DIAZINC

(Zinc Sulphate Monohydrate)

20 mg/ 5ml

Oral Solution

COMPOSITION

Each 5ml contains:

Zinc Sulphate Monohydrate equivalent to elemental Zinc 20mg

DESCRIPTION

Supplementary zinc benefits children with diarrhea because it is a vital micronutrient essential for protein synthesis, cell growth and differentiation, immune function, and intestinal transport of water and electrolytes. Zinc is also important for normal growth and development of children both with and without diarrhea.

INDICATIONS

Zinc is not an antidiarrheal drug.

It is recommended by WHO in following conditions as supplement;

- Acute diarrhoea
- Recurrent diarrhoea

DOSAGE AND ADMINISTRATION

Six months & above:

One teaspoonful or 5ml once daily (10-14 days) or as directed by the physician.

Under six months:

Half teaspoonful or 2.5ml once daily (10-14) days or as directed by the physician.

A measuring spoon is provided for accurate measurement of dosage.

It is recommended that doses be administered between meals, and a repeat dose 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 remaining until the next dose.

CONTRAINDICATION

It is contraindicated in patients with hypersensitivity to zinc.

PRECAUTION AND WARNING

Concurrent administration of zinc salt with penicillamine might diminish the effect of Penicillamine. The absorption of Zinc, although poor may be decreased by various compounds including some foods. Chelation may occur with tetracyclines.

DRUG INTERACTION

Tetracycline Antibacterials: Zinc may reduce the absorption of concurrently administered

tetracyclines, also the absorption of zinc may be reduced by tetracycline; 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. 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.

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.

SIDE EFFECTS

In clinical trials in children, administration of zinc (as sulfate) was associated with vomiting or regurgitation.

In one study, vomiting was reported very commonly (\geq 10%) and regurgitation was reported commonly (\geq 1% to <10%)—in 5.2% in 14% and 5.2% of 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).

REPORTING OF SIDE EFFECTS

In case of any adverse event or experience report at pv@searlecompany.com

PRESENTATION

Diazinc oral Solution of 20mg/5ml is available in amber colored glass bottle containing 60ml solution.

REGISTERATION NUMBER

Diazinc Oral Solution 60ml: 061874 Manufacturing License Number: 000647

INSTRUCTIONS

- To be sold on the prescription of a registered medical practitioner only.
- Protect from sunlight and heat.
- Store below 30°C.
- Keep all medicines out of sight and reach of children.
- Keep bottle tightly closed.
- Shake well before use.

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

U.S.P. Specification.

Manufactured by:

The Searle Company Limited

32-Km, Multan Road, Lahore-Pakistan.

Marketed by:

IBL HealthCare Limited,

One IBL Centre, 2nd Floor, Plot # 1,

Block 7 & 8, D.M.C.H.S, Tipu Sultan Road,

Off Shahra-e-Faisal, Karachi - Pakistan.

DATE OF PUBLICATION OF THE PACKAGE INSERT

June 2021

SPL/SPC-DIAZ.S/621-000(001)