SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

CARYL COUGH SYRUP

2. Qualitative and quantitative composition

Active ingredients	
Bromhexine	4mg/5ml
Salbutamol sulphate	1mg/5ml
Guaiphenesin	50mg/5ml

3. Pharmaceutical form

Oral liquid: A clear homogeneous reddish syrup with a raspberry flavour and a sweet taste free from any visible impurities

4. Clinical particulars

4.1 Therapeutic indications

Caryl expectorant is indicated for relief of cough associated with chronic bronchitis,bronchial asthma,emphysema and other bronchpulmonary disorders where bronchospasm,mucous plugging and problem of expectoration co excist.

For oral administration.

4.2 Posology and method of administration

Adults and children over 12 years: 10ml

The dose should be taken with twice its volume of water three or four times in 24 hours.

Children under 12 years: Not recommended

Elderly: The normal adult dose is still appropriate in the elderly.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

If symptoms persist consult your doctor.

Keep all medicines out of the reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically significant interactions.

4.6 Pregnancy and lactation

The safety of this product during pregnancy has not been established, although there is no good evidence of an association between first trimester exposure to either ammonium chloride or guaiphenesin and foetal abnormalities. The safety of the product during lactation has not been established, although use during this period would not be considered to constitute a hazard.

4.7 Effects on ability to drive and use machines
No adverse effects known.

4.8 Undesirable effects
May occasionally produce gastrointestinal discomfort, nausea and vomiting.

4.9 Overdose
Symptoms of overdosage include nausea, vomiting, thirst, headache, hyperventilation and progressive drowsiness, leading to profound acidosis and hypokalaemia.

Treatment consists of the correction of acidosis and electrolyte loss by the intravenous administration of sodium bicarbonate or sodium lactate, together with potassium supplements by mouth. Otherwise treatment should be symptomatic and supportive.

5. Pharmacological properties

5.1 Pharmacodynamic properties
Bromhexine hydrochloride acts as a mucokinetic and mucolytic agent. It decreases mucus viscosity by altering its structure. It depolymerises mucopolysaccharides directly as well as by liberating lysosomal enzymes and network of fibres in tenacious sputum is broken. It induces thin copious bronchial secretion.

As a beta-adrenergic stimulant for relief of bronchospasm such as occurs with asthma, bronchitis, emphysema. It has a highly selective action on the receptors in bronchial muscle and in therapeutic dosage, little or no action on the cardiac receptors.

Guaifenesin is thought to exert its pharmacological action by stimulating receptors in the gastric mucosa. This increases the output from secretory glands of the gastrointestinal system and in reflex increases the flow of fluids from glands lining the respiratory tract. The result is an increase in volume and decrease in viscosity of bronchial secretions. Other actions may include stimulating vagal nerve endings in bronchial secretory glands and stimulating certain centres in the brain which in turn enhance respiratory fluid flow. Guaifenesin produces its expectorant action within 24 hours.

5.2 Pharmacokinetic properties
Absorption: Bromhexine hydrochloride is rapidly absorbed from the gastrointestinal tract and bioavailability is about 20%. **Distribution:** It is widely distributed to body tissues in a highly protein bound form; Bromhexine crosses the blood brain barrier and small amounts cross the placenta, **Metabolism:** It undergoes extensive first-pass metabolism in the liver. **Excretion:** It is excreted primarily in the urine mainly as metabolites.

Salbutamol is readily absorbed from the gastro-intestinal tract and is subject to first pass metabolism in the liver. Peak plasma concentrations occur within one to four hours after oral administration. After multiple oral doses of salbutamol 4mg four times a day, steady-state plasma concentrations are obtained after 3 days. About half is excreted in the urine as an inactive sulphate conjugate following oral administration. The bioavailability of orally administered salbutamol is about 50%.

Absorption

Guaifenesin is well absorbed from the gastro-intestinal tract following oral administration, although limited information is available on its pharmacokinetics. After the administration of

600 mg guaifenesin to healthy adult volunteers, the C_{max} was approximately 1.4 ug/ml, with t_{max} occurring approximately 15 minutes after drug administration.

Menthol is well absorbed from the gastrointestinal tract following oral administration.

Distribution

No information is available on the distribution of guaifenesin or menthol in humans.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included.

6. Pharmaceutical particulars:

6.1 List of excipients:

- Propylene glycol B.P 2016
- Glycerin. B.P 2016
- Sodium benzoate B.P 2016
- Potassium sorbate B.P 2016
- Sodium Saccharin B.P 2016
- Sodium citrate B.P 2016
- Celocell 100H B.P 2016
- Citric acid anhydrous B.P 2016
- Chloroform B.P 2016
- Menthol B.P 2016
- Ponceau 4R colour (Inhouse)
- Pineapple flavour (Inhouse)

6.2 Incompatibilities:

None stated.

6.3 Shelf life:

3 years from the date of manufacture.

6.4 Special precautions for storage:

Do not store above 30°C, Protect from direct sunlight.

6.5 Nature and contents of the container:

60ml in glass / PET bottles, packed in unit boxes.

6.6 Special precautions for disposal:

No special requirements.

7. Registrant:

Biodeal Laboratories Limited,
Plot No. 123, Lunga Lunga Road, Industrial Area,
P.O. Box 32040 – 00600,
Nairobi, Kenya.

8 Manufacturer:

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Plot No. 123, Lunga Lunga Road, Industrial Area,
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9. Date of First Registration/Renewal

Date of first Authorization: 26th September 2007

10. Date of Revision of text:

Last Review: 30th June 2020
Next Review: 30th June 2022

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