

PATIENT INFORMATION LEAFLET

DIMAG 365 mg sachets containing single dose powder For oral use.

- **Active substance:** Each sachet contains 670 mg magnesium carbonate equivalent to 365 mg magnesium ion, and 342 mg magnesium oxide.
- **Excipients:** Citric acid anhydrous, sorbitol (E420), sodium cyclamate, sodium bicarbonate, sodium saccharine, polyvinyl pyrrolidone K30, lemon flavor, FD&C yellow no. 5 (E102).

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, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not give 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.*
- *Please completely follow the instructions in this information leaflet. Do not use **higher or lower** doses other than what is recommended to you.*

What is in this leaflet:

- 1. What DIMAG is and what is it used for?**
- 2. Before using DIMAG**
- 3. How to take DIMAG?**
- 4. Possible side effects**
- 5. How to store DIMAG?**

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

- DIMAG sachet contains magnesium carbonate and magnesium oxide as active substances.
- Magnesium is included in the medicine group named as mineral supporting products.
- DIMAG is packed with coated paper/AL/LDPE and it contains 10, 20 or 30 sachets in each box.

- DIMAG is indicated in the treatment of,
-Ameliorating the symptoms occurred in deficiency of magnesium

-Heart and vascular system: Acceleration of hearth beat, irregularity of heart rate, heart attack, angina pectoris (chest pain caused by narrowing/obstruction of heart-feeding vessels), mild hypertension

-Nerve and muscles: Sudden and excess spasm in muscle (tetany), spasm formation in muscle, stomach-intestine cramps, increased stimulability of muscle and nerves, calf cramps, cramped conditions in infants and young children and stress

-Gynecological diseases, related to birth and baby: Preterm spasms, cervical failure, early hymen rupture, spasm in pregnancy (eclampsia [disease with seizure attacks, increase of blood

pressure, presence of protein in urine and water holding of the body]/pre-eclampsia [disease with increase of blood pressure in pregnancy, protein presentation in urine and water holding of the body], tocolysis which requires the use of betamimetic (stopping prolonged contractions of the progeny), painful menstruation

-Orthopedics: Calcification and ossifications

-Prevention of renal calculus formation (prevention of repetition of calcium oxalate urolithiasis)

-Diabetes and migraine (a type of headache)

2. Before you take DIMAG

DO NOT take DIMAG in the conditions stated below.

If;

- You are hypersensitive to any of the ingredients in DIMAG
- You have severe renal failure or insufficiency

Take special care with DIMAG in the following conditions.

If;

- You have severe renal failure, ask your doctor before using this medicine
- You use Digital group medicines used in heart failure
- You take lithium treatment for change of emotion and control of depression state due to excitement disorder
- Your magnesium level is under 1.5 mEq/L
- It may cause diarrhea depending on a disease or a use medicine in patients above middle age. Tell your doctor in case of diarrhea occurrence

These alerts at any time in the past even if it is true for you, please consult your doctor.

Using DIMAG with food and drink

DIMAG should be taken with food. Usage in fasting condition may cause diarrhea.

Pregnancy

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

Do not use DIMAG during pregnancy without consulting your doctor.

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

Breast-feeding

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

Do not use DIMAG during breast feeding period without consulting your doctor.

Driving and using machines

DIMAG has no negative effect on driving and using machines.

Important information about some of the excipients in DIMAG

If your doctor has previously told you that you have intolerance to some sugars due to the presence of sorbitol (E420) in this medicinal product, you should consult your doctor before taking this medicinal product.

DIMAG contains FD&C yellow no. 5 (E102) as a coloring agent so it may cause allergic reactions.

One sachet contains 106.30 mg (4.67 mmol) sodium ion. This case should be considered for the patients having controlled sodium diet.

Taking with other medicines

Other drugs may affect the treatment with DIMAG. If you use any of the drugs below, tell your doctor definitely.

