APPROVED PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S2**

1. NAME OF MEDICINE

ALLERGEX® ELIXIR (2 mg/ 5 ml)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:

Chlorpheniramine maleate	2 mg
Preservatives:	
Methylparaben	0,12 % *m/v*
Propylparaben	0,016 % *m/v*
Contains sugar:	
Sucrose	2,55 g
Contains Ethanol	0,50 % v/v

For a full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Clear raspberry red syrup with fruity-clove odour. Free with visible matter.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Allergic and anaphylactic conditions such as hay fever, vasomotor rhinitis, urticaria, angioedema, drug reactions, contact dermatitis, atopic dermatitis, insect bites, pruritus and pruritus vulvae.

4.2 Posology and method of administration

Adults: 10 ml every 4 to 6 hours, up to a maximum of 60 mL in 24 hours.

Children: 2-5 years: ½ - 1 medicine measure 3 times daily.

6-12 years: 2 medicine measure 3 or 4 times daily.

Not recommended for children under 2 year of age.

Method of administration

Oral administration

4.3 Contraindications

Hypersensitivity to Chlorpheniramine or to any of the excipients of ALLERGEX

Elixir listed in section 6.1.

Epilepsy. Premature infants or neonates. Acute attacks of asthma.

Do not use in children under 2 year of age.

4.4 Special warnings and precautions for use

- Avoid the use of alcohol or CNS depressants
- Inform your physician if taking other medications (see section 4.5).
- Drowsiness may occur (see section 4.4).
- Geriatrics – Dizziness, confusion and hypotension is more likely to occur in geriatric patients taking antihistamines.

Due to the antimuscarinic properties, chlorpheniramine maleate should be used with care in conditions such as narrow angle glaucoma, urinary retention and prostatic hypertrophy.

Antihistamines may suppress positive skin test results and should be stopped several days before the test.

ALLERGEX ELIXIR contains sucrose

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

ALLERGEX ELIXIR contains methylparaben and propylparaben

May cause allergic reactions (possible delayed).

ALLERGEX ELIXIR contains ethanol

This medicine contains 19.7 mg of alcohol (ethanol) in each 5 ml, which is equivalent to

0,02496 ml/ 5ml (0,50 % v/v). The small amount of alcohol in this medicine will not have any noticeable side effects.

4.5 Interaction with other medicines and other forms of interactions

Monoamine oxidase inhibitors may enhance the antimuscarinic effects of antihistamines and antihistamines have an additive antimuscarinic action with other antimuscarinic medicines such as atropine and tricyclic antidepressants.

Sedating antihistamines may enhance the sedative effects of the CNS depressants including alcohol, barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives, and antipsychotics.

Antihistamines may suppress positive skin test results and should be stopped several days before the test.

4.6 Fertility, pregnancy and lactation

Fertility

No data available

Pregnancy

ALLERGEX ELIXIR should not be administered during the early months of pregnancy because of foetal abnormalities in animal studies.

Lactation

ALLERGEX ELIXIR is not recommended in nursing infants as it may cause unusual excitement or irritability.

4.7 Effects on ability to drive and use machines

The use of this medicine leads to drowsiness which is aggravated by the simultaneous intake of alcohol. Patients should be warned not to drive a motor vehicle, operate dangerous machinery or climb dangerous heights, as impaired decision making could lead to accidents.

4.8 Undesirable effects

System organ class	Frequency	Undesirable effects
Blood and lymphatic system disorders	Unknown	Haemolytic anaemia, blood dyscrasias
Immune system disorders	Unknown	Allergic reaction and cross sensitivity to related medicines may be produced
Metabolism and nutritional disorder	Unknown	Increased appetite
Nervous system disorders	Frequent	Sedation
	Unknown	Lassitude, incoordination, dizziness, headache
Eye disorders	Frequent	Blurred vision

Ear and labyrinth disorder	Unknown	Tinnitus
Cardiac disorders	Frequent	Tachycardia
	Unknown	Tremors, convulsions
Vascular disorders	Unknown	Hypotension
Respiratory, thoracic and mediastinal disorders	Unknown	Tightness of the chest
Gastrointestinal disorders	Frequent	Nausea
	Unknown	Vomiting, diarrhoea or constipation, anorexia and epigastric pain
Renal and urinary disorders	Unknown	Difficulty in micturition and dysuria
Musculoskeletal and connective tissue disorders	Unknown	Muscular weakness

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

May also report to Adcock Ingram Limited using the following email:

Adcock.AEReports@adcock.com

4.9 Overdose

Overdosage may be fatal especially in infants and children in whom the main symptoms are Central Nervous System (CNS) stimulation and antimuscarinic effects, including ataxia, excitement, hallucinations, muscle tremors, convulsions, dilated pupils, dry mouth, flushed face and hyperpyrexia. Deepening coma, cardiorespiratory collapse and death may occur.

In adults, the usual symptoms are of CNS depression with drowsiness, coma and convulsions. Hypotension may occur. Elderly patients are more susceptible to the CNS depressant and hypotensive effects even at therapeutic levels.

Treatment: Symptomatic and supportive.

5. PHARMACEUTICAL PROPERTIES

5.1 Pharmacodynamics properties

Category and Class: A 5.7.1 Medicines affecting autonomic functions

Pharmacotherapeutic Group: Antihistamines

ATC code: R06AB02

Mechanism of action

Chlorpheniramine maleate is an antihistamine that acts by competing with histamine for H1-receptor sites on effector cells. It thereby prevents but does not reverse responses mediated by histamine alone.

5.2 Pharmacokinetic properties

ALLERGEX ELIXIR is well absorbed from the gastrointestinal tract. Following oral administration, peak plasm concentrations are achieved in 2-3 hours and effects usually last 4-6 hours. It has a plasm half-life of about 4-8 hours. Widely distributed throughout the body, including the central nervous system, and is excreted as metabolites in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol (E 422)

Ethanol 96 %

Oil of aniseed 339601

Oil of coriander 420913

Oil of cloves 400606

Oil of cassia 100091

Oil of orange Valenica LR 12772

Colour red F1127 C.I 14720/42090

Sucrose/Sucrose solution

Methylparaben (E 218)

Propylparaben (E 216)

Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at or below 25 ºC, in a cool place. Protect from light.

KEEP OUT OF THE REACH OF CHILDREN.

6.5 Nature and contents of container

50 ml Amber glass bottle and 50 ml amber PVC bottle with 24 mm snap on pilfer proof.

100 ml Amber glass, 100 ml Amber PET bottle with 28 mm EXPE screw generic closure and 100 ml Amber PVC bottle with 24 mm white snap-on cap.

2,5 L amber HDPE container with white polypropylene screw.

200 ml PVC bottle medical round with 31 mm L.L.D.P.E closures snap on pilfer and 200 ml amber glass 28 mm MEDROPP GENERIC bottle with white polypropylene 28 mm cap with liner.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand,1685

Customer Care: 0860 ADCOCK / 232625

8. REGISTRATION NUMBER

C807 (Act 101/1965)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

September 1970

10. DATE OF REVISION OF TEXT

6 May 2026

Namibia: NS1 14/57.1/0479

Botswana: B9324115 S3