SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT
ZINCO 30 mg Fort syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 5 ml (1 spoon) syrup contains

Active substance(s):
30 mg zinc (as 132 mg zinc sulphate heptahydrate).

Excipient(s):

Sorbitol (%70) (E420)	750.0 mg
Sucrose	250.0 mg
Fructose	500.0 mg
Sodium cyclamate	5.0 mg
Sodium hydroxide	100.0 mg
Methyl paraben sodium (E219)	5.0 mg
Sunset yellow (E110)	0.03 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Syrup
Yellow solution with aromatic odor (orange)

4. CLINICAL PARTICULARS
4.1. Therapeutic indications
It is used for the treatment or prevention of zinc deficiency.

4.2. Posology and method of administration
Posology/ frequency of administration and duration of the treatment
Unless otherwise recommended by the doctor, it is used once a day as indicated below.

Age	Recommended amount (mg/day)	Tolerated maximum amount (mg/day)	Dose
7-12 months	3	5	0,5 mL
1-3 years	3	7	0,5-1 mL
4-8 years	5	12	1,5-2 mL
9-13 years	8	23	2,5-3 mL
14-18 years	11	34	3-5 mL
Over 19 years	11	40	5-6 mL

Method of administration:
For oral use only.
It can be taken before, after, or during the meals with measuring pipette.

Additional information for special populations:
Renal/hepatic failure:
The efficacy and safety of zinc in patients with renal and hepatic insufficiency have not been studied.

In renal failure, accumulation of zinc in the body may increase, so caution should be exercised in cases of renal failure.

Pediatric population:
Zinc should be administered to pediatric patients as described in the posology section. It should not be used in infants between 0-6 months, since dose adjustment cannot be made unless recommended otherwise by the doctor.

Geriatric population:
The safety and efficacy of zinc in elderly have not been evaluated.

4.3. Contraindications
It is contraindicated in patients who are allergic to zinc salts or any of the other ingredients of the syrup.

4.4. Special warnings and precautions for use
It is not appropriate to use zinc in adult diarrhea of unknown cause.

Products containing 30 mg of zinc are not suitable for use in the treatment of pediatric diarrhea due to the high amount of zinc given at one time.

It can be used with foods, but concomitant intake of zinc with food rich in calcium, phosphorus or phytate should be avoided. The use of the drug should be discontinued and a doctor should be consulted in patients who develop severe nausea, vomiting or acute dyspepsia.

Long-term or high-dose intake may be associated with copper deficiency.

This medicinal product contains 58.8 mg sodium in every 5 ml. This should be considered for patients on a controlled sodium diet.

Patients with rare hereditary fructose intolerance, glucose-galactose malabsorption, or sucrase-isomaltase insufficiency should not use this medication because of the content of sucrose, fructose and sorbitol.

This medicinal product contains sunset yellow (E110) which may cause allergic reactions.

This medicinal product contains methyl paraben which may cause allergic reactions (possibly delayed.

4.5. Interaction with other medicinal products and other forms of interaction
Concomitant intake of zinc salts with tetracyclines and penicillamines may reduce the efficacy of zinc; therefore a 3-hour interval should be allowed between the intake of these agents and zinc salts.

High doses of iron preparations inhibit the absorption of zinc, and zinc uptake may reduce iron absorption.

Zinc may reduce the absorption of fluoroquinolones (ciprofloxacin, levofloxacin, moxifloxacin, norfloxacin, and ofloxacin).

Oral contraceptives may reduce plasma zinc levels.

Food rich in whole or fiber as well as dairy products may reduce zinc absorption.

Calcium salts may reduce zinc absorption.

It can reduce the absorption of sparfloxacin when using zinc over 30 mg per day. Therefore ZINCO FORT should be taken at least 2 hours after sparfloxacin.

Penicillamine and trientin may reduce zinc absorption; also zinc may reduce the absorption of these two agents.

Antacids reduce the bioavailability of zinc sulfate.

Also food rich in phytic acid (inositol) and coffee may form chelate with zinc compounds. In order to ensure optimum absorption of oral zinc salts, zinc salts should not be taken with foods and drinks (except for water).

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

Pediatric population
No interaction studies on pediatric populations have been performed.

4.6. Fertility, pregnancy and lactation
Pregnancy category C.

Women of childbearing potential/Birth control (contraception)
Oral contraceptives may reduce plasma zinc levels.
Zinc supplementation in women of childbearing potential should be supervised by a physician.

Pregnancy
ZINCO FORT should be used under medical supervision during pregnancy.
Animal studies are insufficient with respect to effects on pregnancy /and-or/ embryonal/foetal development/ and-or/ parturition/ and-or/ postnatal development. The potential risk for humans is unknown.

ZINCO FORT should not be used during pregnancy unless clearly necessary.

Its safety in pregnancy has not been proven. Zinc passes into the placenta and breast milk.

Pregnant and lactating mothers can use it under the supervision of a doctor. At the end of the studies, it was understood that the need for Zn^{2+} increased in pregnant women. It should be used in pregnant women after risk/benefit assessment by the doctor.

Breast-feeding
ZINCO FORT is excreted in human breast milk. Thus, it should be used under medical supervision during lactation.

Fertility
There is no impact on the reproductive capability.

4.7. Effects on ability to drive and use machines
There were no investigations on the ability to drive and use machines for the target population.

