

Oral Drops / Syrup Vitamin / Mineral

FORMULATION:

Oral Drops:

Each mL contains:

Ascorbic Acid, USP 50 mg
Zinc Sulfate Monohydrate 13.72 mg
(equivalent to 5 mg elemental Zinc)

Syrup:

Each 5 mL contains:

(equivalent to 10 mg elemental Zinc)

PRODUCT DESCRIPTION:

Ascorbic Acid + Zinc 50 mg / 5 mg per 5 mL Syrup (Oral Drops) is a clear to slightly hazy, orange to orange yellow to orange brown syrup with apple flavor.

Ascorbic Acid + Zinc 100 mg / 10 mg per $\,$ 5 mL Syrup is a clear to slightly hazy, orange to light yellow syrup with apple flavor.

WHAT IS IN THE MEDICINE?

This nutritional supplement contain Ascorbic Acid (Vitamin C) + Zinc.

Young children are growing up rapidly and their immune system may not yet be fully developed. Hence, supplementation with vitamin C and Zinc may be beneficial. Vitamin C and Zinc help boost immune function and, with their antioxidant effect, help the body's natural defense against the damaging free radicals. 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 their DNA, which is required for cells to multiply. Hence, zinc is needed for normal growth for infants and young children, cell renewal and repair.

STRENGTH OF THE MEDICINE

Please see formulation

WHAT IS THIS MEDICINE USED FOR?

Ascorbic Acid (Vitamin C) is used in the treatment and prevention of Vitamin C deficiency. It completely reverses symptoms of deficiency.

Zinc has been proven to help proper growth and development of children. Zinc also helps in the correction and prevention of the most common childhood infections like pneumonia and diarrhea.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?

Oral Drops:

6 - 11 months: 0.5 mL to 1 mL

1 - 2 years: 1 mL

Orally, once a day. Or as prescribed by the physician.

Syrup:

- 2 6 years: 5 mL (1 teaspoonful)
- 7 12 years: 10 mL (2 teaspoonfuls)

To be taken once a day for supplementation. 2 to 4 times a day for therapeutic use, or as prescribed by the physician.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?

Do not use after the expiry date on the label.

Contraindicated in those persons who have shown hypersensitivity to any component of this preparation.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE?

Do not take more than the recommended dosage.

UNDESIRABLE FEFECTS

Ascorbic acid

Ascorbic acid is usually well tolerated. However, nausea, vomiting, heartburn, abdominal cramps, fatigue, flushing, insomnia, and sleepiness have been reported with high doses (i.e., 1 g or more daily) Zinc

Gastrointestinal side effects such as nausea and vomiting are seen with doses of elemental zinc greater than 30 mg.

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

The amounts of nutrients in the product are not expected to interact with food or medicines.

WHAT SHOULD YOU DO WHEN YOU MISS A DOSE?

If the child misses the dose for the day just give the next dose and the subsequent doses at the usual recommended schedule, i.e., once a day.

Do not double the dose unless recommended by a doctor.

WHAT ARE THE SIGNS AND SYMPTOMS OF OVERDOSE?

Ascorbic acid

Prolonged intake of Ascorbic acid (Vitamin C) in excess of 2 g/day may lead to nausea, abdominal cramps, diarrhea, and nose bleeds.

Zinc

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

WHAT TO DO WHEN YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE? If you have taken more than the recommended dosage, consult a doctor.

WHEN SHOULD YOU CONSULT A DOCTOR? If any undesirable effect occurs.

If the child is taking other vitamin-mineral supplement.

AVAILABILITY:

Oral Drops: Amber glass bottle x 15 mL sealed with aluminum cap.

Syrup: Amber glass bottle x 60 mL and 120 mL sealed with aluminum cap.

ADR REPORTING:

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph
Patient should seek medical attention immediately at the first sign of any adverse drug reaction.

REGISTRATION NUMBER:

Oral Drops: DRP-8600 Svrup: DRP-8601

DATE OF FIRST AUTHORIZATION:

Oral Drops: 10 February 2016 Syrup: 10 February 2016

STORE AT TEMPERATURES NOT EXCEEDING 30°C. PROTECT FROM LIGHT.

Maufactured by: HIZON LABORATORIES, INC. Assumption Road, Sumulong Highway, Antipolo City