

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE MEDICINAL PRODUCT

**CARBOSYMAG, capsule.**

## 2. 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 known as having a recognised action: Sunset yellow S (E 110).

For a complete list of excipients, see the section 6.1

## 3. PHARMACEUTICAL FORM

Capsule.

## 4. CLINICAL PARTICULARS

### 4.1. Therapeutic indications

Symptomatic treatment of heartburn associated to the abdominal distension.

### 4.2. 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.

### 4.3. Contraindications

Linked to the magnesium: severe renal failure.

### 4.4 Special warnings and precautions for use

This medicine must be used with precautions in case of chronic dialysis (see the section 4.3). This medicine contains a colouring agent sunset yellow azo S (E 110) and can cause allergic reactions

#### **4.5 Interactions with other medicinal products and other forms of interaction**

Antacids interact with certain other medicines absorbed by oral route.

##### **Combinations calling for special precautions**

As a precaution, antacids should be taken at an interval from other medicines.

Allow an interval of more than 2 hours, if possible, with:

- Kayexalate (*oral route*): Reduction of the ability of the resin to bind potassium, with the risk of metabolic alkalosis in renal 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-lincosamides (*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*)
- Thyroxine

##### **Combinations to be taken into account**

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

#### **4.6. Pregnancy and breast-feeding**

##### **Pregnancy**

There are no reliable teratogen data in animals.

In clinical use, presently there are insufficient relevant data to assess the possible malformative or foetotoxic effect of aluminium or magnesium hydroxides when they are administered during pregnancy.

In view of its low absorption, the use of this medicine should only be envisaged during pregnancy if necessary.

Take into consideration the presence of magnesium ions being able to affect 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.

#### **4.7 Effects on the ability to drive and use machines**

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

#### **4.8 Adverse effects**

Disorders affecting transit (diarrhoea).

The use of this medicine at high doses can induce darker coloration of the stools.

#### **Reporting of suspected adverse reactions**

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 médicament et des produits de santé (ANSM) in the network of the Regional Centres of Pharmacovigilance – Website: [www.ansm.sante.fr](http://www.ansm.sante.fr)

#### **4.9. 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 suffering from the renal failure.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

ANTACID/ANTIFLATULENT

(A: Digestive system and metabolism)

Experimentally, according to the method known as Vatiez'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).

#### **5.2. 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.

#### **5.3. Preclinical safety data**

Unspecified.

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1. 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.

## **6.2 Incompatibilities**

Not applicable.

## **6.3.Shelf life**

2 years.

## **6.3. Special precautions for storage**

No special precautions for storage.

## **6.4. Nature and contents of the container**

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

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

96 green capsules + 96 orange capsules in blister strips (PVC/Aluminium)

## **6.5.Special precautions for disposal**

No special requirement.

## **7. MARKETING AUTHORISATION HOLDER**

Laboratoires GRIMBERG

19, rue Poliveau

75005 PARIS

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).

356 154-9: 96 green capsules + 96 orange capsules in blister strips (PVC/Aluminium)

## **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

21/12/1998/

## **10. DATE OF REVISION OF THE TEXT**

21/02/2011