1. **Name of the medicinal product**

2. De-Shalom Cough Expectorant

3. **Qualitative and quantitative composition**

Each 5 ml contains: Chlorpheniramine Maleate 2mg
Liquorice liquid Extract 0.25ml
Ammonium Chloride 150mg
Menthol 2mg

4. **Pharmaceutical form**

A brown syrupy liquid

5. **Clinical particulars**

5.1 **Therapeutic indications**

De-Shalom Cough Expectorant is indicated as an antitussive, for the relief of persistent, dry, irritating cough.

5.2 **Posology and method of administration**

AGE	DOSAGE	TIME
3 Months-1 year	2.5ml	3 Days
1-5years	5ml	3 Days
6-12years	7.5ml	3 Days
Adult	15ml	3 Days

Do not exceed the stated dose.

Keep out of the reach and sight of children.

5.3 **Contraindication**s

De-Shalom Cough Expectorant is contraindicated in individuals with known hypersensitivity to the product or any of its components.

5.4 **Special warnings and precautions for use**

This product may cause drowsiness; if affected, individuals should not drive or operate machinery.

Chlorpheniramine should not be taken by individuals with narrow-angle glaucoma or symptomatic prostatic hypertrophy. Subjects with moderate to severe renal or hepatic dysfunction should exercise caution when using this product (see pharmacokinetics).

5.5 **Interaction with other medicinal products and other forms of interaction**

This product contains Chlorpheniramine and therefore may potentiate the effects of alcohol, and other CNS depressants.

As Chlorpheniramine possess some anticholinergic activity, the effects of anticholinergics (e.g. some psychotrophic drugs and atropine) may be potentiated by this product. This may result in tachycardia, mouth dryness, gastrointestinal disturbances (e.g. colic), urinary retention and headache.

5.6 **Pregnancy and lactation**

Chlorpheniramine has been in widespread use for many years without apparent ill consequence. Chlorpheniramine is known to cross the placenta and has also been detected in breast milk.

De-Shalom Cough Expectorant should therefore only be used when the potential benefit of treatment to the mother exceeds any possible hazards to the developing foetus or suckling infant.

5.7 **Effects on ability to drive and use machines**

This product may cause drowsiness; if affected, individuals should not drive or operate machinery.

This medicine can impair cognitive function and can affect a patient's ability to drive safely.

Undesirable effects

Chlorpheniramine may cause: drowsiness; dizziness; gastrointestinal disturbance; dry mouth, nose and throat; difficulty in urination or blurred vision.

5.8 **Overdose**

Symptoms and signs

The effects of acute toxicity of De-Shalom Cough Expectorant may include drowsiness, hyperpyrexia, anticholinergic effects, lethargy, nystagmus, ataxia, respiratory depression, nausea, vomiting, and hyperactivity.

Treatment

Treatment of overdose should be symptomatic and supportive. Measures to promote rapid gastric emptying (with syrup of ipecac-induced emesis or gastric lavage) and, in cases of acute poisoning, the use of activated charcoal, may be useful. The intravenous use of physostigmine may be efficacious in antagonising severe anticholinergic symptoms.

6. **Pharmacological properties**

6.1 **Pharmacodynamic properties**

Chlorpheniramine

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

Menthol has mild local anaesthetic and decongestant properties.

6.2 **Pharmacokinetic properties**

Absorption

Chlorpheniramine and menthol are well absorbed from the gut following oral administration. Peak serum levels of Chlorpheniramine following a 50 mg oral dose are reached at between 2 and 2.5 hrs after an oral dose. Due to individual differences in the metabolism of dextromethorphan [See Metabolism & Elimination], pharmacokinetic values are highly variable. After the administration of a 20 mg dose of dextromethorphan to healthy volunteers, the C_{max} varied from < 1 µg/l to 8 µg/l, occurring within 2.5 hrs of administration.

Distribution

Chlorpheniramine

Chlorpheniramine is widely distributed throughout the body, including the CNS. Following a 50 mg oral dose of Chlorpheniramine, 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

Chlorpheniramine

Chlorpheniramine 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 Chlorpheniramine 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

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.

Pharmacokinetics in Renal Impairment

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

Hepatic Impairment

After intravenous administration of 0.8 mg/kg Chlorpheniramine, 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.

Pharmacokinetics in the Elderly

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

6.3 **safety data**

The active ingredients of De-Shalom Cough Expectorant are well-known constituents of medicinal products and their safety profiles are well documented. The results of pre-clinical studies do not add anything of relevance for therapeutic purposes.

7. **Pharmaceutical particulars**

7.1 **List of excipients**

- Aspartame
- C.M.C
- Ethanol
- Glycerine
- Methyl Paraben
- Propyl Paraben

7.2 **Incompatibilities**

None known

7.3 **Shelf life**

24 Months

7.4 **Special precautions for storage**

Store below 30°C. Keep out of the Reach of Children

7.5 **Nature and contents of container**

100 ml amber bottle

7.6 **Special precautions for disposal and other handling**

No special requirements apart from NAFDAC guidelines

8. **Marketing authorisation holder**

DE-SHALOM PHARM LAB NIG. LTD.

Km 4, Iloko-Ijesa Road, Ilesa, Osun-State, Nigeria.

Phone:08034088756

Email: deshalompharm@gmail.com