SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

ALLERBAN® Syrup 2 mg / 5 ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains Chlorpheniramine Maleate BP 2.0 mg.
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Clear pink syrup.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of symptoms caused by allergic conditions such as hayfever, allergic rhinitis, perennial rhinitis, vasomotor rhinitis, urticaria and skin rashes, angioneurotic oedema, drug and serum reactions, food allergy, insect bites etc, which are responsive to antihistamines. Indicated for the symptomatic relief of itch associated with chickenpox

4.2 Posology and method of administration

Adults and children over 12years: - 10ml 4 to six times daily. Do not exceed 24mg (12 teaspoonfuls) daily. The elderly should not exceed 12mg (6 teaspoonfuls) daily.

Children:	6 months to 1 year	- 2.5ml twice daily (1mg twice daily)
	1 year to 5 years	- 2.5ml-5ml three times daily; maximum dose 6mg (3 teaspoonfuls)
	6 years to 12 years	- 10ml three to four times daily maximum dose 12mg (6 teaspoonfuls)

Duration of treatment depends on reason for and response to treatment. Consult your doctor or pharmacist for advice.

Method of administration
For oral administration.

4.3 Contraindications

Chlorpheniramine is contraindicated in patients who are hypersensitive to antihistamines or any of the excipients in the syrup listed in section 6.1.
Chlorpheniramine is contraindicated in patients who have had treatment with monoamine Oxidase Inhibitors (MAOIs) within the last 14 days as the anticholinergic properties of chlorpheniramine are intensified by MAOIs.

4.4 Special warnings and precautions for use

Chlorpheniramine has an anticholinergic effect and should be used with caution in patients with epilepsy, raised intra-ocular pressure including glaucoma, prostatic hypertrophy, severe hypertension, cardiovascular disease, bronchitis, bronchiectasis, asthma, hepatic impairment. Children and the elderly patients are more likely to experience the neurological anticholinergic effects and paradoxical excitation (e.g. increased energy, restlessness, nervousness).
The effects of alcohol may be increased and therefore should be avoided. Chlorpheniramine should not be used with other antihistamine containing products such as antihistamine containing cough and cold medicines.
Patients with rare hereditary problems of fructose intolerance should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction
Alcoholic drinks and certain other central nervous system depressants such as anxiolytics or hypnotics can potentiate the sedative effects of chlorpheniramine.
Phenytoin metabolism is inhibited by chlorpheniramine and this can cause phenytoin toxicity.
The anticholinergic effects of chlorpheniramine are intensified by the use of other anticholinergic drugs such as atropine, tricyclic antidepressants and MAOI's (see contraindications).

4.6 Pregnancy and lactation
Pregnancy
There are no adequate data for the use of chlorpheniramine in pregnant women, the potential risk in humans is unknown. Use during the third trimester may result in reactions in the newborn or premature neonates, therefore it should not to be used during pregnancy unless considered essential by a physician.
Lactation
Chlorpheniramine maleate and other antihistamines may inhibit lactation and may be secreted into the breast milk. Should not to be used during lactation unless considered essential by a physician.

4.7 Effects on ability to drive and use machines
As with all antihistamines, dizziness, drowsiness, blurred vision and psychomotor impairment may occur. Extreme caution should be advised when driving or operating machinery.

4.8 Undesirable effects
Adverse reactions which have been observed in clinical trials and which are considered to be common (occurring in ≥1% to <10% of subjects) or very common (occurring in ≥10% of subjects). The frequency of other adverse events identified during post-marketing use is unknown.
Blood and lymphatic system disorders:
Unknown: haemolytic anaemia, blood dyscrasias
Immune system disorders:
Unknown: allergic reaction, angioedema, anaphylactic reactions
Metabolism and nutrition disorders:
Unknown: anorexia
Psychiatric disorders:
Unknown: confusion, excitation, irritability, nightmares, depression
Nervous system disorders:
Very common: sedation, somnolence
Common: disturbance in attention, abnormal coordination, dizziness, headache
Eye disorders:
Common: blurred vision
Ear and labyrinth disorders:
Unknown: tinnitus
Cardiac disorders:
Unknown: palpitations, tachycardia, arrhythmias
Vascular disorders:
Unknown: hypotension
Respiratory, thoracic and mediastinal disorders:
Unknown: thickening of bronchial secretions
Gastrointestinal disorders:
Common: nausea, dry mouth
Unknown: vomiting, abdominal pain, diarrhoea, dyspepsia
Hepatobiliary disorders:
Unknown: hepatitis including jaundice
Skin and subcutaneous tissue disorders:
Unknown: exfoliative dermatitis, rash, urticaria, photosensitivity
Musculoskeletal and connective tissue disorders:
Unknown: muscular twitching, muscle weakness