4.8. Undesirable effects
The specified undesirable effects listed are classified according to the following rules:
Very common (≥1/10); common (≥1/100 to <1/10); not common (≥1/1.000 to <1/100); rare (≥1/10.000 to <1/1.000); very rare (<1/10.000), not known (can not be estimated based on available data).

Blood and lymphatic system disorders:
Not common: Neutropenia, leukopenia-anemia

Immune system disorders:
Very rare: Allergic reactions

Nervous system disorders:
Not common: Dizziness, headache, nervousness, drowsiness

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

Gastrointestinal disorders:
Common: Vomiting
Not common: Nausea, abdominal pain, indigestion, gastric irritation, gastritis, dyspepsia, diarrhea

General disorders and administration site conditions:
Not known: Irritability, lethargy and headache
Long-term intake may be associated with copper deficiency.

4.9. Overdose and treatment
In case of overdose the following symptoms may occur: hypotension, dizziness, drowsiness and vomiting.

Zinc sulphate is corrosive in overdose. 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. Preservatives as milk and water should be given. Chelating agents such as sodium calcium edetate may be useful.

5. PHARMACOLOGICAL PROPERTIES
5.1. Pharmacodynamic properties
Pharmacotherapeutic group: Mineral supplements
ATC Code: A12CB01

Zinc is an essential trace element with the required daily amount of 0.3 mg/kg body weight. The major sources of zinc are lettuce and green salad, brewer's yeast, liver, sea foods and milk. Milk contains about 2-3 g/liter of zinc.

Zinc is required in order to perform the function of metalloenzymes of more than 2000 such as carbonic anhydrase, carboxypeptidase A, alcohol dehydrogenase, alkaline phosphatase and RNA polymerase. Zinc is mainly used in stabilization of DNA, RNA and protein throughout the body. It is also required to form structure in nucleic acids, proteins and cell membranes and is involved in physiological functions such cell growth and division, sexual maturation and reproduction, wound healing, immunity, dark adaptation and scotopic vision, normal taste and smell perception. The biochemical functions of zinc are becoming more apparent in zinc deficiency. The most affected tissues from zinc deficiency are fast-growing tissues (connective tissue in the wound granulations, sperm, embryo, fetal cells).

Acute toxicity of oral zinc compound is low. For adults, the use of the 1-2 g of zinc sulphate (134-168 ml:1.5-2.5 syrup bottle) at a time and the use of the 3-5 g of zinc sulphate (403-373 ml:4-7 syrup bottle) at a time may lead to toxic symptoms and death, respectively.

It has been noted that symptoms of chronic toxicity which may occur with oral administration of the high therapeutic doses (even at doses of 660 mg/day) for a long time were not detected. It should be monitored whether the plasma copper levels are decreased.

5.2. Pharmacokinetic properties

General characteristics

Zinc sulfate heptahydrate is a water-soluble white crystalline powder. ZINCO FORT is a yellow and clear solution. The pH of the solution is 3.0 – 6.0.

Absorption:

Oral zinc is absorbed by a specific mechanism from the small bowel (60% in duodenum, 30% in ileum and 10% in jejunum). Like iron, it is isolated in mucosal cells by the zinc-binding proteins and then transmitted to serum albumin in blood through mucosal cell membrane. The dietary zinc is transferred to plasma by passing the enterocyte with intraluminal message.

Distribution:

Normal plasma concentration is between 0.7 and 1.5 g/ml. The 84% of zinc is bound to albumin in plasma, %15 bound to α2-macroglobulin and %1 bound to amino acids. The plasma concentration of a patient received 50 mg of oral zinc (equivalent to 220 mg of zinc sulphate) is reached to 2.5 g/ml in 2-3 hours. The plasma half-life is 3 hours. In human blood, 80% of the zinc is found in carbonic anhydrase enzyme in erythrocytes, 3% in leukocytes, and a small amount in platelets. Dietary zinc, hormones (glucocorticoids, glucagon, epinephrine), stress, inflammatory diseases affect the zinc level in plasma.

In case of the zinc deficiency, the loss in each tissue is different; zinc level in plasma, liver, bone and testis decreases while remains same in hair, skin, hearth and skeletal muscle.

Biotransformation:

It does not undergo biotransformation and is excreted unchanged.

Elimination:

The 2.5-5.5 mg/day of zinc is excreted from the gastrointestinal tract. Renal excretion is the fixed amount in tubular secretion with the 300-700 microgram/day. It is also excreted in sweat.

Linearity/Non-linearity:
The pharmacokinetics is linear. Plasma levels show an increase depending on the administered doses.

5.3. Preclinical safety data
Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients
Xylitol
Sorbitol (%70) (E420)
Fructose
Sodium cyclamate
Citric acid monohydrate
Sodium hydroxide
Methyl paraben sodium (E219)
Sucrose
Orange aroma
Sunset yellow (E110)
Deionized water

6.2. Incompatibilities
There was no evidence for the incompatibilities of ZINCO FORT with any drug or substance.

6.3. Shelf life
24 months

6.4. Special precautions for storage
Store at room temperature below 25°C.

6.5. Nature and contents of container
Each box contains an amber-colored glass bottle (Type III) with a pilfer-proof HDPE cap and a 5 ml pipette.

6.6. Special precautions for disposal
Any unused product or waste material should be disposed of in accordance with “Directive on Control of Medical Waste” and “Directive on the Control of Packaging and Packaging Waste”.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

219/14

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: 14.05.2009
Date of latest renewal: 20.07.2015

10. DATE OF THE REVISION OF THE TEXT

11.05.2020