CARBOSORB® X

(ACTIVATED CHARCOAL) SUSPENSION

1 NAME OF THE MEDICINE

Activated charcoal.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Carbosorb X suspension contains 0.2 g/mL activated charcoal.

Each bottle of Carbosorb X contains 50 g of activated charcoal in 250 mL of suspension.

Excipients with known effect: sugars (as sucrose).

For the full list of excipients, see Section 6.1 List of Excipients.

3 PHARMACEUTICAL FORM

Carbosorb X is a black, viscous suspension.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

For the treatment of poisoning and drug overdosage by oral ingestion.

4.2 DOSE AND METHOD OF ADMINISTRATION

To be fully effective, Carbosorb X should be administered as soon as possible after oral ingestion of the poison as activated charcoal can only adsorb that portion of the drug not absorbed from the gastrointestinal tract. Administration of Carbosorb X is more likely to produce benefit if administered within one hour of poison ingestion.

Carbosorb X may be administered after the stomach contents have been emptied by emesis or gastric lavage, although suspensions of activated charcoal may be used as a lavage fluid. Some situations may require the use of a cathartic in which case the use of Carbosorb XS, as a single dose only, may be appropriate.

Carbosorb X may be administered orally or by nasal or orogastric tube (Dilute with water if required prior to nasal or orogastric tube administration). Prior to administration, the container should be shaken vigorously for a minimum of 30 seconds.

Recommendations as to absolute dosage regimens are difficult to make due to individual patient variations in type of poisoning and patient weight and age.

Adults and children 12 years and over
Single dose: An initial or single dose based on 1 g activated charcoal (equivalent to 5 mL Carbosorb X suspension) per kg bodyweight (to a maximum dose of 50 g) is recommended. Carbosorb X is formulated to be a single dose unit for an average adult.

Repeat doses: Certain patients may require repeat doses of activated charcoal because of the pharmacokinetic properties of the ingested drug or poison. Patients poisoned with sustained or slow release formulations, drugs that undergo enterohepatic recirculation and drugs subject to gastrointestinal dialysis fall into this category. Based on experimental and clinical studies, repeat dose activated charcoal should be considered in patients who have ingested a life threatening amount of carbamazepine, dapsone, phenobarbitone, quinine or theophylline. Although further studies are required to establish the optimal dosage regimen, it is recommended that an initial dose of 1 g activated charcoal (equivalent to 5 mL Carbosorb X suspension) per kg bodyweight be given, followed by subsequent doses of suspension every 2-6 hours, at a rate not less than 12.5 g per hour, until the danger of poisoning has passed.

Infants and children (1 month to 11 years)
An initial or single dose based on 1 g activated charcoal (equivalent to 5 mL Carbosorb X Suspension) per kg bodyweight (to a maximum dose of 50 g) is recommended. Repeat doses should be administered only when necessary and must be accompanied by monitoring of fluid and essential electrolytes.

4.3 CONTRAINDICATIONS

Carbosorb X is contraindicated in poisoning with strong acids and alkalis and those poisons for which its adsorptive capacity is too low (ferrous sulfate and other iron salts, cyanides, tolbutamide and other sulfonylureas, malathion, dicophane, lithium, ethanol, methanol, ethylene glycol and hydrocarbons).

Carbosorb X is contraindicated in patients who have an unprotected airway or a gastrointestinal tract that is not anatomically intact.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Carbosorb X should not be administered concomitantly with systemically active emetics such as ipecacuanha, since it adsorbs the active components making them unavailable systemically. Emetics may be given to induce vomiting prior to administration of Carbosorb X. Induced emesis should not be used if the patient is drowsy, unconscious, fitting or if the patient is likely to become drowsy within 30 minutes of taking the emetic.

Aspiration of activated charcoal and gastric contents is a potentially serious complication. Patients who have an absent or impaired gag reflex, are comatose or drowsy, or have ingested large amounts of CNS depressant drugs or drugs that may cause seizures require airway protection, for example in the form of a cuffed endotracheal tube, to protect against aspiration. Vomiting of activated charcoal may contribute to the occurrence of aspiration. Care should, therefore, be taken in patients who have been administered systemically active emetics and when patients are extubated. Consideration should be given to withholding Carbosorb X for an adequate time interval prior to extubation.

In the event of an antidote to a specific poison being available this should be the first choice for treatment. Specific antidotes should not be used in conjunction with activated charcoal as they themselves may be adsorbed and inactivated by activated charcoal. Since activated charcoal adsorbs many drugs, any concurrent medication should be given parenterally.

Carbosorb X should be used with extreme caution in patients with ileus, decreased or absent bowel sounds, or who have ingested a large amount of drugs that may impair peristalsis. The concomitant use of supportive agents that decrease gut motility (e.g. atropine, morphine, verapamil) should be avoided if possible due to the increased risk of gastrointestinal obstruction with repeat doses of activated charcoal. Patients who are at risk of haemorrhage or gastrointestinal perforation due to recent surgery or pathology could be further compromised by administration of Carbosorb X.