Renal and urinary disorders:
Unknown: Urinary retention
General disorders and administration site conditions:
Common: fatigue
Unknown: chest tightness
*Children and the elderly are more susceptible to neurological anticholinergic effects and paradoxical excitation (e.g. increased energy, restlessness, nervousness).
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
Symptoms and signs
The estimated lethal dose of chlorpheniramine is 25 - 50mg/kg body weight. Symptoms and signs include sedation, paradoxical excitation of the CNS, toxic psychosis, convulsions, apnoea, anticholinergic effects, dystonic reactions and cardiovascular collapse and arrhythmias.
Treatment
Symptomatic and supportive measures giving special attention to cardiac, respiratory, renal and hepatic functions and fluid and electrolyte balance. If overdose occurs by the oral route treatment with activated charcoal should be considered, provided there are no contraindications for use and the overdose has been taken recently (within an hour of ingestion). Treat hypotension and arrhythmias vigorously. CNS convulsions may be treated with i.v. diazepam. Haemoperfusion may be used in severe cases.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Chlorpheniramine is a potent H_1 – blocking drug. Antihistamines diminish or abolish the actions of histamine in the body by competitive reversible blockade of the histamine H_1-receptor sites in tissues. Chlorpheniramine also has an anticholinergic activity.
Antihistamines act to prevent the release of histamine, prostaglandins and leukotrines and have been shown to prevent the migration of inflammatory mediators. The actions of chlorpheniramine include the inhibition of histamine on smooth muscle, capillary permeability and therefore reduction of oedema and wheal in hypersensitivity reactions such as allergy and anaphylaxis.

5.2 Pharmacokinetic properties
Chlorpheniramine maleate is absorbed relatively slowly from the gastrointestinal tract and peak plasma concentrations occur between 2.5 and 6 hours after oral administration. It is reported that only 25 to 50% of an oral dose is absorbed as it appears that chlorpheniramine undergoes considerable first pass metabolism. Metabolites include desmethyl- and didesmethylchlorpheniramine. Chlorpheniramine distributes widely in the body and penetrates into the CNS. In the circulation, about 70% of chlorpheniramine is bound to plasma proteins.
Excretion of unchanged drug and metabolites is mainly via the urine and is dependent on urinary pH and flow rate. The elimination half-life is widely variable and has been reported to range from 2 to 43 hours. However, the duration of action is only 4-6 hours which is shorter than might be predicted.
It is reported that in children, absorption is faster and more extensive, and there is a quicker clearance with a shorter half-life.

5.3 Preclinical safety data
None provided.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Sucrose BP
Glycerine
Ethanol 96%
Methylparaben
Propylparaben
Liquid Raspberry Flavour R101
Raspberry Red H1227
Sodium Hydroxide
Purified Water

6.2 Incompatibilities
None Stated

6.3 Shelf life
The shelf-life of this product is 24 months

6.4 Special precautions for storage
Store in a cool dry place, at or below 30°C.

6.5 Nature and contents of container
100ml white round HDPE bottle with LDPE concap
100ml medical round amber glass bottle with polypropylene screw cap.

6.6 Special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Name of Applicant
VARICHEM
PHARMACEUTICALS (PVT) LTD

8. Name of Manufacturer / Principal
Varichem Pharmaceuticals (Pvt) Ltd
194 Gleneagles Road,Willowvale
Harare, Zimbabwe
Tel: +263 (04) 620181-7,Fax: +263 (04) 660424
Email: marketing@varipharm.co.zw

9. Registration Number
TBA

10. Category for Distribution
Pharmacy Only

11. Last Date Of Revision Of This Package Insert
October 2020