1 NAME OF THE MEDICINAL PRODUCT

Activated Charcoal 200 mg/ml Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Activated charcoal 200mg/ml

Each 250 ml bottle of Oral Suspension contains 50 g activated charcoal

3 PHARMACEUTICAL FORM

Oral suspension

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Emergency treatment of acute oral poisoning or drug overdose. Activated Charcoal adsorbs toxic substances and reduces or prevents systematic absorption. The shorter the time interval between ingestion of the toxicant and the administration of Activated Charcoal, 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 Activated Charcoal may be beneficial. In severe intoxication, repeated administration of Activated Charcoal 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
One full bottle (250 ml; equivalent to 50 g activated charcoal), repeated, if necessary, taken as soon as possible after ingestion of poison. For multiple dose therapy, the dose may be repeated every 4-6 hours.

Children aged under 12 years
Half of one bottle (125 ml; equivalent to 25 g activated charcoal), repeated, if necessary, taken as soon as possible after ingestion of the poison. If a large quantity of toxicants has been ingested, and where there is a risk to life. In these circumstances, the administration of the full 50 g dose is indicated. For multiple dose therapy, the dose may be repeated every 4-6 hours.

Children under 1 year of age:
For single dose therapy, 1 g or 5 ml 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

Activated Charcoal 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 Activated Charcoal 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.

Activated Charcoal 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 enter enteric recycling.

When ipecac syrup is used to induce emesis, it is recommended that Activated Charcoal 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 Activated Charcoal is contra-indicated in persons who are not fully conscious.

4.4 Special warnings and precautions for use

Activated Charcoal 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. Activated Charcoal is of little or no value in the treatment of poisoning with cyanides, alcohols, iron salts, malathion and DDT.

Activated Charcoal 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.

Activated Charcoal 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 doses activated charcoal therapy.

Both the patient and health care professionals should be aware that Activated Charcoal 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 doses 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

Activated Charcoal 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,

Activated Charcoal 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

Activated Charcoal 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

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

PL 00289/1489

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26/06/2025