



TRANSLATION BY PROTINA

**Translation of the German**

**Package Leaflet**

**Information for the user**

**Magnesium-Diasporal® 300 mg**

Granules for oral solution

For adults

***Read all of this leaflet carefully before you start using this medicine because it contains important information for you.***

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- If you do not feel better within 1 month after taking, you must talk to a doctor.

What is in this leaflet

1. What Magnesium-Diasporal® 300 mg is and what it is used for
2. What you need to know before you take Magnesium-Diasporal® 300 mg
3. How to take Magnesium-Diasporal® 300 mg
4. Possible side effects
5. How to store Magnesium-Diasporal® 300 mg
6. Contents of the pack and other information

### **1. What Magnesium-Diasporal® 300 mg is and what it is used for**

Magnesium-Diasporal® 300 mg is a mineral preparation and contains the active ingredient magnesium (as magnesium citrate).

Magnesium-Diasporal® 300 mg is used in the treatment and prevention of magnesium deficiency in adults.

Signs of severe magnesium deficiency include neurological and muscular symptoms (tremor, muscle spasms, tetany) and personality changes.

### **2. What you need to know before you take Magnesium-Diasporal® 300 mg**

**Do not take Magnesium-Diasporal® 300 mg:**

- if you are allergic to magnesium citrate or any of the other ingredients of this medicine (listed in section 6)
- if you have severe renal impairment (glomerular filtration rate < 30 ml/min)
- if you have disorders of conduction on the heart that causes slow heartbeat (bradycardia)

### **Warnings and precautions**

It is recommended to talk to your doctor or pharmacist before taking Magnesium Diasporal® 300 mg.

### **Children and adolescents**

There is no experience of treating children and adolescents. Therefore the use in children and adolescents is not recommended.

### **Use of Magnesium-Diasporal® 300 mg and other medicines**

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

You should avoid taking other medicines at the same time if possible. Allow 2 to 3 hours between taking this and your other medicines to reduce the possibility of interaction.

- In the case of **fluorides** and **tetracycline** the time interval of 2–3 hours should be **strictly** respected.
- Antibacterial antibiotics (aminoglycoside antibiotics), substances elevating urination (thiazide, furosemide) and substances blocking the production of stomach acid (omeprazole, pantoprazole) as well as the active substances cisplatin, cyclosporin A, foscarnet, cetuximab, erlotinib, pentamidine, rapamycin and amphotericin B may cause **magnesium deficiency**. Ask your doctor if you need to adjust your daily dose of magnesium.

### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Magnesium-Diasporal® 300 mg can be used during pregnancy and during breast-feeding without concerns. Based on long-term experience, no effects of magnesium citrate on male and female fertility are anticipated.

### **Driving and using machines**

Magnesium-Diasporal® 300 mg has no or negligible influence on the ability to drive and use machines.

### **Magnesium-Diasporal® 300 mg contains sucrose and sodium**

This medicine contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

In case of frequent and/or permanent use, Magnesium-Diasporal® 300 mg may be harmful to your teeth (caries) because of the sugar content.

This medicine contains 40 mg sodium (main compound of cooking/table salt) in each sachet. This is equivalent to 2% of the recommended maximum daily dietary intake of sodium for an adult.

### **3. How to take Magnesium-Diasporal® 300 mg**

Always take this medicine exactly as described in this leaflet as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

### **Renal impairment**

The use of magnesium has to be avoided when renal function is severely limited.

### **The recommended dose is**

Adults: 1 sachet daily.

1 sachet of Magnesium Diasporal® 300 mg granules corresponds to 300 mg magnesium.

### **Method and route of administration**

Dissolve 1 sachet of Magnesium-Diasporal® 300 mg granules in half a glass of water, juice or tea and drink it all.

### **If you take more Magnesium-Diasporal® 300 mg than you should**

No side effects are expected, if your kidneys work properly. Any excessive amount of magnesium will be excreted through your kidneys.

If you have taken more of this medicine than directed, or if a person with severe renal impairment accidentally or if a child accidentally has taken this medicine, please contact your doctor or emergency unit for judgement of the risk and advice.

### **If you forget to take Magnesium-Diasporal® 300 mg**

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

If you have any further question on the use of this medicine, ask your doctor or pharmacist.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Uncommon** (may affect 1 to 10 users in 1.000):

Soft stools to diarrhoea at the beginning of treatment (harmless and will usually decrease in frequency as the treatment advances).

**Very rare** (may affect less than 1 user in 10.000):

Fatigue if Magnesium-Diasporal® 300 mg is used for a longer period of time.

If you get any side effects, you should temporarily interrupt the treatment. After the symptoms improve and/or are eliminated you can restart treatment, with a reduced dosage.

**Reporting of side effects:** If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Bundesinstitut für Arzneimittel und Medizinprodukte, Abt. Pharmakovigilanz, Kurt-Georg-Kiesinger Allee 3, D-53175 Bonn, Website: <http://www.bfarm.de>.

By reporting side effects, you can help provide more information on the safety of this medicine.

#### **5. How to store Magnesium-Diasporal® 300 mg**

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the folding box and the sachet. The expiry date refers to the last day of that month.

#### **6. Content of the pack and other information**

##### **What Magnesium-Diasporal® 300 mg contains**

The active substance is magnesium (as magnesium citrate). One sachet (5 g) contains 300 mg magnesium (as magnesium citrate).

The other ingredients are: sucrose (sugar), anhydrous citric acid, sodium hydrogen carbonate, riboflavin (E 101), orange flavour.

##### **What Magnesium-Diasporal® 300 mg looks like and content of the packs**

Yellow granules with fruity, orange-like flavour.

Magnesium-Diasporal® 300 mg granules for oral solution are available in packages of 20 (N1), 50 (N2) or 100 (N3) sachets per 5 g granules. Multipack for hospital use: 200 sachets per 5 g granules (10 x 20 sachets and 4 x 50 sachets and 2 x 100 sachets). Not all pack sizes may be marketed.

##### **Marketing Authorisation Holder and Manufacturer:**

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This medicinal product is authorised in the Member States of the EEA under the following names:

**Austria** Magnesium-Diasporal® 300 mg

Granulat zur Herstellung einer Lösung zum Einnehmen

**Danmark** Magnesium-Diasporal®

**Germany** Magnesium-Diasporal® 300 mg

Granulat zur Herstellung einer Lösung zum Einnehmen

**Schweden** Magnesium-Diasporal® 300 mg

Granulat till oral lösning

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