

## PATIENT INFORMATION LEAFLET

### ZINCO 30 mg FORT syrup

#### For oral use.

- **Active substance:** Each 5 ml syrup (1 measuring cup) contains 132 mg zinc sulphate heptahydrate equivalent to 30 mg zinc.
- **Excipients:** Xylitol, sorbitol (70%) (E420), fructose, sodium cyclamate, citric acid monohydrate, sodium hydroxide, methyl paraben sodium (E219), sucrose, orange essence, 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, 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 30 mg FORT is and what it is used for?*
2. *Before you use ZINCO 30 mg FORT*
3. *How to use ZINCO 30 mg FORT?*
4. *Possible side effects*
5. *How to store ZINCO 30 mg FORT*

#### **1. What ZINCO 30 mg FORT is and what it is used for?**

- ZINCO 30 mg FORT is a zinc-containing syrup.
- It is available in 100 ml amber colored bottles with a 5 ml pipette.
- It is used for the treatment or prevention of zinc deficiency.

#### **2. What you need to know before you receive ZINCO 30 mg FORT**

#### **DO NOT USE ZINCO 30 mg FORT in the following conditions**

If;

- You are hypersensitive to zinc salts or other ingredients of ZINCO 30 mg FORT.

#### **TAKE SPECIAL CARE WITH ZINCO 30 mg FORT in the following conditions**

Due to insufficient number of studies in individuals with kidney or liver 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 warnings apply to you even at any time in the past.

**Using ZINCO 30 mg FORT with food and drink**

Since concomitant intake of zinc with wholemeal, fibrous food and dairy products decrease the absorption of zinc, you should not take ZINCO 30 mg FORT together with these types of food.

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

**Pregnancy**

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

Use under the supervision of your doctor if necessary during pregnancy.

*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.*

Use under the supervision of your doctor if necessary during breast-feeding.

**Driving and using machines**

There were no investigations on the ability to drive and use machines.

**Important information about some of the excipients of ZINCO 30 mg FORT**

If previously you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before using the medicine since this medicinal product contains fructose, sucrose and sorbitol (E420).

This medicinal product contains 58.8 mg of sodium per 5 ml. This should be considered for patients on the controlled sodium diet.

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

This medicinal product contains methyl paraben sodium (E219) which may cause allergic reactions (possibly delayed).

**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.

High dose iron preparations 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) used for the treatment of diseases caused by bacteria.

Calcium salts may reduce zinc absorption.

Contraceptives may reduce plasma zinc levels.

Whole-grain, fiber foods and dairy products may reduce the absorption of zinc.

Penicillamine and trientin which are agents used for the treatment of excessive copper accumulation in the body and associated Wilson’s disease may reduce zinc absorption; also zinc may reduce the absorption of these two agents.

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

When more than 30 mg of zinc is used per day, it may reduce the absorption of sparfloxacin, an antibiotic. Therefore, ZINCO 30 mg FORT should be taken at least three hours after taking sparfloxacin.

*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 30 mg FORT?

- **Instructions for appropriate method and dose/frequency of administration:**
  - ZINCO 30 mg FORT can be used before, after, or during the meals in adults.
  - Unless recommended otherwise by your doctor; use once a day at the dose indicated below.

Age	Elementary Zinc (mg)	Tolerated Dose (mg)	Dose
6-12 months	3	5	With 0.5 ml pipette (= 3 mg zinc)
1-3 years	3	7	With 1 ml pipette (= 6 mg zinc)
4-8 years	5	12	With 1.5 ml pipette (= 9 mg zinc)
9-13 years	8	20	With 2.5 ml pipette (= 15 mg zinc)
14-18 years	10	30	With 3 ml pipette (= 18 mg zinc)
≥19 years adults	10	40	With 5 ml pipette (= 30 mg zinc)

*“1 ml syrup contains 6 mg zinc.”*

- **Route and method of administration:**
  - ZINCO 30 mg FORT is for oral use only
  - The syrup is taken using the pipette

- **Different age groups:**

#### Use in children:

The use in children is as shown in the table.

#### Use in elderly:

The safety and efficacy of ZINCO 30 mg FORT in elderly have not been evaluated.

- **Special populations:**

#### Kidney/Liver Failure:

The safety and efficacy of ZINCO 30 mg FORT in patients with kidney or liver failure have not been evaluated.

Accumulation of zinc in the body may increase in kidney failure, therefore caution should be exercised in cases of renal insufficiency.

*If you have the impression that the effect of ZINCO 30 mg FORT is too strong or too weak, talk to your doctor or pharmacist.*

**If you used more ZINCO 30 mg FORT than you should:**

*If you may have taken more ZINCO 30 mg FORT 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.

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

**If you forget to use ZINCO 30 mg FORT:**

*Do not take double dose to balance the missed doses.*

**If you stop using ZINCO 30 mg FORT:**

Do not stop taking ZINCO 30 mg FORT before consulting with your doctor.

**4. Possible side effects**

Like all medicines, ZINCO 30 mg FORT may cause side effects in some patients who are sensitive to the substances contained in ZINCO 30 mg FORT.

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 any of the following occur stop using ZINCO 30 mg FORT and IMMEDIATELY inform your doctor or go to the nearest emergency department:**

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

These are all very serious side effects. If you have any of them, this means you have serious allergy to ZINCO 30 mg FORT. You may need emergency medical care or hospitalization. All of these very serious side effects occur very rarely.

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

- Low blood pressure, irregular heartbeat (arrhythmia)

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

Serious side effects are very rare.

**If you notice any of the following, inform your doctor:**

**Common:**

- Vomiting

**Uncommon:**

- Changes in blood values (neutropenia, leucopenia, anemia)
- Nausea
- Abdominal pain
- Dyspepsia
- Gastric sensitivity
- Inflammation of the gastric mucosa (gastritis)
- Diarrhea
- Dizziness
- Headache
- Nervousness
- Lethargy, feeling of drowsiness

These are mild effects of ZINCO 30 mg FORT.

These side effects disappear when the dose is reduced or treatment is discontinued.

*If you notice any side effects not mentioned in this leaflet inform your doctor or pharmacist.*

**5. How to store ZINCO 30 mg FORT?**

*Keep ZINCO 30 mg FORT in the original package and out of the reach and sight of children.*

Store at room temperature below 25°C.

**Use in accordance with the expiry date.**

*Do not use ZINCO 30 mg FORT after the expiry date which is stated on the package.*

Do not use ZINCO 30 mg FORT if you notice any damage to the product and/or package.

***Marketing authorization holder:***

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