1. Carbosorb X

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Activated Charcoal 0.2 g/mL

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of poisoning and medicine overdose 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 medicine not absorbed from the gastrointestinal tract. Administration of Carbosorb X is more likely to produce benefit if administered within one hour or 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 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.

<u>Adults and children 12 years and over:</u>

Single dose:

An initial or single dose based on 1g activated charcoal (equivalent to 5 mL Carbosorb X suspension) per kg bodyweight (to a maximum dose of 50g) 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 medicine or poison. Patients poisoned with sustained or slow release formulations, medicines that undergo enterohepatic recirculation and medicines 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 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 for those poisons for which its adsorptive capacity is too low (ferrous sulphate and other iron salts, cyanides, tolbutamide, and other sulphonylureas, 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 medicines or medicines 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 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 medicines, 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 medicines 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 judgement should be used prior to administration of Carbosorb X to diabetic patients.

4.5 Interaction with other medicines and other forms of interaction

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

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.

4.6 Fertility, pregnancy and lactation

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 foetus during pregnancy.

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

Breast-feeding

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.

Fertility

No fertility data available.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

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

Gastrointestinal disorders:

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

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 and 4.4).

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

Respiratory, thoracic and mediastinal disorders:

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 or 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 and 4.4).

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://pophealth.my.site.com/carmreportnz/s/.

4.9 Overdose
Not applicable.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Charcoal preparations

ATC code: A07BA

Mechanism of action
Activated charcoal is an adsorbent used to remove medicines from the gastrointestinal tract as a treatment for poisoning. Its mechanism of action is by physical adsorption of medicines and toxic agents onto its surface. It is effective in the adsorption of many medicines 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 sulphate and other iron salts, cyanides, tolbutamide and other sulphonylureas, malathion, dicophane, lithium, ethanol, methanol, ethylene glycol and hydrocarbons.

5.2 Pharmacokinetic properties
Not applicable.

5.3 Preclinical safety data
Not applicable.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Propylene glycol

Sodium hydroxide

Glycerol

Sucrose

Citric acid

Purified water

6.2 Incompatibilities
Not applicable.

6.3 Shelf life

24 months.

Carbosorb X is for single use only. Use only once and discard any unused solution.

6.4 Special precautions for storage

Store below 25 ^{o}C.

Do not refrigerate

6.5 Nature and contents of container

White HDPE bottle with PP cap. Pack size of 250 mL oral suspension containing 50 g of activated charcoal.

6.6 Special precautions for disposal

No special precautions for disposal

7. MEDICINE SCHEDULE

General Sale medicine.

8. SPONSOR

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9. DATE OF FIRST APPROVAL

February 2005

10. DATE OF REVISION OF THE TEXT

June 2024

SUMMARY TABLE OF CHANGES

Date	Section(s) changed	Change(s)
June 2024	4.1	Additional instructions regarding nasal or orogastric administration is added
June 2024	4.3	Correction