

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Carbex

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2.8 gram sachet of granules contains:

Sodium Bicarbonate	1.260g
Simeticone	0.042g

Each 10ml bottle of Carbex solution contains:

Citric Acid	1g in 10ml
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For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Separate granules and solution for oral administration.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Gas producing agent for use as an image enhancer in diagnostic procedures of the stomach and upper gastrointestinal tract.

4.2 Posology and method of administration

For oral administration.

The contents of one sachet (2.8g) of Carbex granules are placed on the patient's tongue and then immediately washed down with 10ml of the solution. When used in double contrast radiography, the barium should be swallowed thirty seconds after administration of the Carbex solution.

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

None

4.5 Interaction with other medicinal products and other forms of interaction

None Known.

No interaction studies have been performed.

4.6 Fertility, Pregnancy and lactation

Pregnancy

Safety in human pregnancy has not been established in animal studies and there is no significant data on human exposure. However as simeticone is not absorbed, it is not anticipated that Carbex will have adverse effects on pregnancy.

Breast feeding

As simeticone is not absorbed from the gastrointestinal tract it will not appear in human breast milk.

Fertility

The effect on human fertility has not been evaluated.

4.7 Effects on ability to drive and use machines

Carbex has no or negligible influence on ability to drive and use machines

4.8 Undesirable effects

No known effects.

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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

4.9 Overdose

No cases of overdose have been reported. Theoretically, constipation may occur. Treat with fluids and keep under observation.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Sodium bicarbonate and citric acid react to produce carbon dioxide in the gastrointestinal tract. Simeticone is present to prevent excessive bubble formation during the release of gas.

5.2 Pharmacokinetic properties

Simeticone is not absorbed from the gastrointestinal tract.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbex Granules

Povidone

Mannitol

Lemon flavour

Carbex Solution

Methylparaben.

Propylparaben

Saccharin sodium

Orange flavour

Purified Water

6.2 Incompatibilities

None known

6.3 Shelf life

Shelf life of granules and solution (unopened): 36 months

6.4 Special precautions for storage

Do not store above 25° C.

6.5 Nature and contents of container

Carbex is supplied as a pack containing sufficient for one patient treatment.

The outer package (cardboard carton) contains the following:

Granules: 1 x 2.8g sachets of Carbex granules. The sachet is composed of paper/polyethylene/aluminium foil/surlyn.

Solution: 1 x 10ml bottle of Carbex solution. The bottle is polyethylene with a polypropylene closure.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 05827/0024

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

1st March 2018

10 DATE OF REVISION OF THE TEXT

01/07/2024