SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Asda Chesty & Mucus Cough Relief 100 mg/5 ml Oral Solution
Bell's Healthcare Mucus Cough Guaifenesin 100mg/5ml Oral Solution
Bell's Healthcare Chesty and Mucus Cough 100mg/5ml Oral Solution
Numark Mucus Cough 100 mg/5 ml Oral Solution
Sainsbury's Healthcare Chesty & Mucus Cough 100mg/5ml Oral Solution
Superdrug Chesty Cough Guaifenesin 100 mg/5 ml Oral Solution
Superdrug Mucus Cough Guaifenesin 100mg/5ml Oral Solution
Tesco Health Chesty Cough Relief 100mg/5ml Oral Solution
Lloyds Pharmacy Cough Expectorant 100 mg/5 ml Oral Solution
Co-op Mucus Cough 100 mg/ 5ml Oral Solution
Lloyds Pharmacy Mucus Cough 100 mg/5 ml Oral Solution
Well Pharmaceuticals Mucus Cough 100 mg/ 5ml Oral Solution
Morrisons Chesty Cough Oral Solution 100 mg/5 ml Oral Solution
Careway Cough Expectorant 100mg/5ml Oral Solution
Almus Mucus Cough 100 mg / 5 ml Oral Solution
Health Essentials Chesty Cough 100mg per 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 the 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.
Not recommended for children under 12 years.

4.4 Special warnings and precautions for use

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.

Do not exceed the stated dose.
Do not take with a cough suppressant.
Ask a doctor before use if you suffer from a chronic cough, if you have asthma or are suffering from an acute asthma attack.
Stop use and ask a healthcare professional if your cough lasts for more than 5 days, comes back, or is accompanied by a fever, rash or persistent headache.
Keep all medicines out of the reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

There are no clinically significant interactions.

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

If pregnant or breastfeeding, consult a healthcare professional before use. Although adequate and well-controlled studies in pregnant women have not been performed, the Collaborative Perinatal Project monitored 197 mother-child pairs exposed to guaifenesin during the first trimester.

An increased occurrence of inguinal hernias was found in the neonates. However, Congenital defects were not strongly associated with guaifenesin use during pregnancy in 2 large groups of mother-child pairs.

Breast-feeding
Guaifenesin is excreted in breast milk in small quantities.
Caution should therefore be exercised by balancing the potential benefit of treatment against any possible risks.

4.7 Effects on ability to drive and use machines

No adverse effects known.

4.8 Undesirable effects

The following side effects may be associated with the use of guaifenesin:

Gastrointestinal disorders: Nausea, vomiting/gastrointestinal discomfort.

Immune system disorder: hypersensitivity reactions, including anaphylaxis.

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 or search for MHRA Yellow Card in the

Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

4.9 Overdose

In case of overdose, discontinue use and seek professional assistance immediately.

Overdosage may give rise to nausea and vomiting.
Treatment need only be symptomatic and supportive.

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

13/01/2025