1 NAME OF THE MEDICINAL PRODUCT

Asda Chesty Cough Syrup Guaifenesin Cherry Flavour
Bell’s Healthcare Mucus Cough Guaifenesin 100mg/5ml Oral Solution
Essential Waitrose Chesty Cough Guaifenesin 100 mg/5ml Oral Solution
Numark Mucus Cough Guaifenesin 100 mg/5 ml Oral Solution
Sainsbury’s Adult Chesty Cough Syrup Guaifenesin 100mg/5ml Oral Solution
Sainsbury’s Healthcare Mucus Cough Syrup Guaifenesin 100 mg/5 ml Oral Solution
Superdrug Chesty Cough Guaifenesin 100 mg/5 ml Oral Solution
Superdrug Mucus Cough Guaifenesin 100mg/5ml Oral Solution
Tesco Adult Chesty Cough Syrup
Wilko Mucus Cough 100mg/5ml Oral Solution
Lloyds Pharmacy Cough Expectorant 100 mg/5 ml Oral Solution
Co-op Mucus Cough 100 mg/5 ml Oral Solution
Lloyds Pharmacy Mucus Cough 100mg/5ml Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:

Guaifenesin BP 100 mg

Excipient(s):
Each 5 ml of solution contains 2.4% vol Ethanol (alcohol)

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral solution

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
Expectorant for symptomatic relief of coughs due to upper respiratory tract infections.

4.2 Posology and method of administration
Adults, the elderly and children over 12 years of age take 5 to 10 ml every two or three hours.
Not more than 4 doses should be given in any 24 hours.
Do not exceed the stated dose.
Do not take with any other cough and cold remedies.
Not recommended for children under 12 years
Keep out of the sight and reach of children.

4.3 **Contraindications**

Hypersensitivity to guaifenesin or to any of the excipients.

4.4 **Special warnings and precautions for use**

Not recommended for children under 12 years
Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

This medicinal product contains 2.4vol% Ethanol (alcohol), i.e. up to 191mg per 10ml dose, equivalent to 4.9 ml of beer or 2 ml of wine per 10ml dose. Harmful for those suffering from alcoholism.

4.5 **Interaction with other medicinal products and other forms of interaction**

A metabolite of guaifenesin was found to produce an apparent increase in urinary 5-hydroxyindoleacetic acid and could thus interfere with diagnosis of carcinoid syndrome. Patients should discontinue using this preparation 24 hours before the collection of urine samples for 5-hydroxyindoleacetic acid (5-HIAA) and vanillylmandelic acid (VMA) determination.

Guaifenesin may increase the rate of absorption of paracetamol.

4.6 **Fertility, pregnancy and lactation**

Guaifenesin has been linked with an increased risk of neural tube defects in a small number of women with febrile illness in the first trimester of pregnancy. The product should be used in pregnancy only if the benefits outweigh this risk. There is no information on use in lactation.

4.7 **Effects on ability to drive and use machines**

None known

4.8 **Undesirable effects**

May cause gastro-intestinal discomfort. Large doses may cause nausea and vomiting. Also, hypersensitivity reactions may occur.

**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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 **Overdose**

Very large doses may cause nausea and vomiting. The drug is, however, rapidly metabolised and excreted in the urine. Patients should be kept under observation and treated symptomatically.

5.1 **Pharmacodynamic properties**

Pharmacotherapeutic group: Expectorants
ATC Code: R05CA03

Guaifenesin reduces the viscosity of tenacious sputum and is used as an expectorant. It has been given in doses of 100 mg to 200 mg every 2 to 4 hours.

The active ingredient is not known to cause sedation.

5.2 **Pharmacokinetic properties**

Guaifenesin is readily absorbed from the gastro-intestinal tract. It is readily metabolised and excreted in the urine.

5.3 **Preclinical safety data**

None available.

6 **PHARMACEUTICAL PARTICULARS**

6.1 **List of excipients**

Glucose Liquid
Methyl Hydroxybenzoate BP
Citric Acid Anhydrous BP
Sodium Citrate BP
Sodium Saccharin BP
Carmoisine
Caramel E150
Morello Cherry Flavour
Alcohol 90% BP
Purified Water BP
6.2 **Incompatibilities**
None known

6.3 **Shelf life**
36 months in unopened bottle.

6.4 **Special precautions for storage**
Do not store above 25°C.

6.5 **Nature and contents of container**
Bottle: Amber (Type III) glass
Closures: Child resistant closure (CRC) fitted with low density polyethylene EPE/AL/PET liner
OR
Roll on pilfer proof (ROPP) screw cap fitted with low density polyethylene EPE/AL/PET liner
Sizes: 50 ml, 60 ml, 100 ml, 125 ml, 150 ml, 175 ml, 200 ml, 225 ml, 250 ml and 300 ml.
30 ml CE marked polypropylene measuring cup with 2.5 ml, 3.3 ml, 4 ml, 5 ml, 7.5 ml, 10 ml, 15 ml, 20 ml and 25 ml graduations.
(May not be included in all marketed products)

6.6 **Special precautions for disposal**
None

7 **MARKETING AUTHORISATION HOLDER**
Bell, Sons & Co (Druggists) Ltd
Gifford House
Slaidburn Crescent
Southport
Merseyside
PR9 9AL
8 MARKETING AUTHORISATION NUMBER(S)
   PL  03105/0051

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

   27/07/2010

10 DATE OF REVISION OF THE TEXT

   31/07/2017