FIRST VADIS PHARMACEUTICAL INDUSTRIES LIMITED	
BRAND NAME:	**VADILYN SYRUP**
GENERIC NAME:	**DIPHENHYDRAMINE HCL, AMMONIUM CHLORIDE & SODIUM CITRATE**

1.3 Product information

Enclosed

1.3.1 Summary of product characteristics

Enclosed

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BRAND NAME:	**VADILYN SYRUP**
GENERIC NAME:	**DIPHENHYDRAMINE HCL, AMMONIUM CHLORIDE & SODIUM CITRATE**

1. **Name of the product**

   Vadilyn Syrup

2. **Qualitative & Quantitative composition**

   Each 5 ml contains

   Ammonium Chloride BP 100 mg

   Diphenhydramine HCL BP 14 mg

   Sodium Citrate BP 57 mg

   Menthol BP 1.1 mg

3. **Pharmaceutical Dosage Form**

   Oral Syrup.

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 spoonful to be taken every 4 hours

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

Not suitable for children under 12 years.

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

Do not exceed the stated dose.

Method of Administration

Oral

4.3 Contraindications

• Hypersensitivity to any of the ingredients

• Children below 12 years of age

• Patients on monoamine oxidase inhibitor therapy within previous 14 days.

4.4 Special warnings and precautions for use

Do not combine with other treatments for coughs and colds.

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

Vadilyn Syrup 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:

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, opioid 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 Vadilyn Syrup should not be used during pregnancy particularly as the safety of Vadilyn Syrup in human pregnancy is not established.

Lactation

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

4.7 Effects on ability to drive and use machines

Vadilyn Syrup 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, gastrointestina ldisturbance		
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 airwaysecretion		
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. Healthcare

professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard.

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.

Vadilyn Syrup 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 nerveendings 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.

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

Sucrose, Sodium Benzoate, Glycerol, Citric Acid, Sodium Citrate, Menthol crystals Amaranth, Solvent A.A., Ethanol, C.M.C. Purified Water.

6.2 Incompatibilities

None

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store in a cool and dark place away from light.

6.5 Nature and contents of container

100ml amber pet bottle

6.6 Special precautions for disposal and other handling

No special requirements

7. Marketing authorisation holder

First Vadis Pharmaceutical Industries Limited,

Plot IN/2 Phase 2 Extension, Enugu-

Emene Industrial Layout Enugu State

8. Marketing authorisation number(s)

NAFDAC REG. NO.: 04 – 4148

9. Date of first authorisation/renewal of the authorisation

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10. Date of revision of the text
