

Product Summary

1. Trade Name of the Medicinal Product

Carbomix

2. Qualitative and Quantitative Composition

Charcoal Activated Ph. Eur. 81.3% w/w

3. Pharmaceutical Form

Granules for oral suspension

4. Clinical Particulars

4.1 Therapeutic Indications

Emergency treatment of acute oral poisoning or drug overdose. Carbomix adsorbs toxic substances and reduces or prevents systemic absorption. The shorter the time interval between ingestion of the toxicant and the administration of Carbomix, 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 Carbomix may be beneficial. In severe intoxication, repeated administration of Carbomix is recommended to prevent adsorbed 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

Adults (including the Elderly)

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

Children under 12 years

25g activated charcoal (one small treatment pack or half the contents of the standard pack, repeated if necessary).

If a large quantity of toxicant has been ingested, and where there is a risk to life, a dose of 50g is recommended.

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

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 applicator provided. Carbomix may be administered after emesis or gastric lavage and may be used concurrently with parenteral antidotes such as acetylcysteine.

4.3 Contra-indications

There are no contraindications to the use of Carbomix but see under (4.4).

4.4 Special Warnings and Precautions for Use

The value of Carbomix in the treatment of poisoning by strong acids, alkalis and other corrosive substances is limited. It should also be borne in mind that the presence of charcoal will render difficult any immediate endoscopy that may be required. Carbomix is poor at binding cyanide, iron salts and some solvents including methanol, ethanol and ethylene glycol. In cases where the toxicant has diuretic properties or has been ingested with alcohol. Plenty of fluid should be given after the administration of Carbomix. Carbomix should not be used concurrently with systemically active oral emetics or oral antidotes such as methionine since such agents would be adsorbed by the charcoal.

Interaction with other Medicaments and other forms of Interaction

The purpose of the product is to interact with other medicaments and toxicants taken in overdose. There are no systemic interactions because the product is not absorbed from the gut.

4.6 Pregnancy and Lactation

There is no evidence to suggest that Carbomix should not be used during pregnancy or lactation. The product is not systemically absorbed.

4.7 Effects on Ability to Drive and Use Machines

None (the product is not systemically absorbed).

4.8 Undesirable Effects

In general, Carbomix is well tolerated. Some patients may however experience constipation or diarrhoea. Faecal impaction has been reported in a patient treated for an overdose of a diuretic with alcohol.

4.9 Overdose

Not applicable. In theory severe constipation would result from excessive use and this could be treated with laxatives.

5. Pharmacological Properties

5.1 Pharmacodynamic Properties

Activated charcoal has well documented adsorptive properties and is effective in reducing the absorption of a wide range of toxicants, including drugs taken in overdose, from the gut. In addition, there is evidence that the administration of activated charcoal can enhance the elimination of some compounds by creating an effective concentration gradient from the circulation to the gut.

5.2 Pharmacokinetic Properties

Activated charcoal is not systemically absorbed.

5.3 Preclinical Safety Data

No findings have been reported which add to the prescribing information given in other sections.

6. Pharmaceutical Particulars

6.1 List of Excipients

Citric Acid, Acacia, Glycerol.

6.2 Incompatibilities

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

6.3 Shelf-life

As package for sale – 5 years.

After reconstitution – 24 hours.

6.4 Special Precautions for Storage

Store below 25°C.

6.5 Nature and contents of Container

HDPE bottle and cap 25g and 50g.

6.6 Instructions for Use/Handling

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

thoroughly and taken by mouth. Under medical supervision only. It may be given by intragastric tube and the cap is fitted with a universal applicator for this purpose.

Administration Details

7. Marketing Authorisation Holder

Beacon Pharmaceuticals Ltd, 85, High Street, Tunbridge Wells, TN1 1YG. United Kingdom

8. Marketing Authorisation Number

PL 18157/0020

9. Date of the first authorisation or renewal

22/05/2006

10. Date of revision of the text

22/05/2006