

PATIENT INFORMATION LEAFLET

ZINCO-K 15 mg/5 ml syrup

For oral use.

- **Active substance:** Each 5 ml (1 spoon) syrup contains 66 mg zinc sulfate heptahydrate equivalent to 15 mg zinc.
- **Excipients:** Sorbitol (70%) (E420), maltitol (E965), citric acid monohydrate, methyl paraben (E218), glycerin, orange flavor, sunset yellow (E110) and purified water.

Read this PATIENT INFORMATION LEAFLET carefully before you start using 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, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others.*
- *If you go to a doctor or hospital during the use of this medicine, inform your doctor about this.*
- *Follow the instructions in this leaflet exactly. Do not use **higher or lower** doses than the dose which was recommended for you.*

What is in this leaflet:

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

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

- ZINCO-K, is a syrup that contains zinc and in PET spoon closed with aluminum, in each spoon (5 ml) contains 66 mg zinc sulfate heptahydrate equivalent to 15 mg zinc.
- In each box; Each containing 20 or 28 spoons of 5 ml for single use. Each form of presentation is also packed in PVC separator.
- It is used in the treatment or prevention of zinc deficiency and in the treatment of diarrhea in children.

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

DO NOT use ZINCO-K

If;

- You have a hypersensitivity to zinc salts or any ingredient of ZINCO-K

Use ZINCO-K with CAUTION

It is not appropriate to use zinc in the treatment of adult diarrhea of unknown cause.

Since the amount of zinc given at one time is high in products containing 30 mg of zinc, it is not suitable for use in the treatment of diarrhea in children.

It is suitable to use from 6 months of age in products containing zinc (pipette / syringe) where dosage can be adjusted.

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.

Talk to your doctor if you suffer from kidney and liver disease, because there is no adequate study on those who have kidney and liver disorders.

In case of kidney failure, the accumulation of zinc may increase, therefore it should be used carefully in case of kidney failure.

Long-term usage may cause copper failure.

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

Using ZINCO-K with food and drink

ZINCO-K should not be used with whole-wheat, fibrous foods and milk products, because they decrease the absorption of zinc.

Foods (like whole wheat, flaxseed, cereals, pulses) containing high phytic acid (inositol) and coffee reduce the absorption of zinc compounds. It should not be used with food and drink (except water) to provide the most effective absorption of orally usage zinc salts.

Pregnancy

Consult your physician or your pharmacist before using the medicine.

In case of necessity in pregnancy term, take this medicine under control of your doctor.

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

Breast-feeding

Consult your doctor or pharmacist before using this medicine.

In case of necessity in breast-feeding term, take this medicine under control of your doctor.

Driving and using machines

No study was conducted about its effect on driving and using machines.

Important information about some of the excipients in ZINCO-K

Due to the content of sorbitol (E420) and maltitol (E965), if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Methyl paraben (E218) as ingredient may cause allergic reactions (possibly delayed).

Sunset yellow (E110) as ingredient may cause allergic reactions.

Using with other medicines

The concurrently administration of tetracyclines (as one of antibiotic) and penicilamine (as an agent prevents inflammation) with zinc salts, may cause decrease in efficacy; therefore these medicines should be used with zinc salts at intervals of three hours.

Since high dose of iron preparations decreases the absorption of zinc, they should not be used concurrently.

Zinc may decrease the absorption of the drugs used in the treatment of diseases originated from bacteria in fluoroquinolones group (ciprofloxacin, levofloxacin, moxifloxacin, norfloxacin and ofloxacin).

The absorption of zinc may be reduced by calcium salts.

Contraceptive drugs may decrease the absorption of zinc.

Whole-wheat, fibrous foods and milk products decrease zinc absorption.

Penicilamine and trientine (used in the treatment of high amount of copper accumulation in the body, Wilson disease) may decrease zinc absorption, in the same way zinc may decrease penicilamine and trientine absorption.

Antacids (drugs reducing stomach acidity) decreases the absorption rate and amount of zinc sulfate.

