	Module 1 (Administrative and Product information)
Product Name	STRICOFF Syrup (expectorant)

1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE DRUG PRODUCT

PRODUCT NAME: Diphenhydramine HCL, Ammonium Chloride, Sodium Citrate and Menthol

BRAND NAME: Stricoff Syrup (expectorant)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition

Each 5 ml Syrup (expectorant) Contains:

Ammonium Chloride	BP	140 mg
Diphenhydramine HCL	BP	20 mg
Sodium Citrate	BP	60 mg
Menthol	BP	1.1mg

Excipients: q.s

For complete list of excipients refer section 6.1.

3. PHARMACEUTICALS FORM:


Oral Syrup (Expectorant)

4. CLINICAL PARTICULARS

4.1 Therapeutic Indication:

- The symptomatic relief of cough and associated congestive symptoms
- Helps to ease nonproductive coughs, nasal and chest congestion, sneezing and runny nose associated with the common cold and itchy and watery eyes.

Product Name: Stricoff Expectorant (Diphenhydramine HCL, Ammonium Chloride, Sodium Citrate and Menthol BP)

	Module 1 (Administrative and Product information)
Product Name	STRICOFF Syrup (expectorant)

4.2 Posology and method of administration:

Posology

For oral administration

Adults and Children aged 12 years and over:

10ml per 3 times daily and maximum dose as 30ml

Children 6-12 years :

5 ml 8 hourly

Children 2-5 years :

2.5 ml 8 hourly

The Elderly:

As for adults above (see Pharmacokinetics - The elderly).

Hepatic dysfunction

Caution should be exercised if moderate to severe hepatic dysfunction is present (see Pharmacokinetics - Hepatic dysfunction).

Renal dysfunction

It may be prudent to increase the dosage interval in subjects with moderate to severe renal failure (see Pharmacokinetics - Renal dysfunction).

Do not exceed the stated dose.


Keep out of the sight and reach of children

4.3 Contraindications:

- Stricoff is contraindicated in individuals with known hypersensitivity to Diphenhydramine or L-menthol or to any of the excipients listed in section 6.1.
- Stricoff should not be administered to patients currently receiving monoamine oxidase inhibitors (MAOIs) or within 14 days of stopping treatment (see section 4.5).

4.4 Special warning and precautions for use

Product Name: Stricoff Expectorant (Diphenhydramine HCL, Ammonium Chloride, Sodium Citrate and Menthol BP)

	Module 1 (Administrative and Product information)
Product Name	STRICOFF Syrup (expectorant)

- This product may cause drowsiness. If affected individuals should not drive or operate machinery.
- This product should not be used to sedate a child.
- Diphenhydramine may enhance the sedative effects of central nervous system depressants including alcohol, sedatives, opioid analgesics, antipsychotics and tranquilizers. Alcoholic beverages should be avoided while taking this medicine (see section 4.5).
- Do not use with any other product containing diphenhydramine, including topical formulations used on large areas of skin.
- Subjects with hepatic disease or moderate to severe renal dysfunction should exercise caution when using this product (see Pharmacokinetics - Renal/Hepatic Dysfunction).


Patients with the following conditions should be advised to consult a physician before using this medicine:

- A chronic or persistent cough such as occurs with chronic bronchitis or emphysema, acute or chronic asthma, or where cough is accompanied by excessive secretions
- Susceptibility to angle-closure glaucoma
- Prostatic hypertrophy and/or urinary retention

Other important things to note

- Stricoff contains 3.5 g of glucose and 1 g of sucrose per 5 ml. This should be taken into account in patients with diabetes mellitus.
- Patients with rare hereditary problems of fructose intolerance, glucose- galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.
- This product contains Ponceau 4R (E 124) red colouring which may cause allergic reactions.
- This medicine contains 16.62 mg sodium (main component of cooking/table salt) in each 5 ml. This is equivalent to 0.83% of the recommended maximum daily dietary intake of sodium for an adult.

