SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT
MAGNEZINC 30 mg/300 mg film coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each film tablet contains

Active substance(s):

Zinc	30 mg (82.6 mg zinc sulfate monohydrate equivalent to 30 mg zinc)
Magnesium	300 mg (520.4 mg magnesium oxide equivalent to 300 mg magnesium)

Excipient(s):

Lactose monohydrate	61,60 mg (derived from cow's milk)
Lacquer carmoizine (E122)	0,18 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Film tablet

Pink, film-coated, round tablets

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
MAGNEZINC is used in the prevention/treatment of zinc deficiency and/or in the treatment of Wilson's disease and/or acrodermatitis enteropathica due to its zinc content.

MAGNEZINC is used in the following due to its magnesium content;

Heart and vascular system: Tachycardia, cardiac arrhythmias, development of tolerance to digitalis preparations, myocardial infarction, angina pectoris, hypertension of mild severity,

Nerves and muscles: Tetany, smooth and striated muscle cramps, gastrointestinal cramps, neuromuscular hyperexcitability, cystremia,

Gynaecological and obstetric: Pre-term contractions, cervical incompetence, premature rupture of membranes, spasms in pregnancy (eclampsia/pre-eclampsia), tocolysis requiring betamimetic use, dysmenorrhoea,

Orthopaedics: Calcifications and ossifications,

*Prevention of kidney stone formation: (*prevention of recurrence of calcium oxalate urolithiasis), treatment of migraine, diabetes and magnesium deficiency.

4.2 Posology and method of administration
Posology/frequency of administration and duration of the treatment:
Unless otherwise recommended by the doctor, the daily dose for adults is 1 tablet per day.

Method of administration:

1 tablet is taken orally.
In patients with Wilson's disease, up to 5 tablets per day (150 mg/day) are used in 3 divided doses, while in patients with Acrodermatitis Enteropathica, 2-5 tablets per day (50-150 mg/day) are used.

Additional information for special populations:
Renal failure:
The efficacy and safety of zinc in patients with renal impairment have not been studied.
MAGNEZINC should not be used or its dose should be reduced in case of moderate renal impairment, as the risk of toxic effects may increase.

Hepatic failure:
The efficacy and safety of zinc in patients with hepatic insufficiency have not been studied.
MAGNEZINC should not be used in hepatic coma if there is a risk of renal failure.

Paediatric population:
The safety and efficacy of MAGNEZINC in paediatric patients have not been studied.

Geriatric population:
The safety and efficacy of MAGNEZINC in elderly patients have not been studied.

4.3. Contraindications
MAGNEZINC is contraindicated in individuals who are allergic to the components of the product.

4.4. Special warnings and precautions for use
It is not appropriate to use zinc in adult diarrhoea of unknown cause.

Products containing 30 mg zinc are not suitable for use in paediatric diarrhoea treatment due to the high amount of zinc given in a single dose.

When the magnesium requirement of patients with renal failure increases, the dose should be adjusted by the physician according to the severity of renal failure and should be given under the supervision of a physician.

In addition, zinc salts should not be taken together with penicillin derivatives.

Although there is no report on its teratogenic effect, it is recommended that pregnant and lactating mothers use it under the supervision of a physician.

Due to the lactose in its composition, patients with rare hereditary galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption problems should not use this medicine.

It may cause allergic reactions as it contains lacquer carmoisine (E122).

4.5 Interaction with other medicinal products and other forms of interaction
Zinc sulphate and magnesium oxide should not be used together with tetracyclines as these may chelate with tetracyclines.

Iron preparations reduce the bioavailability of zinc sulphate when the iron/zinc molar ratio is above 25/1, but do not affect it if this ratio is below 2.5/1.

It may reduce the effect of penicillamine when taken with penicillamine.

Zinc above 30 mg per day may reduce the absorption of sparfloxacin, therefore MAGNEZINC should be taken at least 2 hours after sparfloxacin.