- Muscle relaxant drugs (non-depolarize neuromuscular blockers)
- Amino quinolones, nitrofurantoin, penisilamine, tetracyclines, fluoroquinolones (antibiotic)
- Digoxin (heart failure treatment)
- Lithium (change of emotion and control of depression state)
- Sodium polystyrene sulfonate (provides remove of potassium from the body)
- Cellulose sodium phosphate (used to prevent kidney stones)
- Other medicines containing magnesium (including magnesium enemas)
- Barbiturate (drugs used for the treatment of sleeplessness), opioids (substances acting as morphine), hypnotics (somnific drugs)
- Nifedipine (drugs used in hypertension or heart problems)
- When the drugs containing levothyroxine (which is used in the treatment of thyroid diseases) are taken with DIMAG, the two drugs should be taken at least 4 hours apart as the absorption of DIMAG is impaired

Please tell your doctor or pharmacist if you are currently taking or have recently taken any other medicines, with or without a prescription.

3. How to take DIMAG?

- **Instructions for suitable usage and dose/application frequency:**

Unless otherwise recommended by the doctor;

Recommended daily dose is 1-2 sachets for adults and adolescents (12-17 aged).

Recommended daily dose during pregnancy and breast-feeding period is 1-2 sachets.

- **Route and method of administration:**

DIMAG is for oral administration.

Take with food by dissolving it in 150 ml (1 glass of) water.

- **Different age groups:**

Use in children:

Recommended daily dose for children between 6-11 years old is ½ - 1 sachet. It should be taken in control of the doctor in children under 6 years old.

Usage in elderly:

No data available for use in elder population.

- **Special populations:**

Kidney failure:

DIMAG should not be used in patients with severe kidney failure.

Liver failure:

No data available for patients with liver failure.

If you have the impression that effect of DIMAG is too weak or strong, talk to your physician or pharmacist about it.

If you have taken more DIMAG than you should:

If you have taken more than you should from DIMAG, talk to a physician or a pharmacist.

If you forget to take DIMAG:

Do not take a double dose to balance out the forgotten dose.

Possible effects when DIMAG treatment is stopped:

Do not stop taking DIMAG without consulting your doctor.

4. Possible side effects

Like all medicines, side effects can occur in those who are hypersensitive to any ingredients in DIMAG.

If any of the following takes place, stop taking DIMAG and immediately contact your physician or apply to the emergency department of the nearest hospital:

- Severe hypertensive reaction (i.e. mouth and throat swelling, itching, eruption, rash)
- Breath depression
- Coma

These are all very serious side effects.

If you have any of them, this means you have serious allergy for DIMAG. You may need emergency medical care or hospitalization.

If you experience any of the following side effects, immediately contact your physician or apply to the emergency department of the nearest hospital:

- Low blood pressure
- Changes in electrical efficacy of heart (ECG)
- Depression

These are all severe side effects. Emergency medical intervention may be necessary.

Tell your doctor if you notice any of the following:

- Nausea
- Vomiting
- Diarrhea
- Cramp
- Feeling of tiredness
- Weakness
- Wooziness

These are mild side effects of DIMAG.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store DIMAG

Store DIMAG in the package and keep out of the reach and sight of children.

Store at room temperature under 25°C and protect from moisture.

Use in accordance with the expiry date.

Do not use DIMAG after the expiry date, which is stated on the sachet or package.

If you notice decomposition in the product and/or its package, do not take DIMAG.

Marketing authorization holder:

Berko İlaç ve Kimya San. A.Ş.

Yenişehir Mah. Özgür Sok. No: 16-18 Ataşehir/İstanbul, Turkey

+90 216 456 65 70 (Pbx)

+90 216 456 65 79 (Fax)

info@berko.com.tr

Manufacturer:

Berko İlaç ve Kimya San. A.Ş.

Adil Mah. Yörükler Sok. No: 2 Sultanbeyli/İstanbul, Turkey

+90 216 592 33 00 (Pbx)

+90 216 592 00 62 (Fax)

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