SUMMARY OF PRODUCT CHARACTERISTICS

1. 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 6.1.

3. PHARMACEUTICAL FORM

Capsule.

4. CLINICAL DATA

4.1 Therapeutic indications

Symptomatic treatment of dyspeptic states and distension.

4.2 Dosage and route of administration

Oral route.

For adults and children over 6 years of age only.

The dosage unit consists of one blue gastrosoluble capsule and one red gastroresistant capsule to be taken simultaneously.
The usual dosage is 3 dosage units per day (i.e. one blue capsule and one red capsule 3 times a day to be taken before or after the main meals).

4.3 Contraindications

- Hypersensitivity to any of the constituents.
- Children under 6 years of age (risk of inhaling the capsule).

4.4 Special warnings and precautions

Allow an interval between taking Carbosylane and digitalis-type drugs (more than 2 hours, if possible).

4.5 Interactions with other drugs and other forms of interactions

Due to the properties of the charcoal, the possible reduction of the absorption of drugs means that an interval should be allowed between the administration of any other medication (more than 2 hours if necessary) and taking Carbosylane.

Interaction calling for precautions

- **Digitalis-type drugs**

Reduction of the digestive uptake of digitalis-type drugs.
Allow an interval between taking Carbosylane and digitalis-type drugs (more than 2 hours, if possible).

4.6 Pregnancy and lactation

Pregnancy
No teratogenicity study in animals is available.
In clinical use, the use of charcoal does not seem to have revealed any malformative or fœtotoxic effect to date. However, epidemiological studies are required to confirm that there is no risk.
Consequently, and in view of the fact that the charcoal is not resorbed, the use of this drug should not be envisaged during pregnancy unless necessary.

Lactation
This medicine can be prescribed during lactation.

4.7 Effects on the ability to drive vehicles and operate machinery

Not applicable.

4.8 Adverse effects

The use of high dose levels of this medicine can result in dark colouration of the stools.
Some cases of allergic skin reactions (urticaria, anaphylactoid reaction) have been reported post marketing.
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 medicament et des produits de santé (ANSM) in the network of the Regional Centres of Pharmacovigilance – Website: www.ansm.sante.fr

4.9 Overdose

No overdose has been reported, however, use of high dose levels can result in dark colouration of the stools.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ANTIFLATULENT/ INTESTINAL ADSORBENT (A: digestive system and metabolism)

Carbosylane combines 2 active ingredients:
- charcoal, which has adsorbing properties,
- Simeticone, 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.

5.2 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 the active ingredients of this medicine is resorbed by the gastrointestinal mucosa.

5.3 Preclinical safety data

Not specified

6. PHARMACEUTICAL PARTICULARS

6.1 Liste des 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.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

4 years

6.4 Special precautions for storage

There are no special precautions for storage.

6.5 Nature and contents of the outer packaging

24 blue capsules + 24 red capsules in blister (PVC/Aluminium)
48 blue capsules + 48 red capsules in blister (PVC/Aluminium)
96 blue capsules + 96 red capsules in blister (PVC/Aluminium)

6.6 Special precautions for disposal and handling

There are no special requirements.

7. MARKETING AUTHORISATION HOLDER

Laboratoires GRIMBERG
19, rue Poliveau
75005 PARIS
FRANCE

8. MARKETING AUTHORISATION NUMBER(S)

327 312-9 or 34009 327 312 9 9: 24 blue capsules + 24 red capsules in blister (PVC/Aluminium)
327 244-3 or 34009 327 244 3 7: 48 blue capsules + 48 red capsules in blister (PVC/Aluminium)
356 153-2 or 34009 356 153 2 9: 96 blue capsules + 96 red capsules in blister (PVC/Aluminium)

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

16 February 1981 / 16 February 2011

10. DATE OF REVISION OF THE TEXT:

27 September 2012.

11. DOSIMETRY:

Not applicable

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS:

Not applicable

PRESCRIBING AND DISPENSING CONDITIONS

Medicinal product not subject to medical prescription