

SALFOVEROSE SYRUP (20 mg/5 ml)

1-Name of medicinal product

Salfoverose SYRUP

2-Qualitative and quantitative composition

Each 5 ml Syrup contains:-

Zinc Sulphate Heptahydrate 87.926 mg equivalent to 20 mg elemental zinc

Inactive ingredients:

See full excipients in section (6,1)

3-pharmaceutical form

SYRUP

4-Clinical particulars

4.1 Therapeutic indications

Zinc Sulphate Heptahydrate is a source of zinc which is an essential trace element and involved in a number of body enzyme systems

Indications: For the treatment of zinc deficiency

4.2 Posology and method of administration

Method of administration: Oral

Infants under six months: 10 mg elemental zinc (2.5ml) daily.

Children above 6 months: 20 mg elemental zinc (5 ml) daily.

Children:

- children under 10 kg: 22.5 mg elemental zinc (5.6 ml) daily in divided dose.

-children 10 to 30 kg: 22.5 mg elemental zinc (5.6 ml) 1 to 3 times daily.

-Adult and children over 30kg: 45 mg elemental zinc (11.1 ml) 1 to 3 times daily or as directed by physician.

4.3 Contraindications

None.

4.4 special warnings and precautions for use

Accumulation of zinc may occur in cases of renal failure.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

4.5 interaction with other medicinal products and other forms of interaction

Tetracyclin Antibacterials :

Zinc may reduce the absorption of concurrently administered tetracyclines, also the absorption of zinc may be reduced by tetracyclines ;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.

4.6 Pregnancy and lactation

The safety of this product in human pregnancy has not been established . zinc crosses the placenta and is present in breast milk.

4.7 Effect on ability to drive and use machines

Salfoverose is not expected to affect ability to drive and use machines.

4.8 Undesirable effects

Zinc salts may cause abdominal pain , dyspepsia , nausea, vomiting, diarrhoea, gastric irritation and gastritis. There have also been cases of irritability , headache and lethargy observed.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of medicinal product is important . it allows continued monitoring of the benefit /risk balance of the medicinal product .

4.9 Overdose

Zinc sulphate heptahydrate is corrosive in overdosage .Symptoms are corrosion and inflammation of the mucous membrane of the mouth and stomach ; ulceration of the stomach followed by perforation may occur . Gastric lavage and emesis should be avoided .Demulcents such as milk should be given . Chelating agents such as sodium calcium edetate may be useful .

*pharmacological properties

5.1 pharmacodynamics properties

Zinc is an essential trace element involved in many enzyme systems. Severe deficiency causes skin lesion , alopecia , diarrhea , increased susceptibility to infections and failure to thrive in children . Symptoms of less severe deficiency include distorted or absent perceptions of taste and smell and poor wound healing

5.2 pharmacokinetic properties

Zinc is absorbed from the gastrointestinal tract and distributed throughout the body . the highest concentrations occur in hair , eyes, male reproductive organs and bone. Lower levels are present in liver , kidney and muscle, in blood 80% is found in erythrocytes. Plasma zinc levels range from 70 to 110µg/dL and about 50% of this is loosely bound to albumin . About 7% is amino-acid bound and the rest is tightly bound to alpha 2-macroglobulins and other proteins.

6-Pharmaceutical particulars

6.1 List of excipients

Saccharine sodium , sucrose , sodium citrate dihydrate , citric acid monohydrate , strawberry flavor liquid (terpenless) , Banana flavor liquid (terpenless) , Glycerin 99.5% , purified water

6.2 Incompatibilities

None

6.3 Shelf life

Three years.

6.4 Special precautions for storage

Store at temperature below 30°C

keep out of reach of children.

Packing:

Carton box contains amber glass (type II) bottle of 120 ml syrup closed by (**HDPE**) cap with insert leaflet .

Manufactured by :Averroes Pharma for Pharmaceutical Industries