

PATIENT INFORMATION LEAFLET

ZINCO 50 mg hard capsules

For oral use only.

- **Active substances:** Each capsule contains 137.3 mg zinc sulphate monohydrate to 50 mg zinc.
- **Excipient(s):** Starch, lactose (obtained from cow milk), magnesium stearate, talc, gelatin (beef gelatin), carmoisine (E122) and titanium dioxide (E171)

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 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** doses other than the recommended to you.*

What is in this leaflet?

1. *What ZINCO is and what is it used for?*
2. *Before you take ZINCO*
3. *How to take 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 capsule.
- It is available in blisters of 30 or 40 capsules in the blisters.
- It is used for the treatment or prevention of zinc deficiency and the treatment of zinc malabsorption (Acrodermatitis enteropathica) and excessive amounts of copper accumulation in the body (Wilson's disease).

2. Before you take ZINCO

DO NOT take ZINCO in the following cases

If;

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

Take special care with ZINCO

If;

- It is not appropriate to use zinc in the treatment of diarrhea in adults whose cause is unknown.
- 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.
- You have kidney or liver disease as the studies in the patients with such diseases are inadequate
- Prolonged use may cause copper deficiency.

- You are pregnant or breast-feeding, please consult your doctor
 - 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.
- Please consult your doctor, even if these statements were applicable to you at any time in the past.

Taking ZINCO with food and drink

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

Foods containing high phytic acid (inositol) such as wheat bran, flaxseed, cereals, legumes, and coffee reduce the absorption of zinc compounds. To ensure the best absorption (absorption) of orally administered zinc salts, it should not be taken with food and drink (other than water).

Pregnancy

Ask your doctor or pharmacist for advice before taking 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 immediately.

Breast-feeding

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

Zinc is excreted in human breast milk.

ZINCO should not be used during breast-feeding unless it is necessary

Driving and using machines

No studies have been carried to test its effects on the ability to drive or use machinery. It is not expected to affect the ability to drive and use machines.

Important information about some of the excipients of ZINCO

Zinco contains lactose. If previously you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking these tablets.

Zinco may cause allergic reactions due to its carmoisine (E122).

Taking with other medicines

Co-administration of zinc salts with tetracyclines, which is an antibiotic, and penicillamines, which is an anti-inflammatory drug, may reduce the effect, these substances should be used with zinc salts every three hours.

Products containing high doses of iron should not be used together as they will reduce the absorption of zinc.

Zinc may reduce the absorption of fluoroquinolone group drugs (ciprofloxacin, levofloxacin, moxifloxacin, norfloxacin and ofloxacin) used in the treatment of bacterial diseases.

Birth control drugs can reduce blood levels of zinc.

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

Calcium salts can reduce the absorption of zinc.

Using more than 30 mg of zinc per day may reduce the absorption of sparfloxacin, an antibiotic. Therefore, ZINCO should be taken at least two hours after sparfloxacin.

Excess copper accumulation in the body and the drugs used in the treatment of Wilson's disease; Penicillamine and trientine can reduce the absorption of zinc, likewise zinc can decrease the absorption of penicillamine and trientine.

Drugs that reduce stomach acid (antacids) reduce the rate and amount 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 take ZINCO?

- **Instructions for proper use and dose/ administration frequency:**

Unless recommended otherwise by doctor, use as specified below:

In zinc deficiency:

In adult patients, the daily dose is 1 capsule, unless otherwise specified by the doctor.

In Wilson's disease:

In pediatric patients:

The recommended dose for children over 16 years of age and over 50 kg is 150 mg/day; Used 3 times a day.

The dose to be used will be adjusted by your doctor.

In adult patients:

The recommended dose is 150 mg/day. It is recommended to use in three divided doses.

The dose to be used will be adjusted by your doctor.

In those with zinc malabsorption (acrodermatitis enteropathica):

In pediatric patients:

The recommended dose is 1-3 mg/kg/day. The dose to be used will be adjusted by your doctor.

In adult patients:

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

- **Route and method of administration**

ZINCO is for oral use only.

- **Various age groups:**

Children:

Zinc should be administered to pediatric patients as described in the section "Instructions for proper use and dose/ administration frequency"

Elderly:

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

- **Special Populations**

Kidney/Liver failure:

The safety and efficacy of ZINCO in individuals with kidney and liver failure have not been evaluated.

In kidney failure, the accumulation of zinc in the body may increase, so be careful if you have kidney failure.

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

If you take ZINCO more than you should:

Emesis should be avoided. Milk and water should be given immediately.

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

If you forget to take ZINCO:

Do not take double dose to balance the missed doses.

If you stop taking ZINCO:

Do not stop taking 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.

Stop taking ZINCO and inform your doctor immediately or contact your nearest hospital emergency department, if you notice any of the following:

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

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

These very severe side effects occur extremely rarely.

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.

Consult your doctor if you realize any of the following:**Uncommon**

- Nausea
- Vomiting
- Abdominal pain
- Dyspepsia
- Dizziness
- Diarrhea
- Gastric sensitivity
- Inflammation of the gastric mucosa (gastritis)
- Blood table changes (neutropenia, leucopenia)

Very rare

- Changes in electrocardiographic (electrical activity of the heart) in potassium deficiency

In addition, nervousness or irritability to stimulants (irritability), fatigue (lethargy) and headache cases have been observed.

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 its expiry date.

Do not use ZINCO after the expiry date on blister or packaging.

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

Marketing authorization holder:

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