SUMMARY OF PRODUCT CHARACTERISTICS

NAME OF THE MEDICINAL PRODUCT

CARBOSYMAG, capsule.

QUALITATIVE AND QUANTITATIVE COMPOSITION

Green capsule
Activated charcoal ..... 140.00 mg
Simethicone ..... 45.00 mg
Heavy magnesium oxide ..... 180.00 mg
For a green capsule

Orange gastroresistant capsule:
Activated charcoal ..... 140.00 mg
Simethicone ..... 45.00 mg
For an orange capsule

Excipients with known effect: Sunset yellow S (E 110).
For a complete list of excipients, see the section “List of excipients”.

PHARMACEUTICAL FORM

Capsule

CLINICAL PARTICULARS

Therapeutic indications

Symptomatic treatment of heartburn associated to abdominal distension.

Posology and method of administration

Oral route

The dosing unit consists of one green gastrosoluble capsule and one orange gastroresistant capsule to be taken simultaneously.
The usual posology is 3 dosing units per day, i.e. one green capsule and one orange capsule, to be taken before or after the main meals.

Contraindications

Linked to the magnesium: severe renal failure.

Special warnings and precautions for use

This medicine must be used with precautions in case of chronic dialysis (see the section “Contraindications”). This medicine contains a colouring agent sunset yellow azo S (E 110) and can cause allergic reactions.

Interactions with other medicinal products and other forms of interactions

Antacids interact with certain other medicines absorbed by oral route.

Combinations requiring precautions for use

As a precaution, antacids should be taken apart from other medicinal products.

If possible, leave an interval an interval of more than 2 hours with:
- Kayexalate *(oral route)*: Reduction of the ability of the resin to bind potassium, with the risk of metabolic alkalosis in kidney failure patients.

Risk of reduced digestive absorption of the following medicines:
- Antibacterials-antituberculars (ethambutol, isoniazide) *(oral route)*
- Antibacterials-cyclines *(oral route)*
- Antibacterials-fluoroquinolones *(oral route)*
- Antibacterials-lincosanides *(oral route)*
- H2 Antihistamines *(oral route)*
- Atenolol, metoprolol, propranolol *(oral route)*
- Chloroquine *(oral route)*
- Diflunisal *(oral route)*
- Digoxin *(oral route)*
- Biphosphonates *(oral route)*
- Fexofenadine
- Sodium fluoride
- Glucocorticosteroids *(oral route)* (reported for prednisolone and dexamethasone)
- Indomethacin *(oral route)*
- Ketoconazole *(oral route)*
- Lansoprazole
- Phenothiazine neuroleptics *(oral route)*
- Penicillamine *(oral route)*
- Phosphorus *(supplements)*
- Iron salts *(oral route)*
- Thyroxin

Combinations to be taken into account

- Salicylates *(oral route)*: Increased renal excretion of salicylates by alkalinization of the urine.

Pregnancy and breast-feeding

Pregnancy
There are no reliable teratogeny data in animals.
In clinical practice, there are currently insufficiently relevant data enabling evaluation of the malformation-inducing or foetotoxic effect of aluminium and magnesium hydroxides when administered during pregnancy.
Taking into account its poor absorption, this medicinal product is only to be used during pregnancy if necessary.

Take into account the presence of magnesium ions likely to have an impact on transit:
- magnesium salts can induce diarrhoea.
Try to restrict the daily dose and, if possible, the duration for which the medicine is taken.

Breast-feeding
This medicine can be prescribed during breast-feeding.

Effects on ability to drive and use machines

CARBOSYMAG, capsule does not affect the ability to drive and use machines.

Undesirable effects

Transit disorders (diarrhoea).
The use of this medicine at high doses can induce darker coloration of the stools.

Reporting of suspected undesirable effects
Reporting suspected adverse reactions after authorisation 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 Agence nationale de sécurité du medicament et des produits de santé (ANSM) in the network of the Regional Centres of Pharmacovigilance – Website: www.signalement-sante.gouv.fr

Overdose

No case of overdose was reported, however, the ingestion of excessive doses may induce a hypomagnesaemia. The symptoms may include the gastro-intestinal disorders, diarrhoea, vomiting, somnolence, respiratory depression or even a cardiac arrest. The treatment is based on the administration of calcium gluconate. A dialysis may be planned for the patients with renal failure.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

ANTACID/ANTIFLATULENT
ATC code: A07BA51

Experimentally, according to the method known as Vatier's «artificial stomach» in the presence of pig mucosa, adding activated charcoal and simethicone to magnesium oxide produces the following results:
- Theoretical maximum antacid capacity (TMAC): 123 mmol per capsule (TMAC obtained without the charcoal = 64 mmol per capsule).

Pharmacokinetic properties

The green capsule releases charcoal, simethicone and magnesium oxide in the stomach and the orange capsule dissolves in the intestine and releases charcoal and simethicone.

Preclinical safety data

No information is available.

PHARMACEUTICAL PARTICULARS

List of excipients

Composition of the green capsule shell: quinoline yellow (E 104), indigotin (E 132), titanium dioxide (E 171), gelatin.
Composition of the orange capsule shell: erythrosine (E 127), Sunset yellow S (E 110), titanium dioxide (E 171), gelatin.

Composition of the gastroresistant coating: cellulose acetate phthalate, diethyl phthalate.

Shelf life

3 years.

6.4. Special precautions for storage

No special precautions for storage are required.

6.5. Nature and contents of container

24 green capsules + 24 orange capsules in blister strips (PVC/Aluminium)
48 green capsules + 48 orange capsules in blister strips (PVC/Aluminium)

Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with current regulations.

MARKETING AUTHORISATION HOLDER
Laboratoires GRIMBERG SA – 44 avenue Georges Pompidou- 92300 Levallois-Perret - France

8. MARKETING AUTHORISATION NUMBER(S)
349 037-0: 24 green capsules + 24 orange capsules in blister strips (PVC/Aluminium).
349 038-7: 48 green capsules + 48 orange capsules in blister strips (PVC/Aluminium).

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21 December 1998/21 December 2013

10. DATE OF REVISION OF THE TEXT
10 August 2017

PRESCRIBING AND DISPENSING CONDITIONS

Medicinal product is not subject to medical prescription.