NALOLYN® EXPECTORANT

(Chlorpheniramine Maleate BP 2mg/5ml; Ammonium Chloride BP 30mg/5ml; Ipecacuanha Tincture 0.1 ml; Sodium Citrate BP 50 mg/5ml; Menthol USP 1.0mg/5ml)

SUBMITTED BY: NALIS PHARMACEUTICALS LTD

R67-68 NEKEDE-NAZE
INDUSTRIAL CLUSTERS,
NEKEDE, OWERRI,
IMO STATE, NIGERIA.
TEL: +2348085784400, +2349026044603

EMAIL: info@nalispharma.com, www.nalispharma.com

SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC).

1 NAME OF THE MEDICINAL PRODUCT:

Nalolyn Expectorant

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:
Chlorpheniramine Maleate BP……**2 mg**
Ammonium Chloride BP……**30 mg**
Ipecacuanha Tincture……**0.1 ml**
Sodium Citrate BP……**50 mg**
Menthol USP……**1.0 mg**
Excipients……**qs**

3. PHARMACEUTICAL FORM

Oral Syrup

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Nalolyn® expectorant is used for the relief of cough and other accompanying symptoms of common cold and allergy in adult such as running nose; sneezing, watery/itchy eyes, nose, throat and nasal congestion.

4.2 Posology and method of administration

For oral administration.

Dosage:
Three times daily:
6 to 12 years - 1 teaspoonful
12years and above - 1 tablespoonful

4.3 Contraindications

Nalolyn is contraindicated if any of the following conditions is present.

- **Hypersensitivity to any of the components**
- **Impaired renal function with Oliguria**
- **Angle-closure glaucoma**
- **Severe myocardial damage**
- **Premature or full-term neonates**
- **Prostatic hypertrophy with obstructive uropathy**

4.4 Special warnings and precautions for use

When using this product marked drowsiness may occur, avoid alcoholic drinks. Alcohol, sedatives and tranquilizers may increase drowsiness, be careful when driving a motor vehicle or operating machinery. Because of their antimuscarinic actions the sedating antihistamines should be used with care in conditions such as angle-closure glaucoma, urinary retention and prostatic hyperplasia, or pyloroduodenal obstruction; antimuscarinic. Occasional reports of convulsions in patients taking antihistamines suggest a need for caution in patients with epilepsy.
Ammonium salts are contra-indicated in patients with hepatic or renal impairment.

4.5 Interaction with other medicinal products

Sedating antihistamines may enhance the sedative effects of CNS depressants including alcohol, barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives and antipsychotics. Sedative interactions apply to a lesser extent with the non-sedating antihistamines; they do not appear to potentiate the effects of alcohol, but it should be avoided in excess. Sedating antihistamines have an additive antimuscarinic action with other antimuscarinic drugs, such as atropine and some antidepressants (both tricyclics and MAOIs). Potentially hazardous ventricular arrhythmias have occurred when the non-sedating antihistamines asteminzole and terfenadine have been given with drugs liable to interfere with their hepatic metabolism, with other potentially arrhythmogenic drugs including those that prolong the QT interval, or with those likely to cause electrolyte imbalance. It has been suggested that some sedating antihistamines could mask the warming signs of damage caused by ototoxic drugs such as aminoglycoside antibacterials. Antihistamines may suppress the cutaneous histamine response to allergen extracts and should be stopped several days before skin testing.

4.6 Pregnancy and lactation

There is no clear risk of harm when used during pregnancy. However, care should be taken in administration during pregnancy.

4.7 Effects on ability to drive and use machines

This product may cause drowsiness and patients receiving it should not drive or operate machinery.

4.8 Undesirable effects

The following is a list of possible side effects that may occur from the use of nalolyn ® expectorant. These side effects are possible, but do not always occur. Some of the side effects may be rare but serious.
Consult your doctor if you observe any of the following side-effects, especially if they do not go away.
The most common adverse effect of the sedating antihistamines is CNS depression, with effects varying from slight drowsiness to deep sleep, and including lassitude, dizziness and in coordination.
Other adverse effects that are more common with the sedating antihistamines include headache, psychomotor impairment and antimuscarinic effects, such as dry mouth, thickened respiratory-tract secretions, blurred vision, urinary difficulty or retention, constipation and increased gastric reflux.
Occasional gastrointestinal adverse effects of antihistamines include nausea, vomiting, diarrhea, or epigastria pain.
Palpitations and arrhythmias have been reported occasionally with most antihistamines. Antihistamines sometimes cause rashes and hypersensitivity reactions including bronchospasm, angioedema and anaphylaxis and cross-sensitivity to related drugs may occur.

