CARBOSORB® XS

(ACTIVATED CHARCOAL AND SORBITOL) SUSPENSION

1 NAME OF THE MEDICINE

Activated charcoal

Sorbitol

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Carbosorb XS is a suspension containing activated charcoal 0.2 g/mL and sorbitol 0.283 g/mL.

Each bottle of Carbosorb XS contains 50 g of activated charcoal and 70.75 g sorbitol in 250 mL of suspension.

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

3 PHARMACEUTICAL FORM

Carbosorb XS 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 XS 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 XS is more likely to produce benefit if administered within one hour of poison ingestion.

Carbosorb XS may be administered after the stomach contents have been emptied by emesis or gastric lavage.

Carbosorb XS may be administered orally or by nasal or orogastric tube. 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.

Dilution with water if required prior to use with nasogastric and orogastric tubes

Due to the viscosity of Carbosorb XS, dilution with water prior to nasal or orogastric tube administration may be required. The dilution ratio is dependent on a number of variables including the gauge and length of the tube to be used, the size of the syringe used, patient cooperation and individual operator technique. As a guide, a minimum of 0.1 parts water to 1 part Carbosorb XS is recommended for administration via tubes of less than 12 French Gauge.

Adults and children 12 years and over

A single dose based on 1 g activated charcoal (equivalent to 5 mL Carbosorb XS suspension) per kg bodyweight (to a maximum dose of 50 g) is recommended. Carbosorb XS 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.

More than a single dose of Carbosorb XS is contraindicated during repeat dose activated charcoal therapy. Repeat doses of activated charcoal should be accompanied with monitoring of fluid and electrolyte balance.

Children 1 to 11 years

A single dose based on 1 g activated charcoal (equivalent to 5 mL Carbosorb XS suspension) per kg bodyweight (to a maximum dose of 50 g). The presence of sorbitol may produce diarrhoea disturbing fluid and electrolyte balance.

Repeat doses of activated charcoal therapy are not recommended in children and should be administered only when necessary, accompanied by monitoring of fluid and essential electrolytes.

Carbosorb XS is contraindicated in infants less than 1 year of age.

4.3 CONTRAINDICATIONS

Carbosorb XS is contraindicated in poisoning with strong acids and alkalis and for 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 XS is contraindicated in patients who have an unprotected airway or a gastrointestinal tract that is not anatomically intact. It is also contraindicated in patients who have significant fluid or electrolyte abnormalities.

Carbosorb XS is contraindicated in infants less than one year of age due to the possibility of excessive catharsis.

Repeat doses of Carbosorb XS are contraindicated.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Carbosorb XS 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 XS. 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 and sorbitol 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 XS 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 XS 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 XS.

Activated charcoal preparations are known to adsorb minerals, vitamins, enzymes and amino acids from the gastrointestinal tract.

The cathartic effect of sorbitol may produce diarrhoea that may result in electrolyte disturbance or dehydration.

Only a single dose of Carbosorb XS should be given during repeat dose activated charcoal therapy in adults, with consideration of the patient's condition and monitoring of fluid and electrolyte status.

Use in the elderly

Elderly patients may be susceptible to fluid and electrolyte disturbances resulting from excessive catharsis due to sorbitol. Only a single dose of Carbosorb XS should only be given during repeat dose activated charcoal therapy, depending on the patient's clinical condition and with careful monitoring of fluid and electrolyte balance.

The clinical condition of the elderly should therefore be monitored closely during treatment with Carbosorb XS.

Paediatric use

Carbosorb XS is contraindicated in infants less than one year of age due to the possibility of excessive catharsis. Although a single dose may be used in children from 1 to 11 years of age, careful monitoring of fluid and electrolyte balance is required.

See Section 4.2 Dose and Method of Administration.

The clinical condition of children should therefore be monitored closely during treatment with Carbosorb XS.

Effects on laboratory tests

No data available

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

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

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available

Use in pregnancy

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

Activated charcoal is not absorbed from the gastrointestinal tract and is not expected to pose a risk to the fetus during pregnancy. However, the cathartic effect of sorbitol may cause diarrhoea resulting in electrolyte disturbances or dehydration.

Carbosorb XS 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 XS during lactation. Activated charcoal and sorbitol are not absorbed from the gastrointestinal tract so there is no excretion into the breast milk. The cathartic effect of sorbitol may cause fluid and electrolyte disturbances or dehydration in the breastfeeding mother.

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 single doses of Carbosorb XS have been reported. 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 Warning 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).

The presence of sorbitol in Carbosorb XS may produce diarrhoea, resulting in disturbance of fluid and electrolyte balance. There have been case reports of dehydration and electrolyte imbalance in adults. There have also been a few case reports of serious dehydration and electrolyte imbalance in infants and young children, resulting in

permanent disability and fatality. These cases were attributed to excessive repeat doses of sorbitol cathartic (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.

Since sorbitol has a rapid cathartic action the combination of activated charcoal and sorbitol counteracts the constipation produced by charcoal alone, thereby hastening the elimination of the toxic drug. The decreased transit time does not appear to diminish the activity of the charcoal.

Clinical Trials

No data available

5.2 PHARMACOKINETIC PROPERTIES

Absorption

Activated charcoal and sorbitol are 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

Excipients include sodium hydroxide, propylene glycol, glycerol, 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 XS contains 50 g of activated charcoal and 70.75 g sorbitol in 250 mL of suspension.

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

Phebra product code - SOL054

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

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

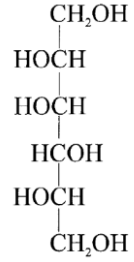
In Australia, any unused medicine or waste material should be disposed of in accordance with local requirements.

6.7 PHYSICOCHEMICAL PROPERTIES

Chemical structure

No chemical structure of activated charcoal is available.

Sorbitol



[1] AUST R 307429

CAS number

Activated charcoal: 7440-44-0

Sorbitol: 50-70-4

7 MEDICINE SCHEDULE (POISONS STANDARD)

Unscheduled

8 SPONSOR

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9 DATE OF FIRST APPROVAL

25 Jul 2018

10 DATE OF REVISION

08 Sep 2021

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
All	PI reformatted to align with new format and minor editorial changes.
2	Revised name and quantity of the active ingredients.
4.3	Updating the spelling of '*sulfate*' and '*sulfonylureas'*
4.6	Amended phrase '*breastfeed mother'* under subheading 'Use in lactation' to read as *'breastfeeding mother'*.
4.8	Editorial update from *utilized* to *utili**s**ed* as per Australian convention.
5.1	Updating the spelling of *'sulfate'* and '*sulfonylureas'*
6.5	Revised name and quantity of the active ingredients. Minor editorial change for better readability.
9	Amended to 25 July 2018 as per ARTG start date.

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