

PACKAGE LEAFLET

CARBOSYLANE, capsule Activated charcoal, simeticone

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 effect, talk to your doctor or pharmacist. This includes any possible side effect not listed in this leaflet. See section 4.

- You must talk to your doctor if you do not feel better or if you feel worse after 10 days.

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

Pharmacotherapeutic group – ATC code: A07BA51, ANTIFLATULENT/ INTESTINAL ADSORBENT

This medicine is indicated in adults and children over 6 years old for the symptomatic treatment of dyspeptic states (indigestion) and meteorism (intestinal distension)

You should talk to your doctor if you do not feel better or if you feel worse after 10 days of treatment.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CARBOSYLANE, capsule ?

Do not take CARBOSYLANE, capsule:

- if you are allergic (hypersensitive) to the actives substances or any of the other ingredients of this medicine listed in section 6.
- In children under 6 years old due to the risk of choking.

Warnings and precautions

If you take another medical treatment keep an interval between taking CARBOSYLANE, capsule and other drugs (more than 2 hours, if possible).

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

Other medicines and CARBOSYLANE, capsule

This medicine can reduce the uptake of other medicines, and these should therefore be administered at an interval from it (more than 2 hours if possible)

Tell your doctor or pharmacist if you are taking, have recently taken or might take 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, as 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 of machines

Not applicable.

3. HOW TO TAKE CARBOSYLANE, capsule?

Posology

For adults and children aged over 6 years old.

This medicine is presented in the form of a blue, gastro-soluble capsule (whose active substances are released in the stomach) and a red gastro-resistant capsule (whose active substances are released in the intestine), to be taken simultaneously.

The usual dosage is 3 doses (one dose = 1 red capsule + 1 blue capsule) per day.

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

Method of administration

Oral route.

One unit dose (red capsule + blue capsule) to be taken simultaneously with a glass of water

Frequency of administration

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

Treatment duration

Treatment duration varies with symptomatology.

If you take more CARBOSYLANE, capsule, than you should:

The use of high dose levels can result in dark colouration of the stools.

Contact your doctor or pharmacist immediately.

If you forget to take CARBOSYLANE, capsule

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

If you stop taking CARBOSYLANE, gélule :

Not applicable.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist for more information

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them:

- dark discolouration of the stools may occur.
- cases of allergic reactions (urticaria, generalised allergic reaction) have been reported after the administration of CARBOSYLANE, capsule
- cases of gastro-intestinal disorders (pain, vomiting, discomfort, constipation or diarrhoea) have been reported following administration of Carbosylane, capsule

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. Web site: 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 CARBOSYLANE, 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 after EXP. The expiry date refers to the last day of that month.

No special storage conditions.

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 CARBOSYLANE, capsule contains

- The active substances are:

Activated charcoal	140 mg
Simethicone	45 mg

For one blue or red capsule.

- The other ingredients are:

Sorbitan oleate, polysorbate 80

Shell of the blue capsule : gelatin, indigotin (E132), titanium dioxide (E171).

Shell of the red capsule : gelatin, erythrosine (E127), titanium dioxide (E171), indigotin (E132).

Gastroresistant coating of the red capsule : cellulose phthalate acetate, diethyl phthalate.

What CARBOSYLANE, capsule looks like and contents of the pack

This medicine contains capsules. Box of 48 (24 doses), 60 (30 doses), 96 (48 doses).

Marketing Authorisation Holder:

LABORATOIRES GRIMBERG SA – 44 avenue Georges Pompidou- 92300 Levallois-Perret - France

Manufacturer:

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This leaflet was last revised in January 2022.

Detailed information on this medicine is available on ANSM website (France)