

PATIENT INFORMATION LEAFLET

ZINCO 15 mg/5 ml syrup

For oral use only.

- **Active substances:** Each 5 ml syrup (one dose) contains 66 mg zinc sulfate heptahydrate equivalent to 15 mg zinc.
- **Excipient(s):** Contains sucrose, methyl paraben (E218), glycerin, orange flavor, sunset yellow (E110) and deionized water.

Read all of this PATIENT INFORMATION LEAFLET carefully before you start taking this medicine, because it contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *When you go to a doctor or hospital while using this medicine, tell your doctor that you are receiving this medicine.*
- *Follow strictly what has written on this leaflet. Do not use **higher or lower** dose other than the dose which was recommended for you.*

What is in this leaflet:

1. *What ZINCO is and what is it used for?*
2. *What you need to know before you use ZINCO?*
3. *How to use ZINCO?*
4. *Possible side effects*
5. *How to store ZINCO?*

1. What ZINCO is and what is it used for?

- ZINCO is a zinc containing syrup. It is available in amber colored bottles of 100 ml with a measuring spoon of 5 ml and pipette of 5 ml.
- It is used for the treatment or prevention of zinc deficiency and the treatment of diarrhea.

2. What you need to know before you use ZINCO?

DO NOT use ZINCO

If;

- You are allergic (hypersensitive) to zinc salts or any of the other ingredients of the ZINCO.

Use ZINCO with CAUTION

Due to insufficient number of studies in individuals with renal or hepatic impairment, please consult with your doctor if you have such a disorder.

Long-term intake may be associated with copper deficiency.

Please consult your doctor, even if these statements were applicable to you at any time in the past.

Using ZINCO with food and drink

Since concomitant intake of zinc with high-fiber food, whole meal bread and dairy products decrease the absorption of zinc, you should not take ZINCO together with these types of food.

Also food rich in phytic acid (inositol) such as wheat bran, flaxseed, cereals, legumes and coffee may decrease the absorption of zinc compounds. In order to ensure maximum absorption of zinc salts which are orally taken it should not be with foods and drinks (except for water).

Pregnancy

Ask your doctor or pharmacist for advice before using the medicine.

Zinc supplementation during pregnancy should be supervised by a physician.

If you notice that you are pregnant during treatment, please consult your doctor or pharmacist immediately.

Breast-feeding

Ask your doctor or pharmacist for advice before using the medicine.

Zinc supplementation during breastfeeding should be supervised by a physician.

Driving and using machines

No studies have been carried to test its effects on the ability to drive or use machinery.

Important information about some of the excipients of ZINCO

Due to sucrose its content if previously you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking these tablets.

If you receive more than 10 grams/dose of glycerin contained in it headache, nausea and diarrhea may occur.

This medicinal product contains methyl paraben (E218) which may cause allergic reactions (possibly delayed).

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

Using with other medicines

Concomitant intake of zinc salts with tetracyclines (a type of antibiotic) or penicillamine (an anti-inflammatory agent) may reduce the efficacy of zinc; therefore a 3-hour interval should be allowed between the intake of these agents and zinc.

Products containing high dose iron should not be taken with zinc, as they may reduce zinc absorption.

Zinc may reduce the absorption of fluoroquinolones (ciprofloxacin, levofloxacin, moxifloxacin, norfloxacin and ofloxacin), a class of antibiotics used for the treatment of diseases caused by bacteria.

Calcium salts may reduce zinc absorption.

Contraceptives may reduce plasma zinc levels.

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

Penicillamine and trientine which are drugs used in the treatment of excessive copper accumulation in the body and the resulting Wilson's disease may reduce zinc absorption and also zinc may reduce the absorption of these two agents.

Drugs that reduce gastric acid (antacids) may reduce the rate and extent of zinc sulfate absorption.

Please tell your doctor or pharmacist if you are taking or have recently taken any other prescription or nonprescription medicine.

