SUMMARY OF PRODUCT CHARACTERISTICS

NAME OF THE MEDICINAL PRODUCT

CARBOSYLANE, capsule

QUALITATIVE AND QUANTITATIVE COMPOSITION

Activated charcoal ..... 140 mg
Simeticone ..... 45 mg
For one blue or red capsule

For a full list of excipients, see section “List of excipients”.

PHARMACEUTICAL FORM

Capsule.

CLINICAL DATA

Therapeutic indications

Symptomatic treatment of dyspeptic states and distension.

Posology and method of administration

Posology

Restricted for adults and children over 6 years old.

The usual posology is 3 dosage forms per day (i.e. one blue capsule and one red capsule 3 times a day to be taken preferably before or after the main meals with a glass of water).

Method of administration

Oral route.

The dosage unit consists of one red gastroresistant capsule and one blue gastrosoluble capsule to be taken simultaneously with a glass of water, preferably before and after the main meals

Duration of treatment

The usual duration of treatment is of 10 days.

Contraindications

- Hypersensitivity to the active substances or to one of excipients mentioned in the section “List of excipients”.
- Children under 6 years old (risk of inhaling the capsule).

Special warnings and precautions for use

In case of a concomitant treatment, take CARBOSYLANE remotely (more than 2 hours, if possible).

If the symptoms persist or worsen or if constipation is prolonged, the patient is advised to take medical advice.

Interactions with other medicinal products and other forms of interactions

Due to the properties of the charcoal, the possible reduction of the absorption of drugs makes any other medication be administered remotely from CARBOSYLANE (more than 2 hours if necessary)..

Fertility, pregnancy and breast-feeding

Pregnancy

No teratogenicity study is available in animals.

In clinical use, the use of charcoal does not seem to have revealed any malformative or fœtotoxic effect up to date. However, epidemiological studies are required to confirm that there is no risk.
Consequently, and due to no resorption of charcoal, the use of this drug should not be envisaged during pregnancy unless necessary.

Breast-feeding

This medicine may be prescribed during breast-feeding.

Fertility

The effect on human fertility has not been studied.

Undesirable effects

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

The following table presents the adverse reactions reported during the use of CARBOSYLANE® in clinical trials and while marketed. Adverse reactions are classified by organ system and frequency using the following convention: very frequent (1/10), frequent (1/100 to 1/10), infrequent (1/1,000 to 1/100), rare (1/10,000 to 1/1,000), very rare (1/10,000), indeterminate frequency (cannot be estimated on the basis of available data).

	Adverse Reactions			
System Class Organ	***Frequent***	***Uncommon***	***Rare***	***Undetermined frequency***
Skin and subcutaneous tissue disorders				*Urticaria*
Immune system disorders				*Anaphylactic-like allergic reaction*
Gastro-intestinal conditions				*Pain, vomiting, discomfort, constipation or diarrhea*

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 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

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Pharmacotherapeutic class: ANTIFLATULENT/ INTESTINAL ADSORBENT (A: digestive system and metabolism), ATC code: A07BA51

Carbosylane combines 2 active ingredients:

- charcoal, which has adsorbing properties,
- simethicone, a physiologically inert substance, which has no pharmacological activity and acts by altering the surface tension of the bubbles of gas, thus causing them to coalesce.

Pharmacokinetic properties
The twin capsules that constitute a dosage unit of this medicine both contain the same active ingredients: activated charcoal and simeticone.

This medicine acts at two complementary levels; the blue capsule releases its active ingredients in the stomach, whereas the red capsule dissolves in the intestine.

Neither of both active ingredients of this medicine is resorbed by the gastrointestinal mucosa.

Preclinical safety data
No information is available

PHARMACEUTICAL PARTICULARS

List of excipients
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.

Shelf life
4 years

Special precautions for storage
No special precautions for storage are required.

Nature and contents of container
24 blue capsules + 24 red capsules in blister (PVC/Aluminium)
48 blue capsules + 48 red capsules in blister (PVC/Aluminium)

Special precautions for disposal and handling
Any unused medicinal product or waste material should be disposed of in accordance with current .

MARKETING AUTHORISATION HOLDER

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

MARKETING AUTHORISATION NUMBER(S)
34009 327 312 9 9: 24 blue capsules + 24 red capsules in blister (PVC/Aluminium)
34009 327 244 3 7: 48 blue capsules + 48 red capsules in blister (PVC/Aluminium)

DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION
16 February 1981 /16 February 2011

DATE OF REVISION OF THE TEXT:
28 May 2019

PRESCRIBING AND DISPENSING CONDITIONS

Medicinal product is not subject to medical prescription