Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Carbomix 50 g Granules for Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Activated Charcoal Activated 50g in 61.5g of granules (81.3 % w/w).

Also contains glycerol (5g/50g activated charcoal) as an excipient.
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Granules for oral suspension.
Odourless black granules.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Emergency treatment of acute oral poisoning or drug overdose.

4.2 Posology and method of administration

Posolgy
Adults: 50g activated charcoal (one standard treatment pack), repeated if necessary.

Children under 12 years: 25g activated charcoal (half the contents of the standard pack), repeated if necessary.

Neonates: Use not recommended

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

Carbomix granules should be mixed with water and swallowed as a suspension under medical supervision only. The contents of the bottle are made up to the red band with water and shaken thoroughly.

The suspension is then taken orally or given by intragastric tube using the universal applicator provided.

Carbomix may be administered after emesis or gastric lavage and may be used concurrently with parenteral antidotes such as acetyl cystine.

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

4.3 Contraindications

Although Carbomix is not contraindicated in poisoning by strong acids and alkalis and other corrosive substances, its value as a detoxicant for these substances is limited. Carbomix is poor in binding cyanide, iron salts and some solvents including methanol, ethanol and ethylene glycol (see section 4.4).

4.4 Special warnings and precautions for use

In cases of poisoning with corrosive substances, such as strong acids or alkalis the presence of charcoal will render difficult any immediate endoscopy that may be required as it may obscure endoscopic visualization of oesphageal and gastric lesions producted by the toxin.

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

Carbomix 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.

Carbomix should be used with caution in patients who have been exposed to toxins which interfere with gastrointestinal motility (e.g. anticholingerics, opiods). Bowel sounds should be monitored frequently to assess peristaltic action, especially in patients undergoing multiple dose activated charcoal therapy (see section 4.8)

Both the patient and health care professionals should be aware that carbomix can produce black stools (see section 4.8). 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).

Carbomix should only be administered to unconscious patients who have a cuffed endotracheal tube in place to protect the airway.

Carbomix contains glycerol as an excipient, which may cause headache, stomach upset and diarrhoea.

4.5 Interaction with other medicinal products and other forms of interaction

Not to be taken with ipecacuanha or other centrally acting emetics; since these would be adsorbed by the Carbomix.

The purpose of the product is to interact (by adsorption) with other medicaments and toxicants taken in overdose.

There are no systemic interactions because the product is not absorbed from the gut.

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, Carbomix 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.

However activated charcoal is essentially inert pharmacologically and is not systematically absorbed from the gastrointestinal tract there is no evidence to suggest that Carbomix should not be used during pregnancy or lactation.

4.7 Effects on ability to drive and use machines

Not applicable – used in acute poisoning situations.

4.8 Undesirable effects

Undesirable effects are listed by MedDRA System Organ Classes.

The following CIOMS frequency rating is used, when applicable:

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), not known (cannot still be estimated from the available data).

Respiratory, thoracic and mediastinal disorders	*Not known:* Airways obstruction1
Gastrointestinal disorders	*Not known:* Black stools (see section 4.4) Gastrointestinal obstruction2 Gastrointestinal disturbances including vomiting, constipation and diarrhoea

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

Activated charcoal has been associated with bezoar formation, intestinal obstruction and, rarely, intestinal perforation following multiple dosing – although a direct causative association has not been demonstrated. Faecal impaction has been reported in a patient treated for an overdose of a diuretic with alcohol.

Aspiration of activated charcoal has been reported to cause airway obstruction and appropriate precautions should be taken.

Activated charcoal will produce black stools which may be alarming to the patient but is medically insignificant.

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: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2. Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

4.9 Overdose

Carbomix is well tolerated and due to its lack of toxicity, over dosage requiring treatment is unlikely. Excessive use may result in constipation which could be treated with laxatives.

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

Citric acid
Acacia
Glycerol

6.2 Incompatibilities

Carbomix should not be used concurrently with systematically active oral emetics or oral antidotes since such agents would be adsorbed by the charcoal.

6.3 Shelf life

Unopened: 3 years
After reconstitution: 24 hours

6.4 Special precautions for storage

Store below 25°C.
Keep container tightly closed.

6.5 Nature and contents of container

HDPE bottle and cap in a pack size containing 50g of activated charcoal (in 61.5g of granules).
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

For instructions on reconstitution and use, see section 4.2.

Product description after reconstitution: black suspension.

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Athlone Pharmaceuticals Limited
Ballymurray
Co. Roscommon
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1418/007/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd December 1992

Date of last renewal: 3rd December 2007

10 DATE OF REVISION OF THE TEXT

September 2022