Zinc may reduce the absorption of ciprofloxacin.

Oral contraceptives may decrease plasma zinc levels.
Antacids reduce the bioavailability of zinc sulphate.

Foods containing high phytic acid (inositol) and coffee form chelates with zinc compounds. Zinc salts taken orally should not be taken with food and beverages (other than water) to ensure optimum absorption.

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

Since it contains magnesium, it should not be used simultaneously with the following drugs:
Diuretics, aminoglycosides (gentamicin, tobramycin, amphotericin B), immunosuppressants (cyclosporine A), cytostatics (cisplatin) because they cause increased renal magnesium loss.

Indomethacin should not be taken as it increases magnesium absorption.

Since the absorption of drugs containing levothyroxine is impaired when taken together with MAGNEZINC, the two drugs should be taken with a break of at least 2 hours.

Additional information for special populations:
No interaction studies have been conducted in special populations.

Pediatric population:
No interaction studies have been conducted in the pediatric population.

4.6. Fertility, pregnancy and lactation
General advise
Pregnancy category: C

Women of childbearing potential/Birth control (contraception)
Animal studies are insufficient with respect to pregnancy / and-or / embryonal / fetal growth / and-or postnatal development. Potential risk is not known for human.

Pregnancy
MAGNEZINC should not be used during pregnancy unless necessary. It can be used under the supervision of a doctor.

Breast-feeding
It can be used under the supervision of a doctor during breastfeeding.

Reproductive ability / Fertility
It has no effect on fertility.

4.7 Effects on ability to drive and use machines
No effects on the ability to drive and use machines have been reported.

4.8 Undesirable effects
The undesirable effects reported are classified according to the following frequency:
Very common (≥1/10); common (≥1/100 to <1/10); not common (≥1/1.000 to <1/100); rare (≥1/10.000 to <1/1.000); very rare (<1/10.000), not known (can not be estimated based on available data).

Immune system disorders
Very rare: Allergic reactions

Cardiac disorders
Very rare: Hypotension, arrhythmia, electrocardiographic changes in potassium deficiency.

Gastrointestinal disorders
Common: Vomiting, darkening of stool.
Rare: Gastrointestinal irritation, nausea, diarrhea, constipation, epigastric fullness
Very rare: Indigestion, heartburn.

These side effects resolve with dose reduction or discontinuation of treatment.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Turkish Pharmacovigilance Center (TÜFAM). (www.titck.gov.tr; e-mail: tufam@titck.gov.tr; tel.: 0 800 314 00 08; fax: 0 312 218 35 99))

4.9 Overdose and treatment
Intoxication does not occur with oral administration in patients with normal renal function.
Patients with kidney failure should be controlled by a physician.

Long-term and high-dose use can cause copper deficiency and anemia. In this case, it may be necessary to take 4 mg of copper sulfate per day to correct the copper deficiency and slow blood transfusion for anemia. In poisoning due to the zinc, gastric lavage is performed and the electrolyte balance is provided. Magnesium-related poisoning is treated by intravenous administration of 100-200 mg of calcium within 5-10 minutes.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Other mineral supplements
ATC Code: A12C

Zinc is a metal in the structure of enzymes such as dehydrogenase, aldolase, peptidase, phosphatase, isomerase, phospholipase, which have important roles in carbohydrate, protein and lipid metabolism. In addition, it is found in large amounts in enzymes bound to pyridine nucleotides and plays a role as a cofactor in many enzymes. As a result of zinc deficiency in the organism, protein and carbohydrate metabolism is disrupted, learning capacity is inhibited, and growth slows down. It was determined that the serum zinc level was low in children with beta-thalassemia, it was observed that these children showed equal development with healthy children after zinc treatment was applied. Zinc has multiple functions such as DNA and RNA synthesis, protein synthesis, insulin activation, wound healing, cell division, taste, sperm production, and immunity.

