

## SUMMARY OF PRODUCT CHARACTERISTICS

### NAME OF THE MEDICINAL PRODUCT CARBOSYLANE CHILD, capsule

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

#### Gastrosoluble blue capsule:

Activated charcoal ..... 70.0 mg  
Simeticone ..... 22.5 mg

Per No. 4 capsule containing 107.5 mg.

Composition of the capsule shell: gelatin, indigotin (E132), titanium dioxide (E171), sulphur dioxide

#### Gastroresistant red capsule:

Activated charcoal ..... 70.0 mg  
Simeticone ..... 22.5 mg

Per No. 4 capsule containing 107.5 mg.

**For the complete list of excipients:** see the section "List of excipients"

### PHARMACEUTICAL FORM

Capsule

### CLINICAL PARTICULARS

#### Therapeutic indications

Symptomatic treatment of dyspeptic states and bloating.

#### Posology and method of administration

##### Posology

##### Pediatric population

RESTRICTED FOR CHILDREN OVER 6 YEARS OLD.

The dosage unit consists in a gastrosoluble blue capsule and a gastroresistant red capsule.

The usual dosage is: 2 doses (of 2 paired capsules) daily from age of 6 to 10 years,  
3 doses (of 2 paired capsules) daily from age of 10 to 15 years

##### Method of administration

These two capsules are to be swallowed simultaneously, preferably at the start of a meal.

##### Contra-indications:

- Hypersensitivity to any of the ingredients of CARBOSYLANE CHILD, capsule
- Children under 6 years old (a risk of the false route)
- Splanchnemphraxis

##### Special warnings and precautions for use:

##### Pediatric population

If your child takes a medication with digitalis, make him/her take CARBOSYLANE CHILD, capsule remotely (more than 2 hours, if possible)

## **Interactions with other medicinal products and other forms of interaction**

### **Pediatric population**

Due to the properties of charcoal, the potential decrease in the absorption of medicinal products requires remote administration of all other medication (more than 2 hours if possible) relative to intake of this medicinal product.

### **Interactions requiring a precaution for use:**

#### **+ Digitalis:**

Decreased digestive absorption of digitalis.

Take the charcoal remotely from the digitalis (more than 2 hours if possible).

### **Fertility, pregnancy and breast-feeding:**

Considering the available data, the use in the pregnant woman or in the breast-feeding woman is possible punctually

### **Undesirable effects**

Use of this medicinal product at high doses may induce a dark colour of the stools.

#### **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 Agence nationale de sécurité du médicament et des produits de santé (ANSM) in the network of the Regional Centres of Pharmacovigilance – Website: [www.signalement-sante.gouv.fr](http://www.signalement-sante.gouv.fr)

### **Overdose:**

#### **Pediatric population**

No case of overdose was reported, however, a black colouring of stools can be observed in high doses.

## **PHARMACOLOGICAL PROPERTIES**

### **Pharmacodynamic properties**

ANTIFLATULENT/INTESTINAL ADSORBENT

(A: gastrointestinal system and metabolism)

Carbosylane Child, capsule combines 2 active substances:

- activated charcoal, which has adsorbent properties,
- simeticone, a physiologically inert substance, which has no pharmacological activity and acts by modifying the surface tension of gas bubbles inducing their coalescence.

### **Pharmacokinetic properties**

The 2 paired capsules which constitute the dosage unit of the medicinal product contain the same active substances: activated charcoal and simeticone.

The medicinal product acts at 2 complementary levels: the blue capsule releases its active substances at gastric level while the red capsule disintegrates at intestinal level.

The two active substances in the medicinal product are not resorbed by the gastrointestinal mucosa.

**Preclinical safety data:** No information is available.

## **PHARMACEUTICAL PARTICULARS**

### **List of excipients**

**Gastrosoluble blue capsule:**

Sorbitan oleate, polysorbate 80

**Composition of the capsule shell:** gelatin, titanium dioxide (E171), indigotin (E132), sulphur dioxide.

**Gastroresistant red capsule:**

Sorbitan oleate, polysorbate 80

**Composition of the gastroresistant coating:** cellulose acetate phthalate, diethyl phthalate, methylene chloride, methanol

**Shelf life**

4 years.

**Special precautions for storage:**

No special precautions for storage are required.

**Nature and contents of container**

24 gastrosoluble blue capsules + 24 gastroresistant red capsules in heat-formed blister packs (PVC + aluminium)

48 gastrosoluble blue capsules + 48 gastroresistant red capsules in heat-formed blister packs (PVC + aluminium)

**Special precautions for disposal and other handling**

Any unused product or waste material should be disposed of in accordance with current regulations.

**MARKETING AUTHORISATION HOLDER**

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

**MARKETING AUTHORISATION NUMBERS:**

- 3400932995486 or 329 954-8: 24 gastrosoluble blue capsules + 24 gastroresistant red capsules in heat-formed blister packs (PVC + aluminium)
- 3400932954384 or 329 543-8: 48 gastrosoluble blue capsules + 48 gastroresistant red capsules in heat-formed blister packs (PVC + aluminium)

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION:**

23 April 1987/23 Avril 2012

**10. DATE OF REVISION OF THE TEXT**

10 August 2017