

Decreased digestive absorption of digitalis.
Take the charcoal remotely from the digitalis (more than 2 hours if possible).

4.6 Pregnancy and lactation:

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

4.7 Effects on ability to drive and use machines: Not applicable.

4.8 Undesirable effects

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

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 médicament et des produits de santé (ANSM) in the network of the Regional Centres of Pharmacovigilance – Website: www.ansm.sante.fr

4.9 Overdose:

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

5. PHARMACOLOGICAL PROPERTIES

5.1 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.

5.2 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.

5.3 Preclinical safety data: Unspecified

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Gastro-soluble blue capsule:

Sorbitan oleate, polysorbate 80

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

Gastro-resistant red capsule:

Sorbitan oleate, polysorbate 80

Composition of the gastro-resistant coating: cellulose acetate phthalate, diethyl phthalate, methylene chloride, methanol

6.2 Incompatibilities: Not applicable

6.3 Shelf life:4 years.

6.4 Special precautions for storage: No special precautions for storage.

6.5 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)

96 gastrosoluble blue capsules + 96 gastroresistant red capsules in heat-formed blister packs (PVC + aluminium)

6.6 Special precautions for disposal: No special requirements

7. MARKETING AUTHORISATION HOLDER

Laboratoires GRIMBERG

19, rue Poliveau
75005 PARIS

8. 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)
- 3400935615268 or 356 152-6: 96 gastrosoluble blue capsules + 96 gastroresistant red capsules in heat-formed blister packs (PVC + aluminium)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION: 23/04/1987

10. DATE OF REVISION OF THE TEXT: 27/09/2012