VADIS PHARMACEUTICAL LIMITED

ADDRESS: PLOT IN/2 PHASE 2 EXTENSION, EMENE INDUSTRIAL LAYOUT, ENUGU

BRAND NAME:	**VADILYN DECONGESTANT SYRUP**
GENERIC NAME:	**PSEUDOEPHEDRINE HYDROCHLORIDE + DIPHENHYDRAMINE HYDROCHLORIDE + SODIUM CITRATE SYRUP**

MODULE 1: ADMINISTRATIVE AND PRODUCT INFORMATION

1. **Name of the product**

   Vadilyn Decongestant syrup

2. **Qualitative & Quantitative composition**

   Pseudoephedrine HCL 10 mg/5ml
   Diphenhydramine HCL BP 14 mg/5ml
   Sodium Citrate BP 57 mg/5ml
   Menthol BP 1.1 mg/5ml

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 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. To aid sleep the patient may start with two 5ml spoonfuls at bedtime followed by two 5 ml spoonfuls every 6 hours.
   Not suitable for children under 12 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

   - 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 Decongestant 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 Decongestant 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 antipsychotics.
- 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 Fertility, pregnancy and lactation

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

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

4.7 Effects on ability to drive and use machines

Vadilyn Decongestant 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	Common ADRs, >1/100, < 1/10	Uncommon ADRs, >1/1,000,	Rare ADRs >1/10,000,
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 disorder			Hypertension

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. If taken at night will assist sleeping. Menthol Subjective relief of upper respiratory congestion, it has mild local anaesthetic and cooling effect. Vadilyn Decongestant 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 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
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

Menthol crystals
Citric acid
Sodium benzoate
Sucrose
Sodium carboxylmethyl cellulose
Ethanol
Alura red

6.2 Shelf life

3 years

6.3 Special precautions for storage

Store in a cool dark place away from light. Store in the original package. Keep container in the outer carton

6.4 Nature and contents of container

Amber coloured pet bottle with aluminium cap as the closure.

6.5 Special precautions for disposal and other handling

No special requirements. Any unused product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorisation holder

Vadis Pharmaceuticals Limited,
Plot IN/2, Phase 2 Emene Industrial Layout,
Enugu-Nigeria.

8. Marketing authorisation number(s)

NRN: B4 - 5271

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MODULE 1: ADMINISTRATIVE AND PRODUCT INFORMATION

9. **Date of first authorisation/renewal of the authorization**

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10. **Date of revision of the text**
