

PATIENT INFORMATION LEAFLET

ZINOBEST 15 mg / 5 ml syrup

For oral administration only.

- **Active pharmaceutical ingredient:** Each 5 ml syrup contains 66 mg Zinc Sulfate Heptahydrate equivalent to 15 mg elemental Zinc.
- **Excipients:** Sodium benzoate, sucrose, orange flavor, quinoline yellow and 0.1 N hydrochloric acid, purified 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 further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others.
- Tell your doctor if you go to a doctor or the hospital when you use this medicine.
- Follow strictly to what is written in these instructions. Do not use **high or low** doses other than the recommended dose for the medication.

What is in this leaflet:

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

Titles are included.

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

ZINOBEST is syrup which includes Zinc. It is presented in a 100 ml colored bottle with 5 ml of 1/2 ml and 1/4 ml marked measuring spoon and 5 ml of pipette.

It is taken for treatment or prevention of zinc deficiency and treatment of diarrhea.

2. What you need to know before you take ZINOBEST?

DO NOT TAKE ZINOBEST in the following situations

If you;

- are allergic (hypersensitive) to Zinc salts or any of the other ingredients of ZINOBEST.

TAKE ZINOBEST CAREFULLY in the following situations

Since there is not enough study with patient who has kidney and liver disease; If you have any such disease, please consult your doctor.

Taking this medicine for a long time may cause copper deficiency.

Please consult your doctor even if these warnings apply to you at any time in the past.

Taking ZINOBEST with food and drink

ZINOBEST should not be taken with wholemeal, fibrous food and dairy products because of these foods reduce Zinc absorption.

Foods containing high phytic acid (inositol) (such as wheat bran, flaxseed, cereals, legumes) and coffee reduce of Zinc compounds absorption. Oral zinc salts should not be taken with food and drinks (except water) to ensure optimal absorption.

Pregnancy

Consult your doctor or pharmacist before taking this medicine.

Take this medicine under the supervision of your doctor if it is necessary during pregnancy.

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

Breast-feeding

Consult your doctor or pharmacist before taking this medicine.

Take this medicine under the supervision of your doctor if it is necessary during breast-feeding.

Driving and using machines

There is no known information on the effect of ZINOBEST on the ability to drive or use machinery.

Important information about some of the ingredients of ZINOBEST

If you have previously been told by your doctor that you have intolerance to some sugars, you should consult your doctor before taking this medicinal product.

This medicinal product contains 0.034 mmol (0.79 mg) Sodium for each 5 ml. This should be considered for patients on a controlled sodium diet.

Other medicines and ZINOBEST

Taking Zinc salts with tetracyclines, an antibiotic types, and penicillamins, which are an anti-inflammatory agents, may cause decrease effect, this substances should be taken with Zinc salts at intervals of three hours.

High-dosed iron preparations should not be taken together because of decreasing Zinc absorption.

Zinc may decrease absorption of the fluoroquinolone group, medicines taken in treatment of bacterial diseases, (ciprofloxacin, levofloxacin, moxifloxacin, norfloxacin and ofloxacin).

Calcium salts may decrease absorption of Zinc.

Contraceptives may decrease plasma Zinc levels.

Wholemeal, fibrous food and dairy products decrease absorption of Zinc.

Penicillamine and trientine (Medicines which are taken for excessive copper accumulation in the body, Wilson disease), may decrease Zinc absorption, in the same way, Zinc may decrease absorption of Penicillamine and trientine.

Antiacids (medicines that reduce gastric acidity) decrease absorption rate and amount of Zinc sulfate.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other prescribed or non-prescribed medicines.

3. How to take ZINOBEST?

Instructions for appropriate using and dose/application frequency:

ZINOBEST is used in adults with measuring spoon or pipette before meals or after meals or with meals.

Diarrhea treatment should not last more than 7 days.

It takes at following doses if not otherwise prescribed by the doctor.

