1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

PRODUCT NAME: STRICOFF EXPECTORANT (FOR CHILDREN)

BRAND NAME: Chlorpheniramine Maleate + Ammonium chloride + Sodium citrate + Menthol Cough Syrup Expectorant

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

PRODUCT NAME: STRICOFF EXPECTORANT (FOR CHILDREN)

Each 5 ml contains

Chlorpheniramine Maleate	BP	1.0 mg
Ammonium Chloride	BP	45.0 mg
Sodium Citrate	BP	22.0 mg
Menthol crystal	BP	2.0 mg
Excipients……...……		q.s

For complete list of excipients refer section 6.1.

3. PHARMACEUTICAL FORM:

An Orange yellow colored flavored syrup

4. CLINICAL PARTICULARS

4.1 Therapeutic Indication:

Stricoff Expectorant (For children) is an expectorant for the symptomatic relief of coughs Cough and other symptoms that accompany coughs and colds, such as runny nose, catarrh, nasal congestion and blocked up sinuses in children aged 2-12.

Stricoff Expectorant (For children) (For Children) helps thin mucus, which aids in clearing congestion and making breathing easier. Whether it's due to a common cold, allergies, or another respiratory issue, Stricoff Expectorant (For children) can help your child find relief. Menthol contained in Stricoff Expectorant (For children) relieves congestion and makes the child's breathing a lot easier.

4.2 Posology and method of administration:

Children aged 2 to 12 years:

Children: 2-5years: 1 teaspoonful(5ml) every 8 hours

6-12years: 2 teaspoonful(10ml) every 8 hours

Not to be used for more than 5 days without the advice of a doctor. Parents and carers should seek medical attention if the child's condition deteriorates during treatment.

Children under 2 years**:** Stricoff Expectorant (For children) is contraindicated in children under the age of 2 years

Adults and children aged 12 years and over: Not Applicable

Method of administration

Stricoff Expectorant (For children) be administered orally

For oral use

Do not exceed the stated dose.

Keep out of the sight and reach of children.

4.3 Contraindications:

Hypersensitivity to the active substance, to the product, or to any of the excipients listed in section 6.1.

• Co-administration of terfenadine is contra-indicated in patients receiving fluconazole at multiple doses of 400 mg per day or higher based upon results of a multiple dose interaction study.

•Allergic reactions including skin rashes (which may be severe and include blistering and peeling), hives and itching

• Stomach pain or discomfort, diarrhoea, vomiting and nausea.

4.4 Special warning and precautions for use

Ask a doctor before use if your child suffers from chronic cough, if he/she has asthma or is suffering from an acute asthma attack.

Stop use and ask a healthcare professional if your child's cough lasts for more than 5 days, comes back, or is accompanied by a fever, rash or persistent headache.

Do not give with a cough suppressant.

Caution should be exercised in the presence of severe renal or severe hepatic impairment.

Not more than 4 doses should be given in any 24 hours.

Do not exceed the stated dose.

Do not take with any other cough and cold medicine.

This medicine contains 5.05g sorbitol in each 10 ml dose.
The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account. The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly. Patients with hereditary fructose intolerance (HFI) should not take/be given this medicinal product. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.
This medicinal product contains 33.04 mg sodium per 10 ml dose, equivalent to 1.65% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

4.5 Drug Interactions

None

4.6 Pregnancy & Lactation

Pregnancy

This product has been formulated specifically for children, and would therefore not normally be taken during pregnancy and lactation.

Breast-feeding

A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Stricoff Expectorant (For children) for children Coughs therapy, taking into account the benefit of breast - feeding for the child and the benefit of therapy for the woman.

Fertility

There is insufficient information available to determine whether Chlorpheniramine Maleate has the potential to impair fertility.

4.7 Effects on ability to drive and use machines:

No studies have been performed on the effects of Chlorpheniramine Maleate on the ability to drive or use machines.

4.8 Adverse Effects

Summary of safety profile

The safety of Chlorpheniramine meleate is based on available data from clinical trials and adverse drug reactions (ADRs) identified during post-marketing experience.

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)

ADRs are presented by frequency category based on 1) incidence in adequately designed clinical trials or epidemiology studies, if available, or 2) when incidence cannot be estimated, frequency category is listed as 'Not known'.

Adverse Drug Reactions Identified during Clinical Trials, Epidemiology studies and Post-Marketing Experience with Guaifenesin. Frequency Category estimated from Clinical Trials or Epidemiology Studies

Body System (SOC)	Incidence	Adverse Event Preferred Term
Immune system disorders	Not known	Hypersensitivity reactions (hypersensitivity, pruritus and urticaria) Rash
Gastrointestinal disorders	Not known	Abdominal pain upper Diarrhoea Nausea Vomiting

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.

4.9 Overdose

The effects of acute toxicity from Chlorpheniramine Maleate may include gastrointestinal discomfort, nausea and drowsiness. When taken in excess, guaifenesin may cause renal calculi.

Management

Treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Expectorant

ATC code: **R05CA03**

Mechanism of action

Chlorpheniramine is a selective inhibitor of histamine H1 receptors. By inhibiting the actions of histamine on smooth muscle, it inhibits vasodilatation and decreases histamine-mediated increases in capillary permeability Chlorpheniramine is indicated for symptomatic relief of allergic rhinitis.

Chlorpheniramine binds to the histamine H1 receptor. This blocks the action of endogenous histamine, which subsequently leads to temporary relief of the negative symptoms brought on by histamine.

5.2 Pharmacokinetic Properties

The pharmacokinetic properties of Chlorpheniramine are similar following administration by the oral route.

Absorption

After oral administration Chlorpheniramine is well absorbed, in the gastrointestinal tract.

Distribution

Not Available

Biotransformation

Chlorpheniramine is metabolised only to a minor extent. Primarily hepatic via Cytochrome P450 (CYP450) enzymes.

Pharmacokinetics in Renal/Hepatic Impairment

There have been no specific studies of Stricoff Expectorant (For children) for children in subjects with renal or hepatic impairment.

Caution is therefore recommended when administering this product to subjects with severe renal or hepatic impairment.

Pharmacokinetics in the Elderly

Not applicable.

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5.3 Preclinical Safety Data:

Effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the human exposure indicating little relevance to clinical use.

Carcinogenesis

There is insufficient information available to determine whether Chlorpheniramine has mutagenic potential.

Mutagenesis

There is insufficient information available to determine whether Chlorpheniramine has mutagenic potential.

Reproductive toxicity

There is insufficient information available to determine whether Chlorpheniramine has the potential to impair fertility.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

List of Excipients:
Citric acid

Sunset yellow

Raspberry

Sodium Benzoate

Sodium Saccharine

Sucrose

Glycerin

Sorbitol 70%

Sodium carboxyl Methyl Cellulose

Methyl paraben

Propyl Paraben

Ethanol.

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

24 Months.

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

6.4 Special precautions for storage:

Do not store above 30° C. Store in the original package.

6.5 Nature and contents of container

Stricoff Expectorant (For children) is an Orange yellow colored flavored syrup

Stricoff Expectorant (For children) is packed 100 ml Amber Pet bottles with ROPP cap Printed with "SAGAR". Logo in a printed outer 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

7. APPLICANT

Name of the Applicant:

SAGAR VITACEUTICALS NIGERIA LIMITED

Business Address:
Commercial district B block,
Plot 6, New Makun City,
Along Lagos/Ibadan Expressway,
Klm 53/55 Sagamu, Ogun state.
NIGERIA.

Manufactured by:

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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