SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Charcodote

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Activated charcoal 200mg/ml

3 PHARMACEUTICAL FORM

Oral suspension

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Emergency treatment of acute oral poisoning or drug overdose. Charcodote adsorbs toxic substances and reduces or prevents systematic absorption. The shorter the time interval between ingestion of the toxicant and the administration of Charcodote, the greater is the benefit for the patient. However, as the absorption of massive drug overdoses is often retarded in acute conditions of intoxication, even the delayed administration of Charcodote may be beneficial. In severe intoxication, repeated administration of Charcodote mix is recommended to prevent absorbed drug being released (in an unbound state) in the lower intestinal tract or to expedite the elimination and prevent the re-absorption of any drug undergoing enterohepatic circulation.

4.2 Posology and method of administration

Posology

If the dose of poison that has been ingested is known, a ratio of 10:1 (activated charcoal: toxin) may be used to determine the optimal dose of activated charcoal, subject to the limits of practicality. In the absence of any information regarding the amount of poison ingested, the following doses are recommended:

Adults (including the Elderly) and children over 12 years

50g activated charcoal (one standard treatment pack), repeated if necessary,

taken as soon as possible after ingestion of poison. For multiple dose therapy, 25-50 grams of activated charcoal every 4-6 hours.

Children aged 1-12 years
25g -50g activated charcoal (half the contents of the standard pack, repeated if necessary), taken as soon as possible after ingestion of the poison. For multiple dose therapy, the dose may be repeated every 4-6 hours.

Children under 1 year of age:
For single dose therapy, 1g or 5ml per kg bodyweight taken as soon as possible after ingestion of poison. For multiple dose therapy, the dose may be repeated every 4-6 hours.

Method of Administration
Charcodote should be given as soon as possible after the ingestion of the potential poison.

The suspension is then taken orally or given by intragastric tube. Induction of emesis is not recommended because there is no evidence that it affects absorption and it may increase the risk of aspiration. If gastric lavage is being used to facilitate stomach evacuation a single dose of Charcodote may be administered early in the procedure. This has the advantage of prompt administration of activated charcoal, but the gastric lavage returns will be black which may make it difficult to evaluate what the patient ingested by visual examination.

Charcodote may be effective even when several hours have elapsed after ingestion of the poison if gastrointestinal motility is reduced by the toxin or if the drug is subject to enterohepatic or enteroenteric recycling.

When ipecac syrup is used to induce emesis, it is recommended that Charcodote be administered only after vomiting has been induced and completed, since ipecac syrup is adsorbed by the charcoal thus preventing emesis.

4.3 Contraindications

Use of Charcadote is contra-indicated in persons who are not fully conscious.

4.4 Special warnings and precautions for use

Charcadote is not recommended for patients who have ingested corrosive agents such as strong acids or alkalis since the activated charcoal may obscure endoscopic visualisation of oesophageal and gastric lesions produced by the toxin. Charcadote is of little or no value in the treatment of poisoning with cyanides, alcohols, iron salts, malathion and DDT.

Charcadote is an adjunct in the management of poisoning emergencies. Prior to its use, proper basic life support measures must be implemented where required as well as the appropriate gastric emptying technique if indicated.

Charcadote should be used with caution in patients who have been exposed to toxins which interfere with gastrointestinal motility (e.g. anticholinergics, opioids). Bowel sounds should be monitored frequently to assess peristaltic action, especially in patients undergoing multiple dose activated charcoal therapy.

Both the patient and health care professionals should be aware that Charcadote will produce black stools (see section 4.8 'Undesirable effects'). A laxative may be given concurrently to accelerate the removal of the activated charcoal- toxin complex, but should be used with caution and only intermittently during multiple dose activated charcoal therapy since profuse and protracted diarrhoea may lead to fluid and electrolyte imbalance.

Aspiration of activated charcoal has been reported to produce airways obstruction and appropriate precautions should be taken (see section 4.8 'Undesirable effects').

4.5 Interaction with other medicinal products and other forms of interaction

Charcodote will adsorb most medicaments and many other chemical substances. If a specific antidote is to be administered the likelihood of its adsorption by activated charcoal should be borne in mind, and a parenteral route of administration used if possible. Thus in the case of paracetamol, Charcodote should not be given as well as oral methionine but may be used alone or in conjunction with intravenous

N-acetylcysteine.

Other concurrent medications to counteract shock or associated infection should also be given parenterally since orally administered drugs may be bound to the activated charcoal in the gut.

4.6 Fertility, pregnancy and lactation

The safety of this medicinal product for use in human pregnancy has not been established. Experimental animal studies are insufficient to assess the safety with respect to the development of the embryo or foetus, the course of gestation and peri and postnatal development.

Activated charcoal is however essentially inert pharmacologically and is not absorbed from the gastrointestinal tract. No hazard is therefore anticipated from its use during pregnancy or lactation.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

Adverse drug reactions (ADRs) are listed below by MedDRA system organ class and by frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10,000 to <1/1000), very rare (<1/10,000) and not known (cannot be estimated from the available data).

System Organ Class	Frequency	Undesirable Effect
Respiratory, thoracic and mediastinal disorders	Not known	Airways obstruction[1]
Gastrointestinal disorders	Not known	Black stools (see section 4.4) Gastrointestinal obstruction[2] Gastrointestinal disturbances including vomiting, constipation and diarrhoea

[1] Aspiration of activated charcoal has been reported to produce airways obstruction (see section 4.4).
[2] Associated with the use of multiple dose activated charcoal therapy.

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

4.9 Overdose

Charcadote is well tolerated and due to its lack of toxicity overdosage requiring treatment is unlikely. A laxative may be administered to enhance elimination of the product.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Activated charcoal has a high adsorptive capacity for a wide range of compounds including many of those which are most commonly encountered in deliberate and accidental poisoning. Substances adsorbed include (but are not limited to) the following:

Aspirin and other salicylates
Barbiturates
Benzodiazepines
Chlormethiazole
Chloroquine
Chlorpromazine and related phenothiazines
Clonidine
Cocaine and other stimulants
Digoxin and digitoxin
Ibuprofen
Mefenamic acid
Mianserin
Nicotine
Paracetamol
Paraquat
Phenelzine and other monoamine oxidase inhibitors
Phenytoin
Propranolol and other beta-blockers
Quinine
Theophylline
Zidovudine

5.2 Pharmacokinetic properties

Activated charcoal is not absorbed from the gastrointestinal tract or subject to any metabolic processes. It is eliminated in the faeces.

5.3 Preclinical safety data

Activated charcoal is essentially inert pharmacologically and it would therefore be expected to be virtually devoid of toxicity, other than any ill effects arising from mechanical obstruction of the gut, or, if inhaled, the lungs.

The excipients in the product are all well-known and widely used in medicinal products and should not give rise to any toxicological problems.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water

6.2 Incompatibilities

None known

6.3 Shelf life

2 years. Use immediately upon opening. Any remaining unused suspension should be discarded after first use.

6.4 Special precautions for storage

Do not store above 25°C. Do not freeze.

6.5 Nature and contents of container

Low density polyethylene bottle with screw cap designed for administration either directly or via an intragastric tube. Each bottle contains 250ml (50g activated charcoal).

6.6 Special precautions for disposal

Shake well before use.

7 MARKETING AUTHORISATION HOLDER

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Whistler Drive,
Castleford,
WF10 5HX,
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8 MARKETING AUTHORISATION NUMBER(S)

PL 00289/1489

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24th August 1999

10 DATE OF REVISION OF THE TEXT

13/07/2023