SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

ZINOBEST 15 mg/5 ml syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient:

Zinc sulphate heptahydrate	66 mg/ 5 ml

Excipients:

Sugar (Sucrose)	2250 mg/ 5 ml
Sodium benzoate	5 mg/ 5 ml

For Excipients, see section 6.1

3. PHARMACEUTICAL FORM

Syrup

Yellow colored, clear solution

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

It is taken in the treatment or prevention of zinc deficiency and in the treatment of diarrhea.

4.2 Posology and method of administration

Posology / Administration frequency and duration:

Diarrhea treatment should not last more than 7 days.

It is taken at the following doses if not otherwise prescribed by the doctor.

Age	**Elemental Zinc (mg)**	**Tolerable Upper Limits (mg)**	**Measure**
6 to 12 months	3	5	1.5 ml pipette
1 to 3 years	3	7	2 ml pipette
4 to 8 years	5	12	4 ml pipette
9 to 13 years	8	20	6 ml pipette
14 to 18 years	10	30	2 measure spoons or 10 ml pipette
19- adults on	10	40	13 ml pipette

Method of Administration:

For oral administration only.

It may be taken before or after meals or with meals by means of a measure spoon or pipette.

Additional information on special populations:

Renal / Hepatic failure: The safety and efficacy of ZINOBEST in patients with renal and hepatic failure has not been studied.

In renal failure, accumulation of zinc in the body may increase, so care must be taken in case of renal failure.

Pediatric population: ZINOBEST should be administered in pediatric patients as indicated in the posology section.

Geriatric population: The safety and efficacy of ZINOBEST in elderly patients has not been examined.

4.3 Contraindications

It is contraindicated in those who have allergy to zinc salts or other constituents of syrup.

4.4 Special warnings and precautions for use

Can be used with meals, but should not be used with calcium, phosphorus or phytate rich foods. In patients with severe nausea, vomiting, or acute dyspepsia, use of the medicine should be discontinued and should be consulted a physician.

Prolonged or overdose may cause copper deficiency.

Due to the presence of sucrose, patients with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

This medicinal product contains 0.034 mmol (0.79 mg) of sodium per 5 ml. This should be considered for patients on a controlled sodium diet.

4.5 Interaction with other medicinal products and other forms of interaction

Zinc salts, tetracyclines and penicillamines may cause a decrease effect in combined intake, these substances should be used with zinc salts at intervals for three hours.

High dosed of iron preparations inhibit the absorption of zinc, zinc intake can also reduce iron absorption.

Zinc may reduce the absorption of fluoroquinolones (ciprofloxacin, levofloxacin, moxifloxacin, norfloxacin and ofloxacin).
Calcium salts may reduce the absorption of zinc.
Oral contraceptives may reduce plasma zinc levels.
Wholemeal, fibrous foods and dairy products reduce the absorption of zinc.
Penicillamine and trientine: May reduce zinc absorption, as well as reduce the absorption of zinc penicillamine and trientine.
Antacids reduce the bioavailability of zinc sulfate.
Foods containing high phytic acid (inositol) and coffee form chelates with zinc compounds.
It should not be taken with food and drinks (except water) to ensure optimal absorption of zinc salts taken from the oral route.

Additional information on special populations
No interaction studies of specific populations have been performed.

Pediatric population
No interaction studies of the pediatric population have been performed.

4.6 Pregnancy and lactation
General advice
Pregnancy is category C.

Women with childbearing potential / Contraception
Oral contraceptives may reduce plasma zinc levels.
Women with potential for childbearing should take this medicine under the control of a doctor.

Pregnancy

ZINOBEST crosses to placenta; for this reason it should be taken for doctor control during pregnancy.

Studies on animals are insufficient in terms of effects on pregnancy / and / or / embryonal / fetal development / and / or / birth / and / or postnatal development.
The potential risk for humans is unknown.
ZINOBEST should not be taken during pregnancy unless it is necessary.

Lactation- Breastfeeding

ZINOBEST passes in to the breast milk; for this reason it should be used for doctor control during breastfeeding.

Reproductive ability/ Fertility

There is no effect on reproductive ability.

4.7 Effects on ability to drive and use machines

No research has been performed of the target population and the performance associated with vehicle or machine use.

4.8 Undesirable effects

The specified adverse effects are classified according to the following rule:

Very common (≥1/10); common (≥1/100 and < 1/10); uncommon (≥1/1.000 and <1/100); rare (≥1/10,000 and <1/1,000); very rare (<1/10,000), not known (cannot be estimated from the available data)

Blood and lymph system disorders

Uncommon: Neutropenia, leukopenia, anemia

Immune system disorders:

Very rare: Allergic reactions

Nervous system disorders:

Uncommon: Dizziness, headache, nervousness, drowsiness

Vascular disorders:

Very rare: Hypotension, arrhythmia, electrocardiographic changes in potassium deficiency

Gastrointestinal disorders:

Common: Vomiting

Uncommon: Nausea, abdominal pain, indigestion, gastric irritation, gastritis, dyspepsia, diarrhea

General disorders and application zone diseases:
Not known: Irritability, lethargy and headache
Prolonged use can lead to copper deficiency.