Age	Elemental Zinc (mg)	Tolerable Upper Limits (mg)	Measure
6-12 Months	3	5	Pipette 1.5 ml
1-3 Years	3	7	Pipette 2 ml
4-8 Years	5	12	Pipette 4 ml
9-13 Years	8	20	Pipette 6 ml
14-18 Years	10	30	2 measuring spoon or pipette 10 ml
Adults over 19 Years	10	40	Pipette 13 ml

Method of administration:

- ZINOBEST is for oral administration only.
- Drink syrup using a measuring spoon or pipette.

Various age groups:

In children:

Please refer table above.

In elderly:

The safety and efficacy of ZINOBEST in elderly patients has not been studied.

Special uses

Kidney/Liver failure:

The safety and efficacy of ZINOBEST in patients with kidney and liver failure has not been studied.

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

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

If you take more ZINOBEST than you should

If you take more ZINOBEST than you should, talk to your doctor or pharmacist.

If you take more ZINOBEST than you should, symptoms can be observed such as low blood pressure, dizziness, vomiting.

For treatment; patient should not be vomited. Milk and water should be given immediately. Consult with your doctor.

If you forget to take ZINOBEST

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

If you stop taking ZINOBEST

Do not stop your treatment with ZINOBEST without consulting your doctor.

4. Possible side effects

Like all medicines, ZINOBEST can cause side effects in people sensitive to substances in the content of ZINOBEST.

Side effects are categorized as:

Very common $\geq 1/10$

Common $\geq 1/100$ and $< 1/10$

Uncommon $\geq 1/1,000$ and $< 1/100$

Rare $\geq 1/10,000$ and $< 1/1,000$

Very rare $< 1/10,000$

Frequency not known (cannot be estimated from the available data)

If any of the following happens, stop taking ZINOBEST and report to your doctor IMMEDIATELY or contact the emergency department of your nearest hospital:

- Hypersensitivity reaction (difficulty in swallowing and breathing, hand-foot swelling, face-lip swelling, rash, syncope)

These are very serious side effects. If these side effects are applied to you, it means you are allergic to against ZINOBEST seriously.

You may need emergency medical intervention or hospitalization.

This very serious side effect is observed quite rare.

If you notice any of following, report to your doctor immediately or contact the emergency department of your nearest hospital:

- Low blood pressure, arrhythmia.

These are all serious side effects.

You may need emergency medical intervention.

Serious side effects are observed rare.

If you notice any of following, talk to your doctor immediately:

- Vomiting
- Blood test changes (neutropenia; decrease in neutrophil count, leukopenia; decrease in white blood cells, anemia; decrease in red blood cells)
- Nausea
- Abdominal pain
- Indigestion
- Headache
- Nervousness
- Drowsiness, dullness
- Gastric sensitivity
- Stomach mucosa inflammation (gastritis)
- Dizziness
- Diarrhea
- Irritability (state of sensitivity and arousal)
- Lethargy (drowsiness, numbness)
- Lack of copper in long-term take

- Electrocardiographic changes in potassium deficiency

These are mild side effects of ZINOBEST.

These side effects disappear when dose was decreased or treatment was stopped.

If you get any side effects, which is not included in this leaflet, report to your doctor or pharmacist.

5. How to store ZINOBEST?

Keep ZINOBEST out of sight and reach of children in its package.

Store at room temperature below 25° C.

Use in accordance with expiration dates.

Do not take ZINOBEST after the expiry date that is stated on the package.

Do not take ZINOBEST if you notice any defects in the product and / or packaging.

Marketing Authorization Holder:

Drogsan İlaçları San. ve Tic. A.Ş.

Oğuzlar Mah. 1370. sok. 7/3

06520 Balgat-ANKARA

Manufacturing Place:

Drogsan İlaçları San. ve Tic. A.Ş.

06760 Çubuk – ANKARA

This patient information leaflet is approved on 27 /12 /2016