is an essential trace element which is present in a wide range of foods. It is found in all tissues.

Zinc sulfate is used for the treatment of acute and persistent diarrhoea in children.

Normal growth and tissue repair depend on adequate zinc levels. Zinc is an integral part of several enzymes important for 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 diarrhoea in populations of children with a high incidence of zinc deficiency, and also to reduce the frequency of recurrence in the subsequent 2–3 months. The benefits of zinc are possibly associated with reconstitution of the immune response. 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 pharmacokinetic values of Zinc (as sulfate) Dispersible Tablets 20 mg have not been determined. Zinc (as sulfate) Dispersible Tablets 20 mg dissolves completely in 5 ml water within 1 minute at room temperature.

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 0.5–1 mg is secreted daily in the biliary tract and excreted in the stool, while 0.5–0.8 mg is excreted daily in the urine.

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

Aspartame
Microcrystalline cellulose
Colloidal silicon dioxide
Crospovidone
Trusil orange ASV flavour
Magnesium stearate

6.2 Incompatibilities:

Not applicable.

6.3 Shelf life:

48 months

6.4 Special precautions for storage

Do not store above 30ºC. Protect from light and moisture. Store tablets in blisters in the provided carton.

6.5 Nature and contents of container

PVC/PVdC-Alu blister of 10 tablets, such 10 blisters in a carton along with the pack insert.

6.6 Special precautions for disposal

No special requirements

7. SUPPLIER

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8. WHO REFERENCE NUMBER (PREQUALIFICATION PROGRAMME)

DI005

9. DATE OF FIRST PREQUALIFICATION

December 2016

10. DATE OF REVISION OF THE TEXT:

March 2017
Section 6 updated in March 2019

Reference list

General

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Posology

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