

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Carbosylane Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Capsule, hard (blue)

Active Ingredients

Activated charcoal	140	mg
Simeticone	45	mg

Gastro-resistant capsule, hard (red)

Active Ingredients

Activated charcoal	140	mg
Simeticone	45	mg

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Two capsules for simultaneous administration consisting of a capsule, hard (blue) and a gastro-resistant capsule, hard (red).

Capsule, hard (blue) is a size 1 capsule with a bright blue opaque body and cap and contains a black powder.

Gastro-resistant capsule, hard (red) is a size 1 capsule with a red opaque body and cap, flat aspect and contains a black powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an anti-flatulent.

4.2 Posology and method of administration

Oral

Adults only :

One red capsule and one blue capsule taken together 3 times a day before and/or after meals. Both capsules should be swallowed in immediate succession with a little water, and not chewed.

4.3 Contraindications

Hypersensitivity to activated charcoal, simeticone or any of the excipients.

4.4 Special warnings and precautions for use

Because of activated charcoal's adsorbing properties, the potential decrease in absorption of drugs means that all other drugs should be administered at least 1 hour before or 1 hour after Carbosylane intake.

4.5 Interaction with other medicinal products and other forms of interaction

See special precautions for use.

4.6 Pregnancy and lactation

The product should only be used when considered essential by the physician.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

With large doses one may note a brownish stools colouration.

4.9 Overdose

None stated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Carbosylane associates two most widely used active ingredients to treat flatulence. These two active ingredients, proven to be effective, have complementary therapeutic properties:

- Adsorbing properties of activated charcoal.
- Antifoaming properties of simeticone.

5.2 Pharmacokinetic properties

The blue capsule releases its active ingredients in the stomach, thereby acting upon disturbances of the upper digestive tract.

The red capsule is gastro-resistant and releases its active ingredients in the intestine thus acting upon disturbances of the lower digestive tract.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Blue capsule, hard

Excipients:

Sorbitan Oleate

Polysorbate 80

Empty blue capsule:

Indigotine (E132)

Titanium Dioxide (E171)

Gelatin

Red gastro-resistant capsule, hard

Excipients:

Sorbitan Oleate

Polysorbate 80

Empty red capsule:

Indigotine (E132)

Erythrosine (E127)

Titanium Dioxide (E171)

Gelatin

Gastro-resistant:

Cellulose Acetate Phthalate

Coating:

Diethyl Phthalate

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

4 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Blister packs: aluminium / PVC.

Aluminium, 20 micrometre thick, sealed with PVC 250 micrometre.

Pack sizes: box of 48 (24 blue capsules and 24 red capsules) and box of 96 (48 blue capsules and 48 red capsules).

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Laboratoires Grimberg
19 rue Poliveau
75005 Paris
France

8 MARKETING AUTHORISATION NUMBER

PA 345/1/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 21 May 2002

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