SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Actidose-Aqua Advance

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Actidose-Aqua Advance contains 1.04 g of Activated Charcoal/5 ml.

3 PHARMACEUTICAL FORM

Suspension for oral administration.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the emergency treatment of acute poisoning and drug overdosage where substances such as those listed in section 5.1 have been ingested. The list is not exhaustive and Actidose-Aqua Advance may be of benefit following ingestion of many other toxins.

Also indicated for a limited number of systemic poisonings resulting from parenteral overdosage or when the ingested toxin has been totally absorbed. This usually involves repeated doses of Actidose-Aqua Advance to remove compounds which undergo enterohepatic recycling or which can diffuse into the gastrointestinal tract along a concentration gradient. Under these circumstances multiple doses of Actidose-Aqua Advance adsorb the toxin thereby preventing its reabsorption and increasing the concentration gradient in favour of further diffusion of the toxin into the gastrointestinal tract. Compounds most effectively transferred by this mechanism are lipophilic, uncharged and not excessively protein-bound. Examples of compounds which can be eliminated more rapidly by “gastrointestinal dialysis” in this way are phenobarbitone and theophylline.

4.2 Posology and method of administration

The container should be shaken thoroughly prior to administration. 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 of age:

For single dose therapy, 50-100 grams of activated charcoal (240-480 ml) taken as soon as possible after ingestion of the poison.

For multiple dose therapy, 25-50 grams of activated charcoal (120-240 ml) every 4-6 hours.

Children aged 1-12 years

For single dose therapy, 25-50 grams of activated charcoal (120-240 ml) 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 one year of age:

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

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 Actidose-Aqua Advance 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.

Actidose-Aqua Advance 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.

4.3 Contraindications

Use of Actidose-Aqua Advance is contra-indicated in persons who are not fully conscious.

4.4 Special warnings and precautions for use

Actidose-Aqua Advance 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. Actidose-Aqua Advance is of little or no value in the treatment of poisoning with cyanides, alcohols, iron salts, malathion and DDT.

Actidose-Aqua Advance 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.

Actidose-Aqua Advance 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 Actidose-Aqua Advance 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

Actidose-Aqua Advance 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, Actidose-Aqua Advance 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

Undesirable effects are listed by MedDRA System Organ Classes.

Assessment of undesirable effects is based on the following frequency groupings:
Very common: ≥1/10
Common: ≥1/100 to <1/10
Uncommon: ≥1/1,000 to <1/100
Rare: ≥1/10,000 to <1/1,000
Very rare: <1/10,000
Not known: cannot be estimated from the available data

Respiratory, thoracic and mediastinal disorders	*Not known:* Airways obstruction[1]
Gastrointestinal disorders	*Not known:* Black stools (see section 4.4 'Special warnings and precautions for use') 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 'Special warnings and precautions for use').
[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. Tel: Freephone 0808 100 3352. Website: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Actidose-Aqua Advance 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 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

Paraq uat

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

Sucrose
Propylene glycol
Glycerine
Citric Acid
Purified water

6.2 Incompatibilities

None known.

6.3 Shelf life

Three years.

6.4 Special precautions for storage

Store at 15 - 30°C. Do not refrigerate.

6.5 Nature and contents of container

(1) Low density polyethylene bottles containing 120 ml.
(2) Low density polyethylene bottles containing 240 ml.
(3) Low density polyethylene tubes containing 120 ml.

6.6 Special precautions for disposal

Shake well before use.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

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10 DATE OF REVISION OF THE TEXT

03/03/2015