Product Name: Stricoff Expectorant (Diphenhydramine HCL, Ammonium Chloride, Sodium Citrate and Menthol BP)

	Module 1 (Administrative and Product information)
Product Name	STRICOFF Syrup (expectorant)

- This medicine contains 0.22 mg benzyl alcohol in each 5ml. Benzyl alcohol may cause allergic reactions.
- Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”). High volumes should be used with caution and only if necessary, especially in subjects with liver or kidney impairment because of the risk of accumulation and toxicity (metabolic acidosis).
- This medicine contains 10 mg sodium benzoate (E 211) in each 5 ml.
- This medicine contains 197 mg of alcohol (ethanol) in each 5 ml. The amount in 5 ml of this medicine is equivalent to less than 5 ml beer or 2 ml wine.
- The small amount of alcohol in this medicine will not have any noticeable effects

4.5 Drug Interactions

Diphenhydramine

CNS depressants: may enhance the sedative effects of CNS depressants including barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives, antipsychotics and alcohol.

Antimuscarinic drugs: may have an additive muscarinic action with other drugs, such as atropine and some antidepressants.


MAOIs: Not be used in patients taking MAOIs or within 14 days of stopping treatment as there is a risk of serotonin syndrome.

Menthol: There are no known drug interactions associated with menthol

4.6 Pregnancy & Lactation

This product should not be used during pregnancy or breastfeeding unless the potential benefit of treatment to the mother outweighs the possible risks to the developing fetus or breastfeeding

Product Name: Stricoff Expectorant (Diphenhydramine HCL, Ammonium Chloride, Sodium Citrate and Menthol BP)

	Module 1 (Administrative and Product information)
Product Name	STRICOFF Syrup (expectorant)

infant.

Pregnancy:

Diphenhydramine has been in widespread use for many years without any apparent ill consequence. Diphenhydramine is known to cross the placenta and, therefore, should only be used during pregnancy if considered essential by a doctor.

Lactation:

Diphenhydramine is excreted into human breast milk, but levels have not been reported. Although the levels are not thought to be sufficiently high enough after therapeutic doses to affect the infant, the use of diphenhydramine during breast-feeding is not recommended.

There are no adequate and well-controlled studies in pregnant women for menthol. Menthol is excreted in breast milk; when 100 mg of menthol was ingested, there was up to 5.87 ug/L of menthol in breast milk.

4.7 Effects on ability to drive and use machines:

This product may cause drowsiness. If affected, the patient should not drive or operate machinery.

4.8 Undesirable effects

Diphenhydramine

Adverse drug reactions (ADRs) identified during clinical trials and post- marketing experience with Diphenhydramine are included in the table below by System Organ Class (SOC). The frequencies are provided according to the following convention:

Very common	≥1/10
Common	≥1/100 and < 1/10
Uncommon	≥1/1,000 and <1/100
Rare	≥1/10,000 and <1/1,000
Very rare	<1/10,000
Not known	(cannot be estimated from the available data)

Product Name: Stricoff Expectorant (Diphenhydramine HCL, Ammonium Chloride, Sodium Citrate and Menthol BP)




Module 1
(Administrative and Product information)

Product Name

STRICOFF Syrup (expectorant)

System Organ Class (SOC)	Frequency*	Adverse Drug Reaction
Blood and Lymphatic System Disorders	Rare	Blood disorders
Immune System Disorders	Rare	Hypersensitivity reactions
Psychiatric Disorders	Uncommon	Irritability Hallucination Nervousness
	Rare	Confusional state
	Very common	Somnolence (usually diminishes within a few days)
	Common	Dizziness Headache Paradoxical stimulation Psychomotor impairment
Nervous System Disorders	Uncommon	Agitation Paraesthesia Sedation
		Convulsion Depression
	Rare	Extrapyramidal effects Insomnia Tremor
	Common	Vision blurred
Ear and Labyrinth Disorders	Uncommon	Tinnitus
Cardiac Disorders	Uncommon	Tachycardia
	Rare	Arrhythmia

Product Name: Stricoff Expectorant (Diphenhydramine HCL, Ammonium Chloride, Sodium Citrate and Menthol BP)