3. How to use ZINCO?

- **Instructions for appropriate method dose/frequency of administration:**

In adults, ZINCO may be given before, after, or during the meals using a spoon or pipette.

Unless recommended otherwise by your doctor, use as specified below:

Age	Elementary zinc (mg)	Tolerated dose (mg)	Dose
6-12 months	3	5	1.5 ml with pipette
1-3 years	3	7	2 ml with pipette
4-8 years	5	12	4 ml with pipette
9-13 years	8	20	6 ml with pipette
14-18 years	10	30	2 dose (spoon) or 10 ml with pipette
≥19 years adults	10	40	13 ml with pipette

- **Route and method of administration:**

ZINCO is for oral use only.

The syrup is taken using the measuring spoon or measuring pipette.

- **Various age groups:**

Use in children:

Use in children is as shown in the table above.

Use in elderly:

The safety and efficacy of ZINCO in elderly have not been examined.

- **Special usage condition**

Kidney/Liver failure:

The safety and efficacy of ZINCO in individuals with renal or hepatic failure have not been examined.

The accumulation of zinc in the body may increase in kidney failure. Therefore, if you have kidney failure, you should be careful.

If you have the impression that the effect of ZINCO is too strong or too weak, talk to your doctor or pharmacist.

If you have used more ZINCO than you should:

If you may have taken more ZINCO than you should, talk to a doctor or pharmacist.

In cases of overdose symptoms such as low blood pressure, dizziness, drowsiness and vomiting may occur.

If you forget to use ZINCO

Do not take double dose to balance the missed doses.

If you stop using ZINCO

Do not stop using ZINCO before consulting with your doctor.

4. Possible side effects

Like all medicines, ZINCO may cause side effects in some patients who are sensitive to the substances contained in ZINCO.

Side effects are classified according to frequency of occurrence as follows:

Very common: may be seen at least 1 in 10 patients.

Common: may be seen less than 1 in 10 patients but 1 in 100 patients or more than 1.

Uncommon: may be seen less than 1 in 100 patients but 1 in 1.000 patients or more than 1.

Rare: may be seen less than 1 in 1.000 patients but 1 in 10.000 patients or more than 1.

Very rare: may be seen less than 1 in 10.000 patients.

Unknown: it cannot be estimated from the available data.

Stop using ZINCO and inform your doctor IMMEDIATELY or contact your nearest hospital emergency department, if you notice any of the following serious side effects:

- Hypersensitivity reaction (difficulty in breathing and swallowing, swelling in the hands/feet, face/lips, rash, faintness etc.)

These are all very serious side effects. If you have any of these, you have a severe allergy to ZINCO and you may need urgent medical treatment or hospitalization.

These very severe side effects occur extremely rarely.

If you notice any of the followings, inform your doctor immediately or contact your nearest hospital emergency department:

- Low blood pressure (hypotension), irregular heartbeat (arrhythmias)

These are all very serious side effects. You may need urgent medical treatment.

These very severe side effects occur extremely rarely.

If you notice any of the following, please tell your doctor:

Common:

- Vomiting

Uncommon:

- Changes in blood count parameters (neutropenia, leukopenia, anemia)
- Nausea
- Abdominal pain
- Dyspepsia
- Gastric sensitivity
- Inflammation of the gastric mucosa (gastritis)
- Diarrhea
- Dizziness
- Headache
- Nervousness
- Paresthesia, drowsiness

These represent mild side effects of ZINCO.

These side effects resolve upon dose reduction or cessation of therapy.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store ZINCO?

Keep out of the sight and reach of children and store in the original package.

Store below 25°C at room temperature.

Use in accordance with expiry date.

Do not use ZINCO after the expiry date.

Do not use ZINCO if you notice any damage on product and/or packaging.

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

Manufacturer:

Berko İlaç ve Kimya Sanayi A.Ş.

Adil Mah. Yörükler Sok. No: 2 Sultanbeyli/İstanbul-Turkey

+90 216 592 33 00 (Pbx)

+90 216 592 00 62 (Fax)

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