4.9 Overdose

General: Symptoms of Nalolyn® expectorant overdose may include:
Excessive sedation may occur.
Large doses of ipecacuanha have an irritant effect on the gastrointestinal tract and persistent bloody vomiting or bloody diarrhea may occur. There have also been several reports of ipecacuanha poisoning due to the unwitting substitution of ipecac fluidextract.
Hypersensitivity: Allergy, characterized by rhinitis, conjunctivitis and chest tightness, has occurred due to inhalation of ipecacuanha dust in packers of ipecacuanha tablets.
Treatment is symptomatic, including gastric lavage, supportive therapy, treatment of convulsions, sedation for restlessness and supportive treatment of hypokalaemia.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Chlorphenamine Maleate
Chlorphenamine Maleate is absorbed relatively slowly from the gastrointestinal tract and peak plasma concentrations occur about 2.5 to 6 hours after oral doses. Bioavailability is low, values of 25 to 50% having been reported. Chlorphenamine appears to undergo considerable first-pass metabolism. About 70% of chlorphenamine in the circulation is bound to plasma proteins.

Ipecacuanha has been used as an expectorant in productive cough in doses of up to about 1.4mg of total alkaloids.

Menthol
Menthol has mild local anaesthetic and decongestant properties. The mechanism by which menthol may act as an antitussive may be related to a strong stimulant effect on cold receptors in the larynx in the absence of cold air. It has been noted that substances which produce a hot sensation in the airway may stimulate the cough reflex, while menthol, which produces a cold sensation, has the opposite effect.

Sodium Citrate
Sodium citrate has no relevant pharmacodynamic activity other than that caused by its alkalinity (e.g. its gastric acid neutralising capacity).

Ammonium Chloride
Ammonium chloride produces mild irritation of the mucous lining of the stomach and this gastorvagal reflex increases the respiratory tract fluid, relieving dryness and soreness of the respiratory passage.

5.2 Pharmacokinetic properties

Chlorpheniramine Maleate
There is wide inter-individual variation in the pharmacokinetics of chlorphenamine; values ranging from 2 to 43 hours have been reported for the half-life. Chlorphenamine is widely distributed in the body and enters the CNS. Chlorphenamine Maleate is extensively metabolized. Metabolites include desmethyl and didesmethylchlorphenamine. Unchanged drug and metabolites are excreted mainly in the urine; excretion is dependent on urinary pH and flow rate. Only trace amounts have been found in the faeces. Duration of action of 4 to 6 hours has been reported; this is shorter than may be predicted from pharmacokinetic parameters.

Menthol

Absorption
Menthol is highly lipid soluble and, when taken orally, is rapidly absorbed from the small intestine.

Distribution
There is insufficient data on the distribution of menthol.

Metabolism
In humans, menthol is partially metabolized to menthol glucuronide by rapid conjugation. Animal studies in rats have demonstrated that menthol then undergoes extensive enterohepatic recirculation after being cleaved from the glucuronide conjugate and reabsorbed in the small intestine. The reabsorbed menthol is then subsequently metabolized by oxidative processes in the liver. There is support for this model in humans as well because menthol has been shown to be oxidized by CYP2A6 in human liver microsomes.

Elimination
A study in humans has demonstrated that approximately 50% of a menthol dose is excreted in the urine as menthol glucuronide. Other studies in rats have shown that menthol glucuronide is excreted in both the bile and the urine, but with the bile containing the majority of menthol glucuronide and with the urine also containing various oxidation products.

Sodium Citrate
Sodium citrate is systemically absorbed and renally eliminated, causing metabolic alkalosis and urine alkalisation in sufficient doses.

Ammonium Chloride
Ammonium chloride increases acidity by increasing the amount of hydrogen ion concentrations. Ammonium chloride can be used as an expectorant due to its irritative action on the bronchial mucosa. This effect causes the production of respiratory tract fluid which in order facilitates the effective cough.

Absorption
Completely absorbed within 3–6 h. In healthy persons, absorption of ammonium chloride given by mouth was practically complete. Only 1 to 3% of the dose was recovered in the feces.

Metabolism
Ammonium ion is converted to urea in the liver; chloride ion replaces bicarbonate.

5.3 Preclinical safety data

None.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium CMC, Propylene Glycol, Methyl Paraben, Propyl Paraben, Glycerine, Citric Acid, Sugar, Strawberry Flavour, Tartrazine Yellow, Sodium Benzoate, Treated Water

6.2 Incompatibilities
None stated except as in 'Interactions with other medicaments'.

6.3 Shelf life
36 months

6.4 Special precautions for storage
Do not store above 30°C.
Keep away from light

6.5 Nature and contents of container

100ml Pet bottles with ROPP caps and measuring device (dispensing cups).

6.6 Special precautions for disposal and other handling
None

7. APPLICANT/HOLDER OF CERTIFICATE OF PRODUCT REGISTRATION

Nalis Pharmaceuticals Ltd

R67-68 Nekede-Naze
Industrial Clusters,
Nekede, Owerri,
Imo State, Nigeria.
Tel: +2348085784400, +2349026044603

Email: info@nalispharma.com, www.nalispharma.com

8. DRUG PRODUCT MANUFACTURER

Nalis Pharmaceuticals Ltd

R67-68 Nekede-Naze
Industrial Clusters,
Nekede, Owerri,
Imo State, Nigeria.
Tel: +2348085784400, +2349026044603

Email: info@nalispharma.com, www.nalispharma.com

9. NAFDAC REGISTRATION NUMBER(S)

A11-0789