# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE MEDICINAL PRODUCT

ZINCO 50 mg hard capsules

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each one capsule contains

**Active substance:**
137.3 mg zinc sulphate monohydrate equivalent to 50 mg zinc.

**Excipients:**
Lactose (derived from cow milk) 100 mg
Carmoizine (E122) 0,58 mg

For a full list of excipients, see Section 6.1.

## 3. PHARMACEUTICAL FORM

Capsule
White powder in red hard gelatin capsules.

## 4. CLINICAL PARTICULARS

### 4.1. Therapeutic indications

It is used in the prevention and treatment of zinc deficiency or in acrodermatitis enteropathica and Wilson's disease.

### 4.2. Posology and method of administration

**Posology/ frequency and duration of administration**
*- In the prevention and treatment of zinc deficiency:*
For adults, the daily dose is 1 capsule, unless otherwise specified by the doctor.

*-In Wilson's disease:*
In children
It is used in three divided doses of 150 mg/day in individuals >16 years of age or >50 kg.

In adults
The daily dose is 150 mg; in 3 divided doses

*- In acrodermatitis enteropathica disease:*
In children
It is used at a dose of 1-3 mg/kg/day.

In adults
It is recommended to use 50-150 mg per day.

**Method of administration**
For oral use only.
It can be taken with meals.

**Additional information on special populations:**

**Renal/Hepatic failure:**
The safety and efficacy of ZINCO in patients with renal and hepatic failure have not been evaluated.

In kidney failure, the accumulation of zinc in the body may increase, so care should be taken in cases of kidney failure.

**Pediatric population**:
It is used as indicated in the posology section in children.

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

**4.3. Contraindications**

It is contraindicated in patients who are allergic to zinc sulphate or any of the other ingredients.

**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 meals, but its use with foods rich in calcium, phosphorus or phytate should be avoided. severe nausea, vomiting or acute indigestion; In patients who develop easy injury or bleeding, the use of the drug should be stopped and a doctor should be consulted.

Taking it for a long time or in high doses can cause copper deficiency.

ZINCO may cause allergic reactions due to the carmoizine (E122) it contains.

As this medicinal product contains lactose, patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

**4.5. Interaction with other medicinal products and other forms of interaction**
Co-administration of zinc salts with tetracyclines and penicillamines may lead to reduced effects, these substances should be used with zinc salts every three hours.

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

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

Oral contraceptives can reduce plasma zinc levels.

Wholegrain, fibrous foods and dairy products reduce the absorption of zinc.

The absorption of zinc may be reduced by calcium salts.

Zinc above 30 mg per day may reduce the absorption of sparfloxacin, so ZINCO should be taken at least 2 hours after sparfloxacin.

Penicillamine and trientine: It can reduce the absorption of zinc, likewise, zinc can decrease the absorption of penicillamine and trientine.

Antacids reduce the bioavailability of zinc sulfate.

Foods containing high phytic acid (inositol) and coffee form chelates with zinc compounds. To ensure optimum absorption of orally ingested zinc salts, it should not be taken with food and drink (other than water).

**Additional information on special populations:**
There were no interaction studies for special populations.

**Pediatric population:**
There were no interaction studies for pediatric population.

**4.6. Pregnancy and lactation**
**General recommendation**
Pregnancy category C

**Women with childbearing capacity/Birth control (Contraception)**
Women of childbearing potential/There is no specific warning for contraception.

**Pregnancy**
Animal studies are inconclusive regarding effects on pregnancy /and-or / embryonal / fetal development / and– or / parturition / and-or / postnatal development. The potential risk for humans is unknown.

It should not be used during pregnancy unless it is necessary.

The safety of ZINCO in pregnancy has not been established. Zinc passes into the placenta and breast milk**.**

Pregnant and lactating mothers can use this medicine under the control of a doctor. Studies have indicated that Zn2 + requirement is increased in pregnancy. It should be used in pregnant women after the risk-benefit assessment performed by a doctor.

**Lactation**
Zinc passes into breast milk.
It should not be used during lactation unless it is necessary.

**Reproduction/Fertility**
There is no impact on the reproductive capability.

**4.7. Effects on ability to drive and use of machines**

There were no investigations on the ability to drive and use machines for the target population. It is not expected to affect the ability to drive and use machines.

### 4.8. Undesirable effects

The undesirable effects associated with treatment during clinical trials were classified according to the following frequencies:
Very common (≥ 1/10), common (≥ 1/100 to ≤1/10), uncommon (≥ 1/1.000 to ≤ 1/100), rare (≥ 1/10.000 to ≤1/1.000), very rare (≤ 1/10.000), and unknown (cannot be estimated based on the data available).

**Blood and lymphatic system disorders:**
Uncommon: Neutropenia, leukopenia

**Immune system disorders:**
Very rare: Allergic reactions

**Nervous system disorders:**
Uncommon: Dizziness

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

**Gastrointestinal disorders:**
Uncommon: Nausea, vomiting, abdominal pain, dyspepsia, diarrhea, gastric irritation, gastritis.
The cases of irritability, lethargy and headache have also been observed.
Long-term use can lead to copper deficiency.

### 4.9. Overdose

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 should be given. Chelating agents such as sodium calcium edetate may be useful.

## 5. PHARMACOLOGIC PARTICULARS

### 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 200 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 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 – One-time toxic dose: Acute toxicity of oral zinc compound is low. In adults, the use of the 1-2 g of zinc sulphate (8-16 capsules) at a time and the use of the 3-5 g of zinc sulphate (24-40 capsules) at a time may lead to toxic symptoms and death, respectively.

Chronic toxicity: 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

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, of which 84% is transported by binding to albumin, 15% by binding to α2-macroglobulin and %1 by binding to amino acids. The plasma concentration of a patient received 50 mg of oral zinc 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:
Zinc does not undergo any biotransformation.

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 available.

## 6. PHARMACEUTICAL PARTICULARS
### 6.1. List of excipients

Capsule content
Corn starch
Lactose (derived from cow milk)
Magnesium stearate
Talc

Capsule shell
Gelatin (bovine gelatin)
Carmoisine (E122)
Titanium dioxide (E171)

### 6.2. Incompatibilities

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

### 6.3. Shelf life

60 months

### 6.4. Special precautions for storage

Store in room temperature below 25°C. Keep out of the sight and reach of children and store in the original package.

### 6.5. Nature and contents of container

ZINCO is available in PVC/Aluminum blisters. Each box contains 30 or 40 capsules.
Not all pack sizes may be marketed.

### 6.6. Special precautions for disposal and other handling

6.7. 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 AUTHORIZATION HOLDER

Berko İlaç ve Kimya Sanayi A.Ş.
Yenişehir Mah. Özgür Sok. No: 16-18 Ataşehir/İstanbul-Turkey
+90 216 456 65 70 (Pbx)
+90 216 456 65 79 (Fax)
info@berko.com.tr

## 8. MARKETING AUTHORIZATION NUMBER(S)

178-10

## 9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

Date of the first authorization: 24.04.1996
Date of the renewal of the authorization: 13.05.2010

## 10. DATE OF REVISION OF THE TEXT

11.05.2020