

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

Zincol enteric coating tablets

Active ingredient

Each tablet contains 50 mg zinc (as sulphate)

Inactive ingredients and allergens: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

Zinc supplement.

Therapeutic group: Mineral supplement

Zinc sulphate is a source of zinc, which is an essential trace element that is involved in the function of a number of enzymes in the body.

2. Before using the medicine

Do not use this medicine if:

- you are sensitive (allergic) to zinc sulphate or to any of the other ingredients in this medicine (see section 6).
- you suffer from a copper deficiency.

Special warnings about using this medicine

Before using Zincol, tell your doctor if:

- You suffer from kidney disease.

If it applies to you, it is important that you tell your doctor before taking Zincol, and they will decide what to do. It may still be safe for you to take Zincol.

Drug interactions

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist. Particularly if you are taking:

- copper supplements (see section 2 'Do not take the medicine if')
- tetracycline antibiotics (such as oxytetracycline or doxycycline) used to treat certain bacterial infections
- quinolone antibiotics (such as ciprofloxacin, levofloxacin, moxifloxacin, norfloxacin and ofloxacin) used to treat certain bacterial infections
- calcium salt preparations
- iron preparations
- penicillamine (used to treat rheumatoid arthritis, Wilson's disease, autoimmune hepatitis and cystinuria)
- trientine (used in the treatment of Wilson's disease)

Using this medicine and food

Take this medicine one hour before or two hours after a meal.

Pregnancy and breastfeeding

The safety of Zincol in pregnant women is not known. Zinc has been shown to cross the placenta and is present in breast milk in women taking zinc supplements. Only take this medicine during pregnancy or while breastfeeding if your doctor has advised you to do so.

Consult your doctor or pharmacist before taking any medicine during pregnancy or while breastfeeding.

Driving and using machines

Zincol is not expected to affect the ability to drive or use machines.

Important information about some of this medicine's ingredients

Zincol tablets contain lactose. If you have been told by your doctor that you have an intolerance to certain sugars, contact your doctor before taking this medicine.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine.

The recommended dosage is usually:

1 tablet daily.

Do not exceed the recommended dose. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Please note: Wait at least two hours between taking this medicine and products that contain bran, foods that contain copper, iron or phosphorus such as dairy products, chicken and turkey.

Instructions for use:

Do not split, chew or break the tablets, as the medicine has an enteric coating (barrier).

If you have accidentally taken a higher dose

If you have taken too many tablets or if a child has accidentally swallowed some medicine, immediately go to the closest hospital emergency room and bring the medicine package with you.

If you forget to take Zincol

If you forget to take the tablets, take them as soon as you remember and then continue with the next dose according to the instructions. Do not take a double dose to make up for a forgotten dose.

If you stop taking Zincol

To get the most benefit from Zincol, always finish the course of treatment recommended by your doctor.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Zincol may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

The following side effects have been reported:

- reduced copper levels, potentially leading to copper deficiency
- abdominal pain
- digestion difficulties
- nausea
- vomiting
- diarrhea
- stomach discomfort
- irritability
- headache
- lethargy (a feeling of weariness)

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link "Reporting Side Effects of Drug Treatment" on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package/tray.

Storage conditions

- Store the medicine below 25°C.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Lactose, cellulose powdered, corn starch, povidone, sodium starch glycolate, eudragit L, magnesium stearate, colloidal silicon dioxide, talc, castor oil, dibutyl phthalate, titanium dioxide, quinoline yellow AL lake.

What the medicine looks like and contents of the pack:

A round tablet, with a yellow coating.

Each pack contains 30/90/1000 tablets in blister packs.

Not all pack sizes may be marketed.

Manufacturer and registration holder: Sam-On Ltd., 25 Ehud Kinamon (Haavoda) Street, Bat Yam.

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Registration number of the medicine in the National Drug Registry of the Ministry of Health: 010-61-24158-00