	Module 1 (Administrative and Product information)
Product Name	STRICOFF Syrup (expectorant)

		Palpitations
Vascular Disorders	Rare	Hypotension
	Common	Thickened respiratory tract secretions
Respiratory, Thoracic and Mediastinal Disorders	Uncommon	Chest discomfort Nasal dryness
		Dry mouth
Gastrointestinal Disorders	Common	Nausea Vomiting
Hepatobiliary Disorders	Rare	Liver dysfunction
		Pruritus
Skin and Subcutaneous Tissue Disorders	Uncommon	Rash Urticaria
Renal and Urinary Disorders	Common	Urinary retention
General Disorders and Administration site conditions	Common	Asthenia

(*) Frequency category based on clinical trials with single-ingredient diphenhydramine

Menthol


Adverse reactions to menthol at the low concentration present in Stricoff CHESTY COUGHS (ORIGINAL) are not anticipated.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization 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,

4.9 Overdose

Product Name: Stricoff Expectorant (Diphenhydramine HCL, Ammonium Chloride, Sodium Citrate and Menthol BP)

	Module 1 (Administrative and Product information)
Product Name	STRICOFF Syrup (expectorant)

Symptoms and signs

Diphenhydramine

Mild to Moderate Symptoms:

Drowsiness, anticholinergic syndrome (mydriasis, flushing, fever, dry mouth, urinary retention, decreased bowel sounds), tachycardia, mild hypertension, nausea and vomiting are common after overdose. Agitation, confusion and hallucinations may develop after moderate poisoning.

Severe Symptoms:

Effects may include delirium, psychosis, seizures, coma, hypotension, QRS widening, and ventricular dysrhythmias (including torsades de pointes), but are generally only reported in adults after large ingestions. Rhabdomyolysis and renal failure may rarely develop in patients with prolonged agitation, coma or seizure. Death may occur as a result of respiratory failure or circulatory collapse.

In children, CNS excitation, including hallucinations and convulsions may appear; with larger doses, coma or cardiovascular collapse may follow.

Menthol

Excessive use of menthol may lead to abdominal pain, vomiting, flushed face, dizziness, weakness, tachycardia, stupor, and ataxia.

Treatment


Treatment of overdose should be symptomatic and supportive. The benefit of gastric decontamination is uncertain. Consider activated charcoal (charcoal dose: 50 g for adults; 1 g/kg for children) only if the patient presents within 1 hour of ingestion of a potentially toxic amount. Seizures may be controlled with Diazepam or Thiopental Sodium. The intravenous use of Physostigmine may be efficacious in antagonising severe anticholinergic symptoms.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties

Diphenhydramine possesses antitussive, antihistaminic and anticholinergic properties. Experiments have shown that the antitussive effect (resulting from an action on the brainstem) is discrete from its antihistaminic effect.

Product Name: Stricoff Expectorant (Diphenhydramine HCL, Ammonium Chloride, Sodium Citrate and Menthol BP)

	Module 1 (Administrative and Product information)
Product Name	STRICOFF Syrup (expectorant)

The duration of activity of diphenhydramine is between 4 and 8 hours.

Menthol has mild local anaesthetic and decongestant properties.

5.2 Pharmacokinetic properties

Absorption

Diphenhydramine and menthol are well absorbed from the gut following oral administration. Peak serum levels of diphenhydramine following a 50 mg oral dose are reached at between 2 and 2.5 hours.

Distribution

Diphenhydramine is widely distributed throughout the body, including the CNS. Following a 50 mg oral dose of diphenhydramine, the volume of distribution is in the range 3.3 - 6.8 l/kg, and it is some 78% bound to plasma proteins.

Metabolism and Elimination


Diphenhydramine undergoes extensive first pass metabolism. Two successive N-demethylations occur, with the resultant amine being oxidised to a carboxylic acid. Values for plasma clearance of a 50 mg oral dose of diphenhydramine lie in the range 600-1300 ml/min and the terminal elimination half-life lies in the range 3.4 - 9.3 hours. Little unchanged drug is excreted in the urine. Menthol is hydroxylated in the liver by microsomal enzymes to p-methane-3,8 diol. This is then conjugated with glucuronide and excreted both in urine and bile as the Glucuronide.

