

PATIENT INFORMATION LEAFLET

ZINCO-K 15 mg/5 mL syrup

Oral administration.

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

Read all of this 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 additional questions, please contact your physician or pharmacist.*
- *This medicine has been prescribed personally for you . Do not give it on to others.*
- *During the use of this drug product, when you visit a physician or go to a hospital, tell your physician that you are using this drug.*
- *Please completely follow the instructions in this information leaflet. Do not use **higher or lower** doses other than what is recommended to you.*

In this leaflet:

1. **What is ZINCO-K and what is it used for?**
2. **Things to pay attention to before using ZINCO-K**
3. **How is ZINCO-K used?**
4. **What are the probable side effects?**
5. **Store of ZINCO-K**

Titles are included.

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 15 mg zinc equivalent to 66 mg zinc sulfate heptahydrate.
- In each box; Each containing 20 or 28 spoons of 5 ml in one use. 20 spoons are also packed in PVC separator.
- It is used for the treatment or prevention of zinc deficiency.

2. Before you take ZINCO-K

Do not take ZINCO-K in the conditions below

If;

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

Take special care with ZINCO-K in the conditions below

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.

These alerts at any time in the past even if it is true for you, please consult your doctor.

Taking 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 administered 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 excipients in ZINCO-K

Due to sorbitol and maltitol in its contents, If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

It contains less than 10 g of glycerin in a 5 ml dose. No negative effect due to glycerin as a cause of dose is expected.

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

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

Taking 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 of the product ; when both are being given an interval of at least three hours should be allowed.

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 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.

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 ZINCO-K used?

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

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

Unless otherwise the doctor recommended use in doses mentioned below.

Age	Elemental Zinc (mg)	Tolerable Dose (mg)	Spoon
9-13 ages	8	20	1
14-18 ages	10	30	2
19-above adults	10	40	2

- **Route of administration and method:**

ZINCO-K is only for oral administration.

It is administered directly from the spoon.

- **Different age groups:**

- Usage in children:**

Usage in children is as mentioned above.

- Usage in elders:**

The safety and efficacy of ZINCO-K was not studied on elder patients.

- **Special populations:**

- Kidney/Liver failure:**

The safety and efficacy of ZINCO-K was not studied on 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 take 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 take ZINCO-K:

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

Possible effects may occur when ZINCO-K treatment is stopped:

Do not take a double dose to make up for a forgotten dose.

4. What are the probable side effects?

Like all medicines, side effects can occur in those who are hypersensitive to any ingredient in ZINCO-K.

Side effects can be classified as:

Very common (can be observed in at least one in 10 patients)

Common (can be observed less than one in 10 patients, however more than one in 100 patients)

Uncommon (can be observed less than one in 100 patients, however more than one in 1000 patients)

Rare (can be observed less than one in 1000 patients, however more than one in 10000 patients)

Very rare (can be observed in at least one in 10000 patients)

Not known (cannot be estimated from the available data)

If any of the following takes place, stop using ZINCO-K and immediately contact your physician or apply to the emergency department of the nearest hospital:

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

These are all very serious side effects. If you have any of them, this means you have serious allergy to ZINCO-K. You may need emergency medical care or hospitalization.

These very severe side effects have been seen quite rarely.

If you experience any of the following side effects, immediately contact your physician or apply to the emergency department of the nearest hospital:

- Hypotension, irregular heart beat (arrhythmia)

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

The serious side effects are observed very rarely.

If you experience any one of the followings tell your doctor immediately:

- Vomiting
- Blood table changes (neutropenia, leucopenia, anemia)
- Nausea
- Stomachache
- Indigestion
- Headache
- Feeling of nervous and dizziness
- Hypokinemia
- Stomach sensitivity

- Inflammation in stomach mucosa (gastritis)
- Dizziness
- Diarrhea

These are mild side effects of ZINCO-K.

These side effects disappear when the dose is decreased or the treatment is stopped.

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

Reporting side effects

If you have any side effect that is mentioned or not mentioned in this leaflet, contact your doctor, pharmacist or nurse. Moreover, notify the side effects that you face to Turkish Pharmacovigilance Center (TUFAM) by clicking “Side effect notification” icon in www.titck.gov.tr website or calling 0 800 314 00 08 side effect notification line. You will contribute to be taken more information about safety of the medicine that you are using by notifying the side effects occur.

5. Storage of ZINCO-K

Store ZINCO-K in the package and keep out of the reach and sight of children.

Keep at room temperature under 25°C.

Do not use ZINCO-K after the expiry date.

Use ZINCO-K before the expiry date stated on the blister or package.

Do not use ZINCO-K if you notice that the pack is damaged or shows signs of tampering.

Do not throw away drugs that have expired or are not used! Deliver to the collection system determined by the Ministry of Environment and Urbanism.

Marketing Authorization Holder:

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