

50G GRANULES FOR ORAL SUSPENSION (ACTIVATED CHARCOAL)

Please read this leaflet carefully before you take Carbomix. It is possible that you may have been treated with Carbomix before you were able to read this leaflet. If you would like any more information, or are not sure about anything, you should ask your doctor or pharmacist.

In this leaflet:

- 1. What Carbomix is and what it is used for
- 2. Before you take Carbomix
- 3. How to take Carbomix
- 4. Possible side effects
- 5. How to store Carbomix
- 6. Further information

1. WHAT CARBOMIX IS AND WHAT IT IS USED FOR

The active ingredient of Carbomix is activated charcoal in the form of very fine granules. Carbomix is used as an emergency treatment for acute oral poisoning or drug overdose. It works by absorbing the drugs or toxic substances so reducing their absorption into the blood or helping to eliminate them from the body. Carbomix itself is not absorbed into the blood and passes through the gut unchanged.

Carbomix is usually taken under medical supervision.

For single use only.

2. BEFORE YOU TAKE CARBOMIX

You should not take Carbomix if you have taken a medicine to make you sick or an oral antidote such as methionine as they will be absorbed by Carbomix.

Tell your doctor or pharmacist if you are taking any other medication.

Carbomix is of limited use in treating poisoning by the following:

- corrosive substances (such as acids or alkalis)
- cyanide, iron salts
- some solvents such as methanol, ethanol (the alcohol in alcoholic drinks) and ethylene glycol

The presence of Carbomix may make any immediate endoscopy that may be required, difficult.

Carbomix may stain if spilt.

Pregnancy and breast-feeding

Tell your doctor or pharmacist if you are pregnant or breast-feeding.

Important information about an ingredient of this medicine

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

3. HOW TO TAKE CARBOMIX

If a doctor has prescribed Carbomix for you, you should follow his/her instructions. Carbomix granules should be mixed with water and swallowed as a suspension (about 400ml). The contents of the bottle should be made up to the red band with water and shaken thoroughly. Carbomix should be taken as soon as possible after the potential poison has been swallowed. It is important to take the whole dose.

The usual adult dose is 50g. Children under 12 years should be given 25g (half the contents of the 50g bottle after it has been made up with water) unless there is a risk to life, in which case a dose of 50g is recommended. The dose may be repeated if necessary, usually under medical supervision.

If the poison has diuretic properties (i.e. increases urine output) or has been taken with alcohol, plenty of fluid should be drunk after taking Carbomix.

Carbomix can be taken after vomiting or after having a stomach pump. It may be given by tube into the stomach, under medical supervision only. A universal applicator is provided for this purpose.

DO NOT EXCEED THE RECOMMENDED DOSE

Remember to tell any doctor or pharmacist who is giving you advice about other medical conditions that you have taken Carbomix.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Carbomix may cause side effects, although not everyone will get them. Some patients may experience constipation or diarrhoea. Rarely, blockage or perforation of the intestine have been associated with multiple dosing with activated charcoal. Activated charcoal will usually produce black stools.

Reporting of side effects

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via UK: the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

IE: HPRA Pharmacovigilance, Earlsfort Centre, Earlsfort Terrace, IRL - Dublin 2 Tel: +353 1 6764971; Fax: +353 1 6762517

Website: www.hpra.ie

E-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE CARBOMIX

Keep out of the reach and sight of children. Store below 25°C. Keep container tightly closed.

Do not use Carbomix after the expiry date which is shown on the label and the carton of each pack, after "use by". This refers to the last day of the month.

Dispose of any unused suspension after 24 hours.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. FURTHER INFORMATION

What Carbomix contains: The active ingredient is 81.3% activated charcoal 50g in 61.5g granules. The other ingredients are citric acid, acacia and glycerol.

What Carbomix looks like and the contents of the pack: Carbomix is black granules in plastic bottles which contain 50g activated charcoal.

Marketing Authorisation Holder:

UK MAH: Kent Pharma UK Limited, 2nd Floor, Connect 38, 1 Dover Place, Ashford, Kent, England, TN23 1FB.

IE MAH: Athlone Pharmaceuticals Limited, Connaught House, 1 Burlington Road, Dublin 4, Ireland.

Manufacturer: Norit Nederland B.V., 7891 EV Klazienaveen, The Netherlands. United Kingdom Product Licence number: PL 51463/0098

Republic of Ireland Product Authorisation number: PA 1418/007/001

Carbomix is distributed in the Republic of Ireland by: United Drug plc.

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