

VADIS PHARMACEUTICAL LIMITED

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

BRAND NAME:	VADIS COUGH EXPECTORANT SYRUP
GENERIC NAME:	EPHEDRINE HYDROCHLORIDE + DIPHENHYDRAMINE HYDROCHLORIDE + AMMONIUM CHLORIDE SYRUP

MODULE 1: ADMINISTRATIVE AND PRODUCT INFORMATION

1. Name of the product

Vadis Cough Expectorant Syrup

2. Qualitative & Quantitative composition

Ephedrine HCL 15 mg/5ml
Diphenhydramine HCL BP 15 mg/5ml
Ammonium Chloride 150 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 5ml 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

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Do not combine with other treatments for coughs and colds.

Vadis Cough Expectorant Syrup should be used with caution in patients with the following conditions:

prostatic hypertrophy, urinary retention, susceptibility to 'closed angle' glaucoma and hepatic disease.

Vadis Cough Expectorant 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 Vadis Cough Expectorant Syrup should not be used during pregnancy particularly as the safety of Vadis Cough Expectorant in human pregnancy is not established.

Lactation

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

4.7 Effects on ability to drive and use machines

Vadis Cough Expectorant 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,		Tremor, convulsions,

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	drowsiness, headache		extrapyramidal disorder, dizziness
Psychiatric Disorders			Confusion, depression, sleep disturbances
Renal and Urinary Disorder	Urinary retention		
Respiratory Disorder	Increased upper airway secretion		
Vascular disorder			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 Ephedrine HCL (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. Ephedrine HCL Subjective relief of upper respiratory congestion, it has mild local anaesthetic and cooling effect. Vadis Cough Expectorant 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.

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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.

Ephedrine HCL After absorption Ephedrine HCL 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

Sodium Citrate

Menthol crystals

Citric acid

Sodium benzoate

Sucrose

Sodium carboxymethyl cellulose

Ethanol

Amaranth

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.

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7. **Marketing authorisation holder**
Vadis Pharmaceuticals Limited,
Plot IN/2, Phase 2 Emene Industrial Layout,
Enugu-Nigeria.

8. **Marketing authorisation number(s)**
NRN: A4 - 2550

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

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