Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Benylin Mucus Relief 250mg/5ml Syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains 250 mg carbocisteine (50mg/ml).

Excipients: Each 5ml also contains 7.5 mg methyl parahydroxybenzoate, 47.1 mg sodium and 0.03 mg sunset yellow (E110).

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Syrup
Clear, light yellow solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Mucolytic agent for use in disorders of the lower respiratory tract in which an increase in the amount and viscosity of mucus is a prominent feature.

4.2 Posology and method of administration

Oral administration:

Adults and children over 12 years

Three 5 ml spoonfuls three times a day initially; after a satisfactory response, this may be reduced to two 5 ml spoonfuls three times daily.

Children over 4 years

(6-12 years): One 5 ml spoonful three times a day

(4-5 years): Half to one 5 ml spoonful twice a day (5-10ml).

Not recommended for children under 4 years.

4.3 Contraindications

Hypersensitivity to the active ingredient or to any of the excipients.

Carbocisteine is contra-indicated in cases of active peptic ulcer.

4.4 Special warnings and precautions for use

This product should be used with caution in patients with a history of peptic ulceration, because of the possible effect on the mucous glands of the stomach.

If symptoms persist or get worse, or if new symptoms occur, patients should stop use and consult a physician.

4.5 Interaction with other medicinal products and other forms of interaction

None known, but see Section 6.2 below.

4.6 Fertility, pregnancy and lactation

There are insufficient adequate and well controlled studies in pregnant women. Therefore, Benylin Mucus Relief action should not be used during pregnancy or by nursing mothers.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Side effects of carbocisteine are rare. The most common are gastro-intestinal disorders and nausea which usually subside with the lowering of the dosage or discontinuation of treatment. Nausea, headache and diarrhoea have been reported in association with use of this product.

Allergic reactions including occasional skin rashes and urticaria, angioedema, have been reported.

Post-marketing Data:
Additional adverse drug reactions (ADRs) identified during post-marketing experience with Carbocisteine are included in Table 1.

In this table, the frequencies are provided according to the following convention:

Very common ≥1/10, Common ≥1/100 and <1/10, Uncommon ≥1/1,000 and <1/100, Rare ≥1/10,000 and <1/1,000, Very rare <1/10,000, Not known (cannot be estimated from the available data).

ADRs are presented by frequency category based on 1) incidence in adequately designed clinical trials or epidemiology studies, if available or 2) when incidence is unavailable, frequency category is listed as 'Not known'.

Table 1. Adverse Drug Reactions Identified During Post-Marketing Experience with Carbocisteine. Frequency Category Estimated from Clinical Trials or Epidemiology Studies	
SOC	
Frequency category	Adverse Event Preferred term
Immune System Disorders	
Not known	Drug eruption
Respiratory, Thoracic and Mediastinal Disorders	
Not known	Increased bronchial secretions
Not known	Sputum increased

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. Website: www.hpra.ie.

4.9 Overdose

Reports of overdosage with carbocisteine do not provide consistent data regarding the signs and symptoms of overdose. There is no known antidote.

Treatment is symptomatic and supportive. If vomiting has not occurred it should be induced by conventional means.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Our knowledge of the biochemical activity of carbocisteine is as yet, insufficient to fully explain the beneficial effects observed clinically.

Results from clinical and laboratory studies provide convincing evidence that carbocisteine does not act as a true mucolytic but rather as a 'mucoregulator', correcting intracellular abnormalities of glycoprotein synthesis and normalising the secretory functions of the mucosal epithelium. In other words, carbocisteine produces a delayed re-structuring of mucus which is favourable in terms of clearance by cough or by the mucociliary apparatus.

In addition, carbocisteine appears to have an anti-inflammatory function, probably through its effect on sialomucin synthesis kinin inhibition. Such effects are a bonus in the treatment of the above diseases which are frequently associated with an underlying inflammatory pathology.

Suppression of inflammatory mechanisms will lead to a decrease in vascularity, cell destruction, oedema and bronchospasm and will encourage the rapid return of healthy mucosa. Carbocisteine is therefore attributed with a unique combination of mucoregulatory and anti-inflammatory actions.

5.2 Pharmacokinetic properties

Carbocisteine is rapidly and well absorbed after oral administration and the subsequent kinetics fit a one-component open model. Peak serum concentrations were reached between 1 and 1.7 hours after oral administration and peak values after a 1.5 g dose were 13.38 mg/litre. The plasma half-life was estimated to be 1.33 hours and the apparent volume of distribution was approximately 60 litres. No information is available on the extent of first-pass metabolism or protein binding. Carbocisteine appears to penetrate well into lung tissue and respiratory mucus suggesting a local action.

Significant variation between the patterns of metabolism in man and animals has been noted; the pathways that have been identified in man are acetylation, decarboxylation and sulphoxidation. Two out of three individuals excrete a glucuronic acid conjugate as a minor metabolite. There are no reports of pharmacologically important activity in these metabolites.

There is evidence from these studies that very little of the decarboxy-methylated derivative is produced. The majority of the drug is eliminated by urinary excretion, unchanged.

5.3 Preclinical safety data

The safety profile of carbocisteine is well documented.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol 96%
Sodium hydroxide
Mirabelle flavour
Citric acid monohydrate
Carmellose sodium
Sodium cyclamate
Methyl parahydroxybenzoate (E218)
Disodium edetate
Saccharin sodium
Sunset yellow (E110)
Purified water

6.2 Incompatibilities

Carbocisteine is incompatible with Pholcodine Linctus.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.
Keep the bottle tightly closed.

6.5 Nature and contents of container

125ml, 200ml and 300ml amber glass bottles with ROPP aluminium caps or a 28mm diameter plastic cap, fitted with a Triseal or Polexan-Sarenex wad.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

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