The Elderly

Pharmacokinetic studies indicate no major differences in distribution or elimination of Diphenhydramine compared to younger adults.

Renal Dysfunction

Product Name: Stricoff Expectorant (Diphenhydramine HCL, Ammonium Chloride, Sodium Citrate and Menthol BP)

	Module 1 (Administrative and Product information)
Product Name	STRICOFF Syrup (expectorant)

The results of a review on the use of Diphenhydramine in renal failure suggest that in moderate to severe renal failure, the dose interval should be extended by a period dependent on Glomerular filtration rate (GFR).

Hepatic Dysfunction

After intravenous administration of 0.8 mg/kg Diphenhydramine, a prolonged half-life was noted in patients with chronic liver disease which correlated with the severity of the disease. However, the mean plasma clearance and apparent volume of distribution were not significantly affected.

5.3 Preclinical safety data

Mutagenicity

The results of a range of tests suggest that neither diphenhydramine nor menthol have mutagenic potential.

Carcinogenicity

There is insufficient information to determine the carcinogenic potential of diphenhydramine or menthol, although such effects have not been associated with these drugs in animal studies.

Teratogenicity

The results of a number of studies suggest that the administration of either diphenhydramine or menthol does not produce any statistically significant teratogenic effects in rats, rabbits and mice.

Fertility

There is insufficient information to determine whether diphenhydramine has the potential to impair fertility, although a diminished fertility rate has been observed in mice in one study.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sr. No.	Name of Ingredients	Specification
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Product Name: Stricoff Expectorant (Diphenhydramine HCL, Ammonium Chloride, Sodium Citrate and Menthol BP)



Module 1
(Administrative and Product information)

Product Name	STRICOFF Syrup (expectorant)
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01.	Citric Acid	BP
02.	Sunset Yellow FCF	IHS
0.3	Raspberry	IHS
04.	Sodium Benzoate	BP
05.	Sodium Saccharine	BP
06.	Sucrose	IHS
07	Glycerin	BP
08	Methyl Hydroxy Benzoate	BP
09	Propyl Hydroxy Benzoate	BP

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

Unopened: 36 months

Opened: Discard the bottle 4 months after opening, even if there is syrup remaining.

6.4 Special precautions for storage:

Keep this medicine in a safe place where children cannot see or reach it.

Do not use Stricoff after the expiry date which is stated on the bottle and carton after EXP. The expiry date refers to the last day of that month.


Do not refrigerate or freeze. Store below 30°C.

Stricoff should be disposed of 6 months after opening the bottle.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6.5 Nature and contents of container

Product Name: Stricoff Expectorant (Diphenhydramine HCL, Ammonium Chloride, Sodium Citrate and Menthol BP)

	Module 1 (Administrative and Product information)
Product Name	STRICOFF Syrup (expectorant)

An Orange colored flavored syrup filled in 100ml amber pet bottles .Sealed with Aluminum cap and measuring cup packed in a mono carton

6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements. These measures will help to protect the environment.

7. APPLICANT

Name of the Applicant:

SAGAR VITACEUTICALS NIGERIA LIMITED

Business Address:

Plot 6, New Makun City, Along Lagos/Ibadan expressway,
K/m 53/55 Sagamu, Ogun State,
NIGERIA

Manufactured by:

SAGAR VITACEUTICALS NIGERIA LIMITED.

Plot 6, New Makun City, Along Lagos/Ibadan expressway,
K/m 53/55 Sagamu, Ogun State,
NIGERIA

8. WHO PREQUALIFICATION REFERENCE NUMBER-

Not applicable

9. DATE OF PREQUALIFICATION / RENEWAL OF PREQUALIFICATION-

Not applicable

10. DATE OF REVISION OF THE TEXT-

Not applicable

Product Name: Stricoff Expectorant (Diphenhydramine HCL, Ammonium Chloride, Sodium Citrate and Menthol BP)