

Syrup / Oral Drops MINERAL

FORMULATION

Syrup (Oral Drops) Fach ml contains:

Zinc sulfate monohydrate, USP (equivalent to 10 mg elemental zinc)

Syrup

Each 5 mL (1 teaspoonful) contains: Zinc sulfate monohydrate, USP (equivalent to 20 mg elemental zinc)

PRODUCT DESCRIPTIONS

Zinc Sulfate Monohydrate 27 mg/mL Syrup (Oral Drops) is a turbid, orange syrup with orange flavor. Zinc Sulfate Monohydrate 55 mg/5 mL Syrup is a turbid, viscous, orange syrup with orange flavor.

This product contains Zinc. Zinc helps the body's natural defense against damaging free radical (antioxidant effect) and helps boost immune function.Free radicals are highly reactive and unstable chemicals generated during normal body activities that require oxygen (e.g., respiration, digestion, blood circulation, immune system response, etc.) and after exposure to UV light, cigarette smoke and various pollutants. One major effect of zinc is on the ability of cells to properly replicate the DNA which is required for cells to multiply. Hence, zinc is needed for normal growth.

STRENGTH OF THE MEDICINE

See formulation

WHAT IS THIS MEDICINE USED FOR?

For prevention and treatment of Zinc deficiency.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?

Syrup (Oral Drops)

Children: 1 mL (20 drops) once daily or as prescribed by a physician.

Children: 5 mL (1 teaspoonful) once daily or as prescribed by a physician.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?

If you are allergic to any component of the drug.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE? Do not take more than recommended dos

Do not use after the expiry date on the label.

UNDESIRABLE FEFECTS OF THIS MEDICINE Gastrointestinal and include abdominal pain, dyspepsia, nausea, vomiting, diarrhea, gastric irritation, and gastritis. These are particularly common if

taken on an empty stomach, and may be reduced by giving them with meals.

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?

The amount of zinc in the products is not expected to interact with food or medicine.

WHAT SHOULD YOU DO IF YOU MISS A DOSE? If you miss a dose for the day, just take the next dose and subsequent doses at the usual recommended dose. Do not take a double dose to make up

the missed dose.

SIGNS AND SYMPTOMS OF OVERDOSE

Rare occurrence of acute zinc poisoning have been reported. The toxicity signs observed after ingestion of high zinc doses (4-8 grams) include nausea, vomiting, diarrhea, fever, metallic taste and lethargy (sleepiness).

WHAT TO DO WHEN YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?

If you take more than the recommended dose, consult a doctor.

HOW SHOULD YOU KEEP THIS MEDICINE? Store at temperatures not exceeding 30°C.

Keep out of reach of children.

Protect from heat and light.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?

If you experience any undesirable effect, talk to a doctor.

For suspected adverse drug reaction report to FDA: www.fda.gov.ph

Patient should seek medical attention immediately at the first sign of any adverse drug reaction.

AVAILABILITY

Syrup (Oral Drops): 15 mL Amber Glass Bottle (box of 1's)

Syrup: 60 mL Boston Round Amber Glass Bottle (box of 1's)

REGISTRATION NUMBER

Syrup: DR-XY44313

Syrup (Oral Drops): DR-XY44670

DATE OF FIRST AUTHORIZATION

Syrup (Oral Drops): 18 June 2015 Syrup: 12 March 2015