SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

MAGCAR Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml suspension contains:

Active substance(s):

Calcium carbonate	680 mg
Magnesium carbonate	80 mg

Excipient(s) with known effect:

Sorbitol	750 mg
Methyl paraben	1 mg
Propyl paraben	1.5 mg
Saccharin sodium	5 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension.
Whitish opaque, homogeneous, aromatic flavored (mint-lemon) suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

It is indicated for the symptomatic treatment of the following disorders that require binding of stomach acid.

- Retrosternal burning and pain
- Heartburn and stomach complaints due to gastric acid
- Gastric and duodenal ulcers

4.2 Posology and method of administration

Posology/frequency and duration of administration

For children above 12 years of age and in adults; the recommended dose is 10 ml (=2 scoops; 1 scoop=5 ml) 3 times a day, preferably 1 hour after meals and before bedtime.

If needed, the dose can be increased by 10 ml.

The maximum daily dose of 8 g calcium carbonate (corresponding to 55 ml MAGCAR) should not be exceeded.

If complaints persist for more than 2 weeks during treatment, clinical examination should be performed to rule out the possibility of malignancy and the cause of the persistence of complaints should be clarified.

Method of administration

Shake well before use. The suspension is to be taken with the measuring spoon and without diluting.

Additional information on special populations

Renal failure

It should not be used for long periods in cases of renal failure, and blood levels of calcium and magnesium as well as calcium amounts excreted in urine should be checked. It should not be used in patients with severe renal failure (see section 4.3).

Hepatic failure

It is not applicable as the primary antacid effect is a local effect obtained through neutralization of gastric acid. Calcium and magnesium are not metabolized in the liver.

Pediatric population

It is not recommended for children under 12 years of age.

Geriatric population

As the antacid effect is a local effect, no specific posology is applicable for geriatric population.

4.3 Contraindications

MAGCAR should never be used in the following conditions:

- In patients with hypersensitivity to methyl parahydroxy sodium benzoate and propyl parahydroxy sodium benzoate or any of the ingredients of the medicinal product
- In patients with severe renal failure
- Hypercalcemia and/or conditions resulting in hypercalcemia e.g. hyperparatiroidism, vitamin D overdose, paraneoplastic syndrome
- Nephrolithiasis due to calculi containing calcium deposits

MAGCAR should not be used in the following conditions:

- Hypophosphatemia
- Hypercalciuria

4.4 Special warnings and precautions for use

Prolonged usage should be avoided. The prescribed dose should not be exceeded and if symptoms persist or only partially disappear, further medical advice should be sought. Patients with gastric ulcers or duodenal ulcers should be tested for H.pylori and, if the bacteria are detected, a recognized eradication therapy should be considered.

In general, caution should be exercised in patients with impaired renal function. If calcium carbonate & magnesium carbonate products are to be used in these patients, plasma calcium, phosphate and magnesium levels should be regularly monitored. None of the MAGCAR products should be used in cases of hypercalciuria.

Urinary calcium concentrations should be carefully controlled in patients with hypophosphatemia, recurrent calcium containing renal calculi and nephrocalcinosis.

Long-term uses at high doses can result in undesirable effects such as hypercalcemia, hypermagnesemia and milk-alkali syndrome, especially in patients with renal insufficiency. These products should not be taken with large amounts of milk or dairy products. Prolonged use of these products increases the risk of renal calculi formation.

Other medicines to be used during the same period as MAGCAR must be taken 2 hours before or 2 hours after the administration of MAGCAR. Antacid therapy is not recommended during quinolone treatment (see section 4.5).

This medicinal product contains sorbitol. Patients with rare hereditary problems of fructose

intolerance should not take this medicinal product.
This medicinal product contains methyl paraben and propyl paraben. It may cause (delayed) allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction
Changes in gastric acidity during treatment with antacids may impair the rate and degree of absorption of other medicinal products, if taken concomitantly.
Antacids containing calcium and magnesium have been shown to form unresorbable complexes with antibiotics (e.g. quinolones), cardiac glycosides (e.g. digoxin), levothyroxine and eltromoppag, resulting in decreased absorption. This should be borne in mind when concomitant administration is considered.
If blood calcium levels rise as a result of MAGCAR intake, sensitivity to cardiac glycosides and the risk of heart rhythm disturbances increase.
Antacids used concomitantly with tetracyclines or cephalosporins should be taken at least 2 hours before or 2 hours after these medicinal products.
Vitamin D increases calcium resorption.
Thiazide-type diuretics reduce calcium excretion. Serum calcium should be monitored regularly due to the increased risk of hypercalcemia in concomitant MAGCAR treatment with thiazides.
Calcium salts reduce the absorption of fluorides and iron-containing products, and calcium salts and magnesium salts can hinder the absorption of phosphates.
With concomitant use, there are smaller absorption reductions for chloroquine, allopurinol, non-steroidal anti-inflammatories such as diclofenac, acetylsalicylic acid, penicillamine, digoxin, isoniazid, captopril, or medicinal products such as propranolol, ketoconazole, gabapentin, H2-blockers, bisphosphonates, iron compounds and chlorpromazine.
Antacids may increase the absorption of dicumarol.
In general, a 2-hour interval should be maintained between the intake of acid-binding gastric medicinal products and the intake of other medicinal products, taking into account possible resorption effects.
Dairy products contain high levels of calcium. 1 liter of milk can contain up to 1200 mg of calcium. This information must be taken into account when using MAGCAR.

4.6 Pregnancy and lactation
General advice
Pregnancy category is B.

Women with childbearing potential / Contraception
There are no restrictions for use in women of childbearing potential.