4.9 Overdose and treatment

If overdose is noticed, the following symptoms may be seen: Hypotension, dizziness, and vomiting.

Zinc sulfate is corrosive in overdose. Symptoms are corrosion of the mucous membrane of the mouth and stomach and inflammation; ulceration of the stomach followed by perforation may occur.

Gastric lavage and emesis should be avoided. Milk and water should be given immediately. Chelating agents such as sodium calcium edetate may be useful.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Mineral supports

ATC Code: A12CB01

Zinc is an essential trace element 0.3 mg per kg of body weight per day. Lettuce and green salads, brewer's yeast, liver, seafood and milk are the main zinc sources. There is about 2-3 mg of zinc in the litre of milk.

Zinc is necessary for more than 2000 metalloenzymine functions such as carbonic anhydrase, carboxypeptidase A, alcohol dehydrogenase, alkaline phosphatase, RNA polymerase.

Zinc is mainly used in the body for DNA, RNA and protein stabilization. Construction of nucleic acids, proteins and cell membranes; there is also a requirement for zinc to achieve physiological functions such as cell growth and division, sexual maturation and reproduction, wound healing, body immunity, adaptation to darkness and night vision, and the sense of taste and smell are complete. The biochemical functions of zinc are most pronounced in zinc deficiency. The most rapidly growing tissues (connective tissue in wound granulation, sperm, embryo, fetal cells) are affected by deficiency.

Acute toxicity of oral zinc compounds is low. For adults, 1-2 g of zinc sulfate (134-168 mL: 1.5-2.5 bottle syrup) intake at one time may cause toxic symptoms, 3-5 g of zinc sulphate (403-373 mL: 4-7 bottles of syrup) intake at one time may leads to death.

It has been reported that chronic toxicity symptoms, which may occur when taking high treatment doses (even at doses of 660 mg / day) for a long period of time, are not detected. Whether there is a decrease in plasma copper levels should be monitored.

5.2 Pharmacokinetic properties

General properties

Zinc sulphate heptahydrate, water-soluble white crystalline powder. ZINOBEST is a yellow, clear solution. The pH of the solution is 3.5-5.5.

Absorption:

When zinc is taken orally, it is absorbed by a specific mechanism from the small intestines (60% from duodenum, 30% from ileum, 10% from jejunum).It is sequestered by zinc binding proteins in the mucosa cells as iron and then transmitted to serum albumin through the mucosa cell membrane. Dietary zinc is transmitted to the plasma through the enterocyte by intraluminal communication.

Distribution:

The normal plasma concentration is between 0.7 and 1.5 g / ml, of which is transported 84% by albumine, 15% by α2-macroglobulin and 1% by amino acids. The plasma concentration of the patient receiving oral 50 mg zinc (equivalent to 220 mg zinc sulphate) reaches approximately 2.5 g / ml in 2-3 hours. The plasma half-life is 3 hours. Zinc in the blood is 80% in the carbonic anhydrase enzyme in erythrocytes, 3% in leukocytes and in small amounts in platelets. Dietary intake, hormones (glucocorticoids, glucagon, epinephrine), stress, inflammatory diseases affect the level of plasma zinc. When there is a deficiency, the loss of tissues are not the same; Hair, skin, heart and skeletal muscle remain the same, plasma, liver, bone and testicle zinc level decreases.

Biotransformation:

It does not metabolised, it is discarded unchanged.

Elimination:

Excretion from the gastrointestinal system was calculated to be 2.5 - 5.5 mg / day. The loss from kidney by tubular secretion is fixed; 300-700 micrograms / day. It is also excreted with sweat.

Linearity / Non-linearity:

Pharmacokinetics is linear. Plasma levels increase with given doses.

5.3 Preclinical safety data

None stated.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose

Sodium benzoate

Orange flavor

Quinoline yellow

HCl (0,1 N)

Purified water

6.2. Incompatibilities

There is no evidence that ZINOBEST is incompatible with any drug or substance.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Keep it in its package at room temperature below 25°C.

6.5 Nature and contents of container

Type II colored glass bottle with PE vistop cap.
In a 100 ml colored bottle, it is presented with a 5 ml 1/2 ml and 1/4 ml measure spoon and 1 5 ml pipette.

6.6 Special precautions for disposal and other handling

Unused products or waste materials are disposed of in accordance with the "Medical Waste Control Regulation" and "Packaging and Packaging Waste Control Regulation".

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

222/97

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 31.12.2009

Renewal of the authorisation:

10. DATE OF REVISION OF THE TEXT

27.12.2016