CODOLIN EXPECTORANT (Diphenyhydramin HCL+Ammonium Chloride+Sodium Citrate+Menthol**)**

Summary of Product Characteristics

1. Name of the medicinal product
CODOLIN EXPECTORANT
Diphenhydramine HCL, Ammonium Chloride, Sodium Citrate, Menthol Syrup 100 ML

2. Qualitative and quantitative composition
Each 5ml contains

Diphenhydramine HCL	14mg/5ml
Ammonium Chloride	135mg/5ml
Sodium Citrate	57mg/5ml
Menthol	1.1mg/5ml

For the full list of excipients see section 6.1

3. Pharmaceutical form
Oral Syyrup
A Reddish/brown viscous syrup with a characteristic odour in aa amber bottle

4. Clinical particulars
4.1 Therapeutic indications
For the symptomatic relief of troublesome cough associated with upper respiratory tract congestion

4.2 Posology and method of administration
Oral.
RECOMMENDED DOSE
Children 1 To 5 Years : Half of one 5 ml spoonful every 4 hours Children 6 to 12 years : One 5 ml spoonful every 4 hours Adult and Elderly : One or Two 5 ml spoonful every 4 hours
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DOSAGE SCHEDULE
To be taken three times a day or as required.

4.3 Contraindications
Hypersensitivity to any ofthe ingredients. Children below one year of age. Patients on monomine oxidase inhibitor therapy within previous 14 days. The drug is contraindicated in epileptics.

4.4 Special warnings and precautions for use
Raised intra-ocular pressure, stenosing peptic ulcer, pyloro-duodenal obstruction, prostatic hypertrophy, asthma, hypertension, hyperthyroidism, severe artery disease and hepatic or renal dysfunctions
Use in pregnancy and Lactation: In view of the potential risks versus small benefits, it is recommended that codolin Syrup should not be used during pregnancy and lactation, particularly as the safety of codolin Syrup in human pregnancy is not established.

Effect on ability to drive and use machines: Codolin Syrup may cause drowsiness and the patients so affected should not drive or operate machinery

4.5 Interaction with other medicinal products and other forms of interaction

Additive CNS depressant effects with alcohol and other CNS depressants. Additive anticholinergic effects with other drugs of similar properties.

Monomine oxidase inhibitors prolong and intensifY the anti-cholinergic effects of antihistamines. Diphenhydramine may mask the response of the skin to allergenic skin tests and also the ototoxic symptoms associated with certain antibiotics

4.6 Fertility, pregnancy and lactation

In pregnancy and Lactation: In view of the potential risks versus small benefits, it is recommended that Codolin Syrup should not be used during pregnancy and lactation, particularly as the safety of codolin Syrup in human pregnancy is not established. Effect on ability to drive and use machines: codolin syrup may cause drowsiness and the patients so affected should not drive or operate machinery

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Sedation, incoordination, confusion, occasional allergic or anaphylactic reactions, anticholinergic effects such as blurred vision, dry mouth, tachycardia, urinary hesitancy, constipation, photosensitivity, paradoxical excitability (particularly in children) and tremors

4.9 Overdose

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

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

5. Pharmacological properties

5.1 Pharmacodynamic properties

Diphenhydramine Hydrochloride -It has central sedative, local anaesthetic, spasmolytic and anti-cholinergic (diminishes upper respiratory tract secretions) properties, in addition to its main antihistaminic actions. Ammonium Chloride - Reflexly acting expectorant which reduces viscosity of sputum, making it easierto expectorate. Sodium citrate- Directly acting expectorant. Menthol- Soothing agent

5.2 Pharmacokinetic properties
On oral administration, the components are well absorbed and produce its effect, 30-45 minutes after ingestion. Duration of action is 4-6 hours.

5.3 Preclinical safety data
Not Applicable.

6. Pharmaceutical particulars
6.1 List of excipients
Methyl & Propyl Paraben, Sodium CMC, Erythrosine, Sunset Yellow, Raspberry Flavour, Sodium Sulphite, Sorbitol, Ethanol. Granulated sugar

6.2 Incompatibilities
None.

6.3 Shelf life
36 months

6.4 Special precautions for storage
Store below 30° C.

6.5 Nature and contents of container
100ml: Amber PET bottle with white 28mm Child-resistant cap with Tamper Evident band and EPE

6.6 Special precautions for disposal and other handling
None.

7. Marketing authorisation holder
TUYIL PHARMACEUTICAL INDUSTRY LIMITED
22 New Yidi Road, Ilorin, Kwara State