SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

MAGCAR FORTE 600 mg/70 mg/150 mg/5 ml Suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml suspension contains:

Active substance(s):
Calcium carbonate 600 mg
Magnesium carbonate 70 mg
Sodium alginate 150 mg

Excipient(s) with known effect:
Sorbitol 500 mg
Saccharin sodium 5 mg
Propyl paraben sodium 1 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of symptoms resulting from gastro-esophageal reflux and hyperacidity, such as stomachache, heartburn, feeling of gastric heaviness or fullness, dyspepsia, bloating feeling, nausea and vomiting.

4.2 Posology and method of administration

Posology/frequency and duration of administration
Standard dose is 10 ml = 2 scoops (1 scoop = 5 ml).
In adults and children above 12 years: it is recommended to take the standard dose (2 scoops) 1 hour after meals and before going to bed.
In case of burning sensation in the stomach and/or chest, an additional dose (2 scoops) can be taken in between. The maximum daily dose of 8 g calcium carbonate (corresponding to 60 ml suspension) should not be exceeded.
As in all antacids, if symptoms persist despite the treatment, it is strongly recommended to perform diagnostic examinations to eliminate the possibility of a more serious disease.

Method of administration
Taken by oral route. Shake well before use.

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 FORTE should not be used in the following cases:
- Hypersensitivity to any of the ingredients of this product
- Hypercalcemia and/or conditions and disorders resulting in hypercalcemia
- Nephrolithiasis due to calculus containing calcium residues
- Severe renal impairment
- Hypophosphatemia

4.4 Special warnings and precautions for use
Prolonged usage should be avoided. The recommended dose should not be exceeded. If symptoms persist or partially disappear, medical advice should be sought again.

In general, caution should be exercised in patients with impaired renal function. Plasma phosphate, magnesium and calcium levels should be monitored regularly when patients with impaired renal function use MAGCAR FORTE. In cases of hypercalciuria, MAGCAR FORTE should not be used.

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.

Antacids containing calcium should be used with caution in patients with constipation, hemorrhoids and sarcoidosis.

This medicinal product contains 10 mg sodium saccharin (2 scoops) and 2 mg propyl paraben sodium per dose. This must be taken into account for patients on a controlled sodium diet.

MAGCAR FORTE contains propyl paraben sodium that may cause (delayed) allergic reactions.

MAGCAR FORTE contains saccharin as a sweetener and it can be used in diabetics.

MAGCAR FORTE contains sorbitol. Patients with rare hereditary problems of fructose intolerance should not take this medicinal product.

4.5 Interaction with other medicinal products and other forms of interaction
Changes in gastric pH caused by antacids may alter the rate or degree of absorption of medicines

used concomitantly.

- Antacids containing calcium and magnesium may form complexes with certain substances such as antibiotics (e.g. tetracyclines, quinolones) and cardiac glycosides (e.g. digoxin, levothyroxine and eltrombopag) and their absorption may be reduced. This should be taken into account in concomitant treatments.
- Calcium salts can reduce the absorption of fluorides and iron-containing products. Calcium salts and magnesium salts may interfere with the absorption of phosphates.
- Thiazide diuretics reduce urinary excretion of calcium. Because of the increased risk of hypercalcemia, serum calcium levels should be monitored regularly during concomitant use of thiazide diuretics.

Since there may be changes in the absorption of concomitantly administered medicines, it is recommended to take antacid separately from other medicines (1-2 hours apart).

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

To date, no increased risk of congenital defects has been observed after the use of calcium carbonate, magnesium carbonate and alginic acid / sodium alginate in pregnancy. The risk of hypercalcemia and/or hypermagnesemia cannot be completely excluded in the case of high doses or prolonged use or in the presence of renal impairment.
Data on a large number of cases of exposure during pregnancy do not indicate that MAGCAR FORTE 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.
MAGCAR FORTE can be used in pregnancy provided that it is taken as recommended. However, long-term use of high doses should be avoided. Pregnant women should limit the use of these products to the maximum recommended daily doses (see section 4.2).

Lactation

MAGCAR FORTE can also be used during breastfeeding provided that it is taken as recommended.
It should be considered that MAGCAR FORTE used during pregnancy and breastfeeding provides a significant amount of calcium in addition to dietary calcium. For this reason, the doses of MAGCAR FORTE during pregnancy should be limited to the maximum recommended daily dose and concomitant consumption of excessive amounts of milk (up to 1.2 grams of elemental calcium in 1 liter of milk) and dairy products should be avoided.

Fertility

This medicinal product has no effect on fertility.

4.7 Effects on ability to drive and use machines

MAGCAR FORTE 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.

Metabolism and nutrition disorders

Not known: Especially in patients with impaired renal function, prolonged use of high doses can result in hypermagnesemia or hypercalcemia and alkalosis, which may give rise to gastrointestinal 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 (loss of sense of taste) 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 (calcium accumulation in tissues) and asthenia (weakness, lack of strength) 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

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 healthcare professional must be consulted because other measures of rehydration (e.g. infusions) might be necessary.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antacids, other combinations
ATC code: A02AX

Mechanism of action:
MAGCAR FORTE is a combination of two antacids, calcium carbonate and magnesium carbonate, and sodium alginate. The activity of calcium carbonate and magnesium carbonate is based on neutralization of gastric acid and is locally effective, independent of systemic absorption. Calcium carbonate provides fast, long-lasting and potent neutralization. This effect is enhanced by the addition of magnesium carbonate, which has a high capacity to neutralize the acid. In healthy volunteers, a significant increase in gastric pH was achieved within 3 minutes. 10 ml of a combination of calcium carbonate, magnesium carbonate and sodium alginate has a neutralizing capacity of 32 mEq H^+(final titration pH: 2.5). Regardless of the neutralizing effect of antacids, sodium alginate acts as a physical barrier against reflux by forming a viscous gel that floats on top of the stomach contents.

5.2 Pharmacokinetic properties

General properties

Absorption:
Ca and Mg can be absorbed from soluble chlorine salts. However, the degree of absorption varies depending on the patient and dose. About 10% of calcium and 15-20% of magnesium are absorbed. Absorption of alginic salts is negligible.

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:
Small amounts of Ca and Mg are absorbed, and in healthy subjects, it is usually excreted rapidly by the kidneys. Plasma levels of calcium and magnesium may increase in case of impaired renal function. 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. After oral ingestion, alginic acid is not transformed in the gastrointestinal tract: 80-100% of the digested amount is excreted, because acidic polysaccharides produce an indigestible ionic colloid.

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

5.3 Preclinical safety data

Based on traditional safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential or reproductive toxicity studies, preclinical data do not indicate the existence of any particular hazard to humans.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol
Glycerol
Xanthan gum
Tartaric acid
Benzyl alcohol
Propyl paraben sodium
Mint essence
Chocolate 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 with an aluminum seal ring inside.
Each cardboard box includes 1 bottle containing 100 ml or 200 ml suspension, supplied with a 5 ml measuring spoon.

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

216/94

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

Date of first authorization : 17.09.2008
Renewal of the authorization :

10. DATE OF REVISION OF THE TEXT

10.04.2013