1. NAME OF THE MEDICINAL PRODUCT

DELASED CHESTY COUGH SYRUP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains:
Diphenhydramine HCl BP 14.0mg;
Ammonium Chloride BP 135.0mg;
Sodium Citrate BP 57.0mg;
Menthol BP 1.1mg.

3. PHARMACEUTICAL FORM

Reddish-brown, viscous free flowing liquid with a mentholic odour and minty-salty taste and free from any visible impurities.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the oral symptomatic relief of common coughs (such as dry and/or tickly, or troublesome cough) associated with upper respiratory tract congestion and aids restful sleep

4.2 Posology and method of administration

Posology

One to two 5ml spoonfuls to be taken every 4 hours for patients above 12 years

One 5ml spoonful for patients between 6 and 12 years

To aid sleep the patient may start with two 5ml spoonfuls at bedtime followed by two 5ml spoonfuls every 6 hours.

One 5ml spoonful for patients between 6 and 12 years

Not suitable for children under 6 years.

Do not take more than 4 doses (1 dose = two 5ml spoonfuls) in 24 hours.

Do not exceed the stated dose.

Method of Administration

Oral

4.3 Contraindications

• Children below 6 years of age

• Patients on monoamine oxidase inhibitor therapy within previous 14 days

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Do not combine with other treatments for coughs and colds.

Deleased Chesty Cough should be used with caution in patients with the following conditions : prostatic hypertrophy, urinary retention, susceptibility to 'closed angle' glaucoma and hepatic disease.

Deleased Chesty Cough may cause drowsiness.

Seek medical advice when suffering from chronic or persistent cough and when also suffering from asthma, and acute asthmatic attack or where cough is accompanied by excessive secretions

Keep out of the reach and sight of children.

Excipient Warnings:

Parahydroxybenzoates may cause allergic reactions (possible delayed).

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

4.5 Interaction with other medicinal products and other forms of interaction

Additive CNS depressant effects with alcohol and other CNS depressants including barbiturates, hypnotics, opiod analgesics, anxiolytic sedatives and anti-psychotics.

• Additive anti-muscarinic effects with other drugs of similar properties such as atropine and some anti-depressants.

• Not to be taken in patients taking monoamine oxidase inhibitors (MAOIs) or within 14 of stopping treatment as there is a risk of serotonin syndrome.

• Diphenhydramine can inhibit the oxidative metabolism of some drugs.

• Diphenhydramine may enhance the effects of ephedrine.

• Diphenhydramine may mask the response of the skin to allergenic skin tests and also the ototoxic symptoms associated with certain antibiotics.

4.6 Pregnancy and lactation

Pregnancy

In view of the potential risks versus small benefits, it is recommended that Deleased Chesty Cough should not be used during pregnancy particularly as the safety of Deleased Chesty Cough in human pregnancy is not established

Lactation

In view of the potential risks versus small benefits, it is recommended that Deleased Chesty Cough should not be used during lactation particularly as the safety of Deleased Chesty Cough during lactation is not established

Fertility
No fertility data is available.

4.7 Effects on ability to drive and use machines

Deleased Chesty Cough may cause drowsiness. Do not drive or operate machinery. Avoid alcoholic drink

4.8 Undesirable effects

The overall percentage of treated patients expected to experience adverse reactions is unknown.

Common side effects include:

CNS effects such as nervous drowsiness (usually diminishes within a few days), paradoxical stimulation, nervous headache, nervous psychomotor impairment.

Anti-muscarinic effects such as urinary retention, dry mouth, blurred vision, gastrointestinal disturbances and thickened respiratory tract secretions.

Rare side effects include:

Hypotension, extrapyramidal effects, dizziness, confusion, depression, sleep disturbances, tremor, convulsions, palpitation, arrhythmia, hypersensitivity reactions, blood disorders and liver dysfunction.

Organ system Class	Common ADRs, >1/100, < 1/10	Uncommon ADRs, >1/1,000, <1/100	Rare ADRs >1/10,000, <1/1000
Blood Lymphatic System Disorder			Blood Disorders NOS
Cardiac Disorder			Palpitation, arrhythmia
Eye Disorders	Blurred vision		
Gastrointestinal Disorder	Dry mouth, gastrointestinal disturbance		
General Disorder	Paradoxical drug reaction		
Hepatobiliary Disorder			Liver Disorder

Immune System Disorders			Hypersensitivity
Nervous System Disorders	Psychomotor skills impairment, drowsiness, headache		Tremor, convulsions, extrapyramidal disorder, dizziness
Psychiatric Disorders			Confusion, depression, sleep disturbances
Renal and Urinary Disorder	Urinary retention		
Respiratory Disorder	Increased upper airway secretion		
Vascular Disorders			Hypotension

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.

4.9 Overdose

Symptoms of overdosage include those due to diphenhydramine or menthol (drowsiness, dizziness, ataxia, anti-cholinergic effects, pyrexia, headaches, convulsions, hallucinations, excitement and respiratory depression).

Treatment consists of gastric lavage and aspiration. Administration of activated charcoal may help. Other symptomatic and supportive measures should be provided

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antihistamines for systemic use

ATC Code: R06AA52

Diphenhydramine possesses antitussive, antihistaminic, and anticholinergic properties and suppresses the urge to cough. It also dries up secretions in the nose and chest. Experiments have shown that the antitussive effect is discrete from its sedative effect. Taken at night will assist sleeping

Ammonium Chloride "Traditional" Expectorant.

Menthol Subjective relief of upper respiratory congestion, it has mild local anaesthetic and cooling effect.

Sodium Citrate is chiefly used to soothe the throat.

Deleased Chesty Cough is a thick demulcent, which in the buccal cavity and throat forms a soothing film over the mucous membrane. This brings it into contact with the sensitive nerve endings of the throat lining.

5.2 Pharmacokinetic properties

Diphenhydramine

Is a histamine receptor antagonist. Main site of metabolic transformation is the liver. Oral availability - 50%, Plasma bound - 80%, Half life - 4 hours

Ammonium Chloride

Effectively absorbed from GI tract. Ammonium Ion converted to urea by the liver.

Acid ion released gives mild metabolic acidosis.

Sodium Citrate

Is metabolised after absorption, to bicarbonate.

Menthol

After absorption menthol is excreted in the urine and bile as a glucuronide.

5.3 Preclinical safety data

There are no preclinical data of relevance, within are additional to those already included in other sections of the SmPC

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl paraben
Propyl paraben
Sodium Saccharin
(mesh 40-80)
Sucrose
Alcohol 90%
(Rectified Spirit)
Hydroxyethyl Cellulose (Natrosol HHX250)
Brilliant blue colour FD & C blue blue 1 (E133)
Ponceau 4R Red 7 colour (E124)
Purified water

6.2 Incompatibilities

None stated

6.3 Shelf life

24 Months

6.4 Special Precautions for Storage

It should be stored below 25^0C, in a dry and dark place.
Keep out of reach of children.