PACKAGE LEAFLET

CARBOSYMAG, capsule

Activated charcoal, simeticone, magnesium oxide

Read all of this leaflet carefully before you start taking 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.
- You must talk to a doctor if you do not feel better or if you feel worse.

Keep out of the reach of children

In this leaflet:

- 1. WHAT CARBOSYMAG, capsule IS AND WHEN IT IS USED FOR
- 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CARBOSYMAG, capsule
- 3. HOW TO TAKE CARBOSYMAG, capsule
- 4. POSSIBLE SIDE EFFECTS
- 5. HOW TO STORE CARBOSYMAG, capsule
- 6. CONTENTS OF THE PACK AND OTHER INFORMATION

1. WHAT CARBOSYMAG, capsule IS AND WHEN IT IS USED FOR?

Pharmacotherapeutic group: Digestive tract and metabolism - ATC code: A07BA51

This medicine is indicated in burning of the stomach associated with bloating.

2. WHAT IS THE INFORMATION TO BE AWARE OF BEFORE USING CARBOSYMAG, capsule

Do not take CARBOSYMAG, capsule:

If you have severe renal disease (functional renal failure)

Warnings and precautions

Talk to your doctor or pharmacist before taking CARBOSYMAG, capsule.

DO NOT TAKE THIS MEDICINE WITHOUT MEDICAL ADVICE in case of chronic dialysis.

This medicine can decrease the effects of many other medicines. Always tell your doctor or pharmacist about any other ongoing treatment.

As a precaution, take this medicine remotely from other medicines (an interval of 2 hours if possible).

This medicine contains an azo dye, sunset yellow S (E 110), and may cause allergic reactions.

While using this medicine at the same time, it is recommended to observe certain hygiene and dietary rules:

- do not go to bed immediately after a meal,
- do not sleep flat (raise the head of the bed in order to decrease the frequency of night-time reflux),
- avoid prolonged work bending forward (housework, gardening, etc.),
- avoid excessively large meals.

Other medicines and CARBOSYMAG, capsule

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Pregnancy and breast feeding

This medicine must only be used during pregnancy with medical advice.

If you discover that you are pregnant during treatment, consult your doctor, because only a doctor can decide whether it is necessary to continue the treatment.

This medicine may be prescribed during breast feeding.

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.

Driving and using machines

No effect on the ability to drive and use machines is known or expected.

CARBOSYMAG, capsule contains sunset yellow S (E 110), an excipient with known effect.

3. HOW TO USE CARBOSYMAG, capsule

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

Posology

This medicine is presented in the form of a green (whose active ingredients are released in the stomach) and an orange capsule (whose active ingredients are released in the intestine), to be taken simultaneously.

The usual dosage is 3 doses daily (one dose = 1 green capsule + 1 orange capsule).

Method of administration

Oral route.

Frequency of administration

This medicine should be taken before or after the main meals.

Treatment duration

Treatment duration depends on the symptoms.

If you have taken more CARBOSYMAG, capsule than you should have:

Ingestion of excessive doses of CARBOSYMAG may result in hypermagnesemia. Symptoms may include gastrointestinal pain, diarrhoea, vomiting, drowsiness, respiratory distress and even cardiac arrest. If you have taken CARBOSYMAG more than you should, immediately contact the nearest poison control center or your doctor.

If you forget to take CARBOSYMAG, capsule

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

If you have any further questions 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:

- diarrhoea,
- · dark discolouration of the stools

Reporting of side effects:

If you get any side effect, talk to your doctor or your pharmacist or your nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: National Agency for safety of medicines and health products (ANSM) and network of the Regional Centers of Pharmacovigilance. Website: www.signalement-sante.gouv.fr. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE CARBOSYMAG, capsule

Keep this medicine out of the sight and reach of children.

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

Medicines should not be disposed of via waste-water or household wastes. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What does CARBOSYMAG, capsule, contain?

• The active substances are:

Green capsule:	
Activated charcoal	140.00 mg
Simeticone	45.00 mg
Heavy magnesium oxide	180.00 mg
For one green capsule.	
Orange capsule:	
Activated charcoal	140.00 mg
Simeticone	45.00 mg
For one orange capsule.	

The other ingredients are:

Green capsule:

<u>Shell of the capsule</u>: quinoleine yellow (E 104), indigotin (E132), titanium dioxide (E171), gelatin <u>Gastroresistant orange capsule</u>:

<u>Shell of the capsule</u>: erythrosine (E127), sunset yellow S (E 110), titanium dioxide (E171), gelatin Composition of gastroresistant coating: cellulose phthalate acetate, diethyl phthalate.

What CARBOSYMAG, capsule looks like and contents of the pack

This medicine contains capsules.

Box of 24 green capsules + 24 orange capsules in PVC/aluminum blister or 48 green capsules + 48 orange capsules in PVC/aluminum blister.

Marketing Autorisation Holder:

Laboratoires GRIMBERG SA - 44 avenue Georges Pompidou- 92300 Levallois-Perret - France

Manufacturer:

Laboratoires GRIMBERG SA - ZA des Boutries - rue Vermont - 78704 Conflans Sainte Honorine cedex - France

This leaflet was last revised in August 2017

Detailed information on this medicinal product is available on ANSM website (France)