Pregnancy
Data on a large number of cases of exposure during pregnancy do not indicate that MAGCAR has adverse effects on pregnancy or on the health of the fetus/newborn child. No significant epidemiological data have been obtained so far.
Caution should be exercised when administered to pregnant women.
No increased risk of congenital defects has been observed after the use of these medicinal products by pregnant women.
Calcium carbonate and magnesium carbonate can be used safely during pregnancy when administered in recommended doses. However, long-term and high-dose use should be avoided.
Pregnant women should limit the use of these medicinal products to the maximum

recommended daily doses (see section 4.2).

Lactation
When administered in recommended doses, calcium carbonate and magnesium carbonate can be used safely during breast-feeding. However, long-term and high-dose use should be avoided.

Fertility
It has no effect on fertility.

4.7 Effects on ability to drive and use machines
MAGCAR is not expected to have any effect on driving and using machines.

4.8 Undesirable effects
Undesirable effects are evaluated based on the frequencies below:
Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000), not known (cannot be estimated from the available data).

Listed undesirable effects are based on spontaneous reports. For this reason, it is not possible to provide frequency information for each of them.

Immune system disorders
Not known: Hypersensitivity reactions have been reported very rarely. Clinical symptoms may include rash, urticaria, angioedema and anaphylaxis.
Methyl parahydroxy sodium benzoate and propyl parahydroxy sodium benzoate may cause allergic reactions and even late reactions.

Metabolism and nutrition disorders
Not known: Especially in patients with impaired renal function, prolonged use of high doses can result in hypermagnesemia (with magnesium-containing antacids), hypophosphatemia or hypercalcemia and alkalosis, which may give rise to gastric symptoms and muscular weakness.

Nervous system disorders
Not known: Headache may occur in the context of milk-alkali syndrome.

Gastrointestinal disorders
Not known: Nausea, vomiting, stomach discomfort and diarrhea may occur.
Ageusia may occur in the context of milk-alkali syndrome.

Musculoskeletal, connective tissue and bone disorders
Not known: Muscular weakness may occur.

Renal and urinary disorders
Not known: Azotemia may occur in the context of milk-alkali syndrome.

General disorders and administration site conditions
Not known: Calcinosis and asthenia may occur in the context of milk-alkali syndrome.

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 the national reporting system.

4.9 Overdose
The use of MAGCAR is not expected to cause symptoms of acute intoxication.
Especially in patients with impaired renal function, prolonged use of high doses of calcium carbonate and magnesium carbonate can result in renal insufficiency, hypermagnesemia, hypercalcemia and alkalosis, which may give rise to gastrointestinal symptoms (nausea, vomiting, and constipation) and muscular weakness.
In these cases, the intake of the product should be stopped and adequate fluid intake encouraged.
In severe cases of overdosage (e.g. milk-alkali syndrome), a physician must be consulted because other measures of rehydration (e.g. infusions) might be necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antacids, Combined Complex
ATC code: A02AD01

Mechanism of action:
MAGCAR contains calcium carbonate and magnesium carbonate, which are antacids. The effectiveness of antacids is based on the neutralization of gastric acid. Calcium carbonate and magnesium carbonate have similar neutralization capacities but different buffering pH ranges. The effective buffering capacity range is pH 5.5 to pH 6.5 for calcium carbonate and 6.5 to 7.5 for magnesium carbonate. Therefore, the combination of calcium carbonate and magnesium carbonate provides rapid neutralization. Two tablets given to hungry subjects provided an increase by more than 1 pH unit in 5 minutes. The combination of calcium carbonate and magnesium carbonate can also be used by those on a salt-free diet.

5.2 Pharmacokinetic properties

General properties
Absorption:
Up to 10% calcium and 15-20% magnesium can be absorbed.

Distribution:
Not applicable as the primary antacid effect is a local effect obtained through neutralization of gastric acid.

Biotransformation:
In the stomach, calcium carbonate and magnesium carbonate react with the acid in the gastric fluid, forming water and soluble mineral salts.
$CaCO_3 + 2HCl \rightarrow CaCl_2 + H_2O + CO_2$
$MgCO_3 + 2HCl \rightarrow MgCl_2 + H_2O + CO_2$

Elimination:
A small amount of calcium and magnesium is absorbed, and in healthy subjects, it is usually excreted rapidly by the kidneys. In the case of impaired renal function, plasma concentrations of calcium and magnesium may increase.

Outside the stomach, soluble salts are converted into insoluble salts in the intestinal tract due to the action of various digestive fluids and then excreted in the feces.

Linearity/Non-linearity:
Since calcium absorption is not required for the antacid effect, there is a non-linearity.

5.3 Preclinical safety data
In tests on the subacute toxicity of the combination of calcium carbonate and magnesium carbonate in rats (20 male and 20 female rats), doses of 5 and 15 mg/kg/day were tolerated without any signs of toxicity. This dose corresponds to 10 to 35 times the human dose.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Sorbitol
Glycerol
Xanthan gum
Tartaric acid
Benzyl alcohol
Methyl paraben
Propyl paraben
Mint essence
Lemon essence
Saccharin sodium
Deionized water

6.2 Incompatibilities
None.

6.3 Shelf life
36 months.

6.4 Special precautions for storage
Store at room temperature below 25°C.

6.5 Nature and contents of container
Structure of packaging material:
Non-parenteral (NP) honey-colored glass bottle (Type III) sealed with HDPE cap.
Each cardboard box includes 1 bottle and a measuring spoon of 5 ml.

6.6 Special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

DEVA Holding A.Ş.
Halkalı Merkez Mah. Basın Ekspres Cad. No:1
34303 Küçükçekmece – İSTANBUL / TÜRKİYE

8. MARKETING AUTHORIZATION NUMBER

211/5

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

Date of first authorization : 03.05.2007
Renewal of the authorization :

10. DATE OF REVISION OF THE TEXT

10.04.2013