SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF MEDICINAL PRODUCT

Afrab®Zinc tablet

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 54.9 mg zinc sulfate monohydrate equivalent to 20 mg of zinc.

3. PHARMACEUTICAL FORM

A white round plain tablet on one side and a mark line on the other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Afrab Zinc tablet is an adjunct to oral rehydration therapy in the treatment of acute and persistent diarrhoea in infants and children up to 5 years.

4.2 Posology and method of administration

For children less than 6 months of age: ½ 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.

Method of Administration

Oral administration only

4.3 Contraindications

-Patients with hypersensitive to zinc sulfate monohydrate.
-Patients with copper deficiency.

4.4 Special warnings and precaution for use

Drugs which may inhibit zinc absorption, such as penicillamine, sodium valproate and ethambutol, should not be coadministred with Afrab Zinc 20mg

tablets, unless the risks of discontinuation of the drug are judged to outweigh the benefit of zinc in treatment of the child's diarrhoea.

4.5 Interaction with other medicinal product 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.

4.6 Pregnancy and Lactation

Pregnancy

The safety of Afrab® Zinc 20mg Tablet in pregnancy has not been established.

Lactation

Zinc crosses the placenta and is present in breast milk. The safety of Afrab® Zinc 20mg tablet in lactation has not been established.

4.7 Effects on ability to drive and use machines

There is no evidence regarding the effect of zinc on the ability to drive or use machines; however Afrab® Zinc 20mg Tablet is not expected to have any effect on the ability to drive and use machines.

4.8 Undesirable Effects

-vomiting

-Abdominal pain

-Dyspepsia

-Nausea

-Diarrhoea

-Headache

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 Pharmacodynamics Properties

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 Afrab® 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 Afrab® 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

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

Sodium Starch Glycolate
Trusil Orange Colour
Truesil Pineapple Flavour
Aspartame
Magnesium Stearate
Kolidon Cl-Sf
Aerosil

6.2 Incompatibilities

6.3 Shelf life

3years

6.4 Special precautions for storage

Store below 30°C in a dry place.

6.3 Nature and contents of container

The primary packaging materials used is: Transparent colorless PVC/PVDC/Aluminum blister

One Aluminum / PVC blisters contain 1 x 10 tablets packed in a printed cardboard case.

6.6 Special precautions for disposal and other handling

No special requirements.

7. APPLICANT/MANUFACTURER

Afrab Chem Limited
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