SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

ALLERGEX® TABLETS (4 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:	
Chlorpheniramine maleate	4 mg

Contains sugar: Lactose monohydrate 119,80 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets

Yellow, round, normal convex tablet, scored on one side and embossed with “A” on the reverse side.

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

Posology

Adults and children 12 years or older: One 4 mg tablet every 4 to 6 hours, up to a maximum of 24 mg in 24 hours.

Children 6 to 12 years: 2 mg (Half a tablet) every 4 to 6 hours, up to a maximum of 12 mg in 24 hours.

Paediatric Population

Children up to 6 years: Use is not recommended.

Method of administration

Oral administration

4.3 Contraindications

- Hypersensitivity to Chlorpheniramine or to any of the excipients of ALLERGEX TABLETS listed in section 6.1.
- Epilepsy
- Acute attacks of asthma
- Premature infants
- New-born babies

4.4 Special warnings and precautions for use

- ALLERGEX TABLETS may produce epileptiform seizures in patients with focal lesions of the cerebral cortex. Allergic reactions and cross-sensitivity to related drugs may be produced. Because of its antimuscarinic properties ALLERGEX TABLETS should be used with care in conditions such as narrow angle glaucoma, urinary retention and prostatic hypertrophy.
- Paradoxical CNS stimulation may occur, especially in children with insomnia, nervousness, tachycardia, tremors and convulsions.
- The use of this medicine may lead to drowsiness that is aggravated by the simultaneous intake of alcohol. Patients should be warned not to drive a motor vehicle or operate machinery, as impaired decision-making could lead to accidents.

- The sedative effect of central nervous system depressants including alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and tranquillisers may be enhanced.

  Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take ALLERGEX TABLETS.

  Contains Lactose which may have an effect on the glycaemic control of patients with diabetes mellitus.

  Patients receiving MAO inhibitor therapy should not take ALLERGEX TABLETS. The anticholinergic properties of Chlorpheniramine are intensified by monoamine oxidase inhibitors (MAOIs). (See section 4.5)

4.5 Interaction with other medicines and other forms of interaction

Interactions with other medicines

The sedative effect of central nervous system depressants including alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and tranquillisers may be enhanced.

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

Monoamