Cian Zinc Plus Zinc Sulphate Monohydrate Dispersible Tablets USP 20 mg

COMPOSITION

Each Uncoated Dispersible Tablet Contains:

Zinc Sulphate Monohydrate USP

Eq. to Elemental Zinc 20 mg
Excipients q.s

DESCRIPTION:

Uncoated Dispersible Tablet.

THERAPEUTIC INDICATIONS:

Cian Zinc Plus 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.

POSOLOGY AND METHOD OF ADMINISTRATION:

For acute and persistent diarrhoea

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:

Tablets for oral use.

CONTRAINDICATIONS:

Not applicable

SPECIAL WARNINGS AND PRECAUTIONS FOR USE:

Drugs which may inhibit zinc absorption, such as penicillamine, sodium valproate and ethambutol, should not be coadministred with Cian Zinc Plus Tablet, unless the risks of discontinuation of the drug are judged to outweigh the benefit of zinc in treatment of the child's diarrhoea.

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.

PREGNANCY AND LACTATION:

Pregnancy

The safety of Cian Zinc Plus Tablet in pregnancy has not been established.

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

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 Cian Zinc Plus Tablet is not expected to have any effect on the ability to drive and use machines.

UNDESIRABLE EFFECTS

In clinical trials in children, administration of Zinc Sulphate Monohydrate Dispersible Tablets USP 20 mg was associated with vomiting or regurgitation. In one study vomiting attributed to the tablet was reported very commonly (\geq 10%), i.e. in 14% and regurgitation was reported commonly (\geq 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).

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.

PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group: Other mineral supplements, ATC code: A12CR01

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

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.

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.

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.

SHELF LIFE:

36 Months

PACKAGING

10 Tablets are packed in Alu-PVC blister and such 3 blisters are packed in a carton along with pack insert.

STORAGE CONDITION:

Store protected from light and moisture, at a temperature not exceeding 30°C . Keep the medicine out of reach of children

MARKETED BY:

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MANUFACTURED BY:

CIAN HEALTHCARE LTD.
(An ISO 9001:2015 & WHO-GMP Certified Co.)

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Cian Zinc Plus

ပါဝင်ပစ္စည်းများ

ဇင့် ၂၀ မီလီဂရမ် ပါဝင်ပါသည်။

အရွယ်အစား၊ အရေအတွက်၊ အသားတင် ပမာက

ဆေးလုံး ၁၀ လုံး x ၃ ကဒ်ပါဘူး

သုံးစွဲပုံနည်းလမ်း

ဝမ်းလျော(ပြင်းထန် သို့ ဆက်တိုက်သွားလျှင်)

- အသက်(၆)လအောက် ကလေးများ ဆေးတြမ်း တနေ့တကြိမ် ၁၀ရက် မှ ၁၄ရက်
- အသက် (၆) လ မှ ၅ နှစ် ထိ ကလေးများ ဆေးတလုံး တနေ့တကြိမ် ၁ဂရက် မှ ၁၄ရက် သောက်သုံးနိုင်ပါသည်။

ဆေး တလုံး (သို့) တြေမ်း အား ရေ(သို့)မိခင်နို့ လက်ဖက်ရည်စွန်းတစွန်း (၅ မီလီလီတာ) တွင် ဖျော်၍သောက်ပါ။

ဆေး အား အစာနှင့်တွဲ၍ သောက်သုံးနိုင်ပါသည်။ ဆေးသောက်ပြီး နာရီဝက် အတွင်းအန်လျှင် နောက်တကြိမ် သောက်သုံးနိုင်ပါသည်။

ထားသိုသိမ်းဆည်းမှုအညွှန်း

အပူချိန် ၃ဂ ဒီဂရီအောက်တွင် သိုလှောင်သိမ်းဆည်းပါ။ နေရောင်ခြည်တိုက်ရိုက်ကျရောက်သောနေရာ နှင့် စိုစွတ်သောနေရာတွင် မထားရ။ ကလေးများနှင့်ဝေးရာတွင်ထားပါ။

ကြိုတင်သတိပေးချက်

တစ်နေ့တာလိုအပ်သောပမာကာထက်ပို၍မသောက်သုံးသင့်ပါ။ ဆေးပျော်ဝင်နန်းကိုဟန်တားနိုင်သော ဆေးများဖြစ်သော ပက်နီစလင်ဆေးများ၊ အတက်ရောဂါတွင်သောက်သုံးသောဆေး sodium valporate နှင့် တီဘီရောဂါတွင်သောက်သုံးသောဆေး ethambutol ဆေးများနှင့် တွဲမသောက်ရ။

ဘေးထွက်ဆိုးကျိုး

အော့အန်ခြင်း၊ ဝမ်းဗိုက်မအီမသာဖြစ်ခြင်း နှင့် အစာမကြေခြင်း တို့ဖြစ်နိုင်ပါသည်။