Magnesium is an essential macroelement. It is an essential element in biochemical metabolic processes in chemical bond energy supply (such as oxidative phosphorylation) or consumption (such as ion pump, muscle contraction). Magnesium stabilizes biological membranes and reduces membrane fluidity by forming complexes with phospholipids and ATP. It plays an important role in protein synthesis with its ability to chelate. Magnesium is also a natural and physiological calcium antagonist and vasolidator.

5.2 Pharmacokinetic properties

General characteristics

Absorption and bioavailability:

When magnesium salts are administered orally, approximately 15-30% of the administered dose is absorbed. Absorption probably occurs by active transport. Absorbed magnesium is distributed throughout the body. About half of the magnesium in the body is in soft tissues, with most of the remaining magnesium in the bone. Enteral absorption of magnesium occurs by facilitated diffusion or passive diffusion and is dose proportional. Its half-life is approximately 4.5 hours and absorption is complete in 12 hours.

The saturation curve of zinc is non-linear. When the metabolism of zinc is examined, it is partially absorbed from the gastrointestinal tract after oral administration. Foods such as wholemeal bread, milk, cheese and coffee reduce absorption.

Distribution:

The normal serum concentration is 1.4-2 mEq/L in adults, 1.5-2 mEq/L in children, and 1.5-2.3 mEq/L in newborns and infants. Effective serum magnesium concentrations as an anticonvulsant have been reported to be between 2.5 and 7.5 mEq/L. Magnesium crosses the placenta and is distributed in breast milk. However, it has not been shown to cause any problems in humans.

2-8% of ionic zinc in the blood is bound to low molecular weight serum proteins. Normal plasma concentration is between 0.7 and 1.5 μg/ml. The plasma concentration of the patient who takes 50 mg of elemental zinc orally reaches approximately 2.5 μg/ml in 2-3 hours.

Biotransformation:

Magnesium and zinc are not metabolized.

Elimination:

Magnesium is eliminated via the kidneys, but the rate of excretion varies. The amount of magnesium excreted daily in the urine is about 1.5 g (12 mEq). Magnesium ions are reabsorbed in the ascending arm of the loop of Henle. The plasma half-life is 4.5 hours.

The excretion route of zinc is via faeces. The amount excreted in the urine is small. Of the 13.2 mg zinc that a normal adult takes with food in a day, 5.6 mg is excreted in the feces and 0.1-0.9 mg in the urine. The kidneys normally have no influence on the regulation of serum zinc and its excretion capacity is extremely limited. Urinary excretion does not change even with increased oral intake of zinc, but there is a visible increase in urinary excretion when intravenous zinc is given. The excretion of zinc in the bile is much less than its urinary excretion. Zinc can also be lost through sweat. It has been reported that up to 2-3 mg of zinc is lost through sweat in hot climates. The plasma half-life is 3 hours.

Linearity/Non-linearity:

It shows a linear pharmacokinetic.

5.3. Preclinical safety data
Not available.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients
Tablet
Lactose monohydrate
Corn starch
Croscarmellose sodium
Polyethylene glycol
Povidone K30

Coating material
Hypromellose
Titanium dioxide (E171)
Polyethylene glycol
Lacquer carmoizine (E122)

6.2. Incompatibilities
There is no evidence of incompatibility of MAGNEZINC with any medicine or substance.

6.3. Shelf life
24 months

6.4 Special precautions for storage
Store below 25°C at room temperature.
Keep out of sight and reach of children and in original package.

6.5 Nature and contents of container
MAGNEZINC is available in PVC/PVDC/Al blister packs containing 40 tablets in a cardboard box.

6.6 Special precautions for disposal
Any unused product or waste material should be disposed in accordance with regulations "Medical Waste Control Regulation" and "Packaging Waste Control".

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

231/ 43

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22.04.2011
Date of latest renewal: 29.01.2019

10. DATE OF REVISION OF THE TEXT

11.07.2023