SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC)

Of

DE-SHALOM COUGH EXPECTORANT

1. Name of the medicinal product:

De-Shalom Cough Expectorant

2. Qualitative and quantitative composition:

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

For Full list of the Excipients, See Section 6

3. Pharmaceutical form:

A brown syrupy liquid

4. Clinical particulars

4.1 **Therapeutic indications**

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

4.2 **Posology and method of administration:**

Oral route

AGE	DOSAGE	TIME
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.

4.3 **Contraindication**s

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

4.4 **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).

This product contains aspartame, a source of phenylalanine. Not suitable for individuals with phenylketonuria (PKU)

4.5 **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.

4.6 **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.

4.7 **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.

4.7.1**Undesirable effects**

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

4.8 **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 antagonizing severe anticholinergic symptoms.

5. Pharmacological properties

5.1 **Pharmacodynamic properties**

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.

5.2 **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 hours 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 hours of administration.

Distribution

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 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 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.

5.3 **Preclinical safety data**

Chlorpheniramine Maleate: Preclinical studies have demonstrated that Chlorpheniramine Maleate exhibits a favorable safety profile at therapeutic doses. Toxicological assessments indicate low acute toxicity, with no significant adverse effects observed in animal models at doses up to 10 times the clinical dose. Long-term studies have not shown any carcinogenic potential. Reproductive toxicity studies indicate no teratogenic effects when administered during gestation at recommended doses.

Liquorice Liquid Extract: The active component of liquorice, glycyrrhizin, has been shown to have anti-inflammatory and expectorant properties. However, high doses may lead to adverse effects such as hypertension and hypokalemia. Preclinical data suggest that when used at recommended doses, liquorice extract is generally safe, with no significant reproductive or developmental toxicity observed.

Ammonium Chloride: Ammonium Chloride is recognized as a safe expectorant in preclinical

studies. Toxicological evaluations indicate low toxicity, with adverse effects primarily occurring at significantly elevated doses. Studies have not demonstrated any carcinogenic effects, and reproductive toxicity studies show no adverse outcomes at therapeutic doses.

Menthol: Menthol is commonly used as a flavoring agent and for its mild local anesthetic properties. Preclinical studies suggest that menthol is well tolerated at recommended doses. Toxicological assessments indicate low systemic toxicity, with no significant adverse effects noted in reproductive or developmental toxicity studies.

6. Pharmaceutical particulars

List of Excipients

Aspartame

CarboxyMethylCellulose

Ethanol

Glycerine

Methyl Paraben

Propyl Paraben

6.1 Incompatibilities

None known

6.2 Shelf life

24 Months

6.3 Special precautions for storage

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

6.4 Nature and contents of container

100 ml/200ml amber bottle

6.5 Special precautions for disposal and other handling

No special requirements apart from NAFDAC guidelines

7. Marketing authorisation holder

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