1. NAME OF THE MEDICINAL PRODUCT

Numark Chesty Cough Expectorant
Asda Strong Expectorant Cough Liquid
Tesco Health Dual Action Chesty Cough Relief Oral Solution
Bells Healthcare Dual Action Chesty Cough Oral Solution
Lloyds Pharmacy Dual Relief Chesty Cough Oral Solution
Well Pharmaceuticals Dual Action Chesty Cough Oral Solution
Almus Dual Action Chesty Cough 14 mg/130 mg per 5 ml Oral Solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains
Diphenhydramine hydrochloride BP 14 mg
Ammonium chloride BP 130 mg
Each 5ml of solution contains Sucrose 3.9g
Each 5ml of solution contains 3.6% vol% Ethanol (alcohol)

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Oral solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic relief from coughs due to upper respiratory tract infections.

4.2 Posology and method of administration

Oral liquid
Adults: 5 ml to 10 ml every two or three hours
Children: 6 to 12 years: 5 ml every three or four hours
Elderly as adults.

This medicinal product is contraindicated in children under the age of 6 years (see section 4.3)

Children of 6-12 years of age: not to be used for more than 5 days without the advice of a doctor. Parents or carers should seek medical attention if the child's condition deteriorates during treatment.

Do not exceed the stated dose
Keep out of the sight and reach of children

4.3 Contraindications

Ammonium chloride is contraindicated in the presence of impaired hepatic or renal function.
Monoamine oxidase inhibitors (MAOIs) or within 14 days of stopping treatment (see section 4.5)
• Hypersensitivity to the active substances(s) or any of the excipients
• Not to be used in children under the age of 6 years

4.4 Special warnings and precautions for use

Do not exceed stated dose
Use with caution in prostatic hypertrophy, urinary retention, susceptibility to angle closure, hepatic disease.
The product may cause drowsiness. This product should not be used to sedate a child.
Ask a doctor before use if you suffer from a chronic or persistent cough, if you have asthma, suffering from an acute asthma attack or where cough is accompanied by excessive secretions.

Patients with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

It contains 3.9g of sucrose per 5ml. To be taken into account in people with diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicinal product contains 7.2% vol% ethanol (alcohol) i.e. up to 568 mg per 10 ml dose, equivalent to 14.1 ml beer, 6 ml of wine per 10 ml dose. Harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children and high risk groups such as patient with liver disease or epilepsy.

4.5 Interaction with other medicinal products and other forms of interaction

CNS depressants: may enhance the sedative effects of CNS depressants including barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives, antipsychotics and alcohol.

Antimuscarinic drugs: may have an additive muscarinic action with other drugs, such as atropine and some antidepressants.

MAOIs: Not to be used in patients taking MAOIs or within 14 days of stopping treatment as ther is a risk of serotonin syndrome.

4.6 Pregnancy and lactation

Diphenhydramine: significant incidence of cleft palate and clefts with other defects in children whose mothers had taken diphenhydramine during pregnancy. The warning “Do not take during pregnancy” is included on the label.

4.7 Effects on ability to drive and use machines

Diphenhydramine may cause drowsiness. The warning “may cause drowsiness. If affected, do not drive or operate machinery. Avoid alcoholic drink” is included on the label.

4.8 Undesirable effects

Common side effects

CNS effects: Drowsiness (usually diminishes within a few days), paradoxical stimulation, headache, psychomotor impairment.
Antimuscarinic effects: Urinary retention, dry mouth, blurred vision, gastrointestinal disturbances, thickened respiratory tract secretions.
Rare side-effects: Hypotension, extrapyramidal effects, dizziness, confusion, depression, sleep disturbances, tremor, convulsions, palpitation, arrhythmia, hypersensitivity reactions, blood disorders and liver dysfunction.

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.yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Ammonium chloride: large doses may cause nausea, vomiting, thirst, headache, hyperventilation and progressive drowsiness and lead to profound acidosis and hypokalaemia.

Diphenhydramine: Antihistamines may cause gastrointestinal disturbances, headache, blurred vision, tinnitus, elation or depression, irritability, nightmares, anorexia, difficulty in micturition, dryness of the mouth, tightness of the chest and tingling, heaviness and weakness of the hands.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ammonium chloride has an irritant effect on the gastric mucous membrane. Diphenhydramine has pronounced sedative properties. It also has anti-emetic, anticholinergic and local anaesthetic properties.

5.2 Pharmacokinetic properties

Ammonium chloride is effectively absorbed from the gastro-intestinal tract. The ammonium ion is converted into urea in the liver. The anion liberated into

the blood stream and extra-cellular fluid causes a metabolic acidosis and decreases the pH of the urine. This is followed by transient diuresis.

Antihistamines are readily absorbed from the gastro intestinal tract, metabolised in the liver and excreted usually mainly as metabolites in the urine.

5.3 Preclinical safety data

None available

6.1 List of excipients

Sodium citrate
Levomenthol
Saccharin sodium
Sugar glucose mix
Sucrose
Sorbitol solution 70%
Citric acid anhydrous
Ethanol 90%
Methyl hydroxybenzoate
Cherry flavour
Caramel
Amaranth
Purified Water

6.2 Incompatibilities

None known

6.3 Shelf life

36 months in unopened bottle.

6.4 Special precautions for storage

Protect from light

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: 100ml, 125ml, 150ml and 200ml.
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 Instructions for Use/Handling

None

7. MARKETING AUTHORISATION HOLDER

Name or style and permanent address or registered place of business of the holder of the marketing authorisation.

Bell, Sons & Co (Druggists) Ltd
Gifford House
Slaidburn Crescent
Southport
Merseyside
PR9 9AL

8. MARKETING AUTHORISATION NUMBER

PL 03105/0050

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

07/06/1996 / 07/02/2011

10 DATE OF REVISION OF THE TEXT

07/07/2021