Carbosorb X contains sucrose 0.33 g/mL. Clinical judgment should be used prior to administration of Carbosorb X to diabetic patients.

Activated charcoal preparations are known to adsorb minerals, vitamins, enzymes and amino acids from the gastrointestinal tract. In patients receiving repeat dose regimens, particularly children, monitoring of fluid and electrolyte changes is recommended.

Use in the elderly

No data available.

Paediatric use

See Section 4.2 Dose and Method of Administration.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Carbosorb X may adsorb other orally administered drugs and antidotes. Any concurrent medication required should be given parenterally.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available.

Use in pregnancy

There is little data on the use of Carbosorb X during pregnancy.

Activated charcoal is not absorbed from the gastrointestinal tract and is not expected to pose a risk to the fetus during pregnancy.

Carbosorb X should be used during pregnancy only when necessary. The potential risk to the fetus of both the poisoning and the treatment need to be balanced against the risk of failing to detoxify the mother.

Use in lactation

There is little data on the use of Carbosorb X during lactation. Activated charcoal is not absorbed from the gastrointestinal tract so there is no excretion into the breast milk.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

The effects of this medicine on a person's ability to drive and use machines were not assessed as part of its registration.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Few serious adverse reactions or complications from the use of a single dose of activated charcoal have been reported in poisoned patients.

Faecal discolouration frequently occurs. Black stools may be utilised as a diagnostic sign of gastrointestinal transit.

Vomiting may occur. This could prove hazardous to a patient who has ingested a caustic or volatile substance (see Section 4.3 Contraindications).

Cases of aspiration pneumonia have been reported with the use of activated charcoal slurry for poisoning. Fatalities have been reported due to complications of aspiration. There has been one report of bronchiolitis obliterans and a few reports of progressive respiratory failure resulting in death, due to aspiration of activated charcoal. Care should be taken to ensure adequate airway protection (see Section 4.3 Contraindications and Section 4.4 Special Warnings and Precautions for Use).

There have been several documented case reports of serious gastrointestinal adverse effects with the use of repeat dose activated charcoal. These include intestinal obstructions and charcoal bezoar formation. Fatalities have occurred. Care should be taken in patients with ileus or diminished or absent bowel sounds (see Section 4.3 Contraindications and Section 4.4 Special Warnings and Precautions for Use).

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration 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 at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

For information on the management of overdose, contact the Poisons Information Centre on 131126 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Activated charcoal is an adsorbent used to remove drugs from the gastrointestinal tract as a treatment for poisoning. Its mechanism of action is by physical adsorption of drugs and toxic agents onto its surface. It is effective in the adsorption of many drugs including aspirin, barbiturates, tricyclic antidepressants, digoxin, amphetamines, morphine, cocaine, digitalis and the phenothiazines. The adsorptive capacity of activated charcoal is too low for treatment of poisoning with ferrous sulfate and other iron salts, cyanides, tolbutamide and other sulfonylureas, malathion, dicophane, lithium, ethanol, methanol, ethylene glycol and hydrocarbons.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

Absorption

Activated charcoal is not absorbed from the gastrointestinal tract.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

The excipients include sucrose, propylene glycol, glycerol, sodium hydroxide, purified water and citric acid.

6.2 INCOMPATIBILITIES

See section 4.5 Interactions with Other Medicines and Other Forms of Interactions.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG)[1]. The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25°C. Do not refrigerate.

6.5 NATURE AND CONTENTS OF CONTAINER

Each bottle of Carbosorb X contains 50 g of charcoal as the active ingredient in a 250 mL suspension.

Carbosorb X is contained in a high density polyethylene (HDPE) bottle with a tamper evident screw cap. It is supplied in cartons containing 10 bottles. Single use only.

Phebra product code - SOL052.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

Single use only. Use only once and discard any unused suspension.

6.7 PHYSICOCHEMICAL PROPERTIES

Chemical structure

No chemical structure of activated charcoal is available.

CAS number

7440-44-0.

7 MEDICINE SCHEDULE (POISONS STANDARD)

Unscheduled

[1] AUST R 106470

8 SPONSOR

Phebra Pty Ltd[2], 19 Orion Road, Lane Cove West NSW 2066, Australia.

Telephone: 1800 720 020

Distributed in New Zealand by AFT Pharmaceuticals Ltd. PO Box 33-203 Auckland.

9 DATE OF FIRST APPROVAL

23 Jul 2004

10 DATE OF REVISION

15 Feb 2022

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
6.5	Updated the material of construction of immediate container from low density polyethylene (LDPE) bottle to high density polyethylene (HDPE) bottle.

[2] Carbosorb, Phebra and the Phi symbol are trademarks of Phebra Pty Ltd, 19 Orion Road, Lane Cove West, NSW 2066, Australia.