Absorption of sparfloxacin which is an antibiotic, may be reduced when zinc is used over 30 mg daily. Therefore ZINCO-K should be used at least 2 hours after sparfloxacin.

Please tell your doctor or pharmacist if you are currently taking or have recently taken any other medicines, with or without a prescription.

3. How to use ZINCO-K?

- **Instructions for suitable usage and dose/application frequency:**

ZINCO-K in adults is used before or after the meal or with the meal.

Unless recommended otherwise by the doctor, use the specified doses.

Age	Recommended dose (mg/day)	Tolerable maximum dose (mg/day)	Measure
9-13 years old	8	23	1 spoon (15 mg)
14-18 years old	11	34	1-2 spoons (15 mg-30 mg)
Over 19 years old	11	40	1-2 spoons (15 mg-30 mg)

Zinc can be used as an adjunct to the treatment of diarrhea in children older than 6 months, provided that it is not longer than 7 days and not more than 20 mg/day.

- **Route of administration and method:**

ZINCO-K is only for oral use.

It is drunk directly from the spoon.

- **Various age groups:**

Use in children:

Zinc should be administered to pediatric patients as described in the "Instructions for suitable usage and dose/application frequency". It should not be used in infants aged 0-6 months, since dose adjustment cannot be made, unless recommended otherwise by the doctor.

Use in elderly:

The safety and efficacy of ZINCO-K were not studied in elder patients.

• Special usage cases:

Kidney/Liver failure:

The safety and efficacy of zinc were not studied in patients with kidney and liver failure.

In case of kidney failure, accumulation of zinc may increase, therefore it should be used carefully in case of kidney failure.

If you have the impression that effect of ZINCO-K is too weak or strong, talk to your physician or pharmacist about it.

If you used more ZINCO-K than you should:

If you have used more than you should from ZINCO-K, talk to a physician or a pharmacist.

If you take the syrup as overdose, the symptoms like decrease in tension, dizziness, feeling of dizziness and vomiting may be observed.

If you forget to use ZINCO-K:

Do not take a double dose to balance out the forgotten dose.

If you stop using ZINCO-K:

Do not withdraw the treatment without consulting your doctor.

4. Possible side effects

Like all medicines, ZINCO-K can cause side effects in people sensitive to the ingredients in its contents.

Side effects were listed as shown in the following categories:

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 more than 1 in 1.000 patients or more than 1.

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

If you notice any of the following immediately inform your doctor or go to the nearest emergency department:

- Oversensitive reaction (like difficulty in swallowing and breathing, hand-foot, face-lips swelling, purpura, faint)
- Hypotension, irregular heartbeat (arrhythmia)

These are all very serious side effects. If you have one of them, you may need emergency medical attention or hospitalization may be required.

These very severe side effects have been seen quite rarely.

If you notice any one of the following, consult your doctor:

Common

- Vomiting

Uncommon

- Blood table changes (neutropenia, leucopenia, anemia)
- Nausea
- Stomachache
- Indigestion
- Stomach sensitivity
- Inflammation in stomach mucosa (gastritis)
- Diarrhea
- Dizziness
- Headache
- Irritability
- Drowsiness

Very rare

- Electrocardiographic (electrical activity of the heart) changes in potassium deficiency

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

5. How to store ZİNCO-K?

Keep ZİNCO-K in the original package and out of the reach and sight of children.

Store at room temperature below 25°C.

Use in accordance with expiry date.

Do not use ZİNCO-K after the expiry date which is stated on the package.

Do not use ZİNCO-K if you notice any damage to the product and/or package.

Marketing authorization holder:

Berko İlaç ve Kimya Sanayi A.Ş.
Yenişehir Mah. Özgür Sok. No: 16-18
Ataşehir/İstanbul-Türkiye
+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-Türkiye
+90 216 592 33 00 (Pbx)
+90 216 592 00 62 (Fax)

This patient information leaflet was last approved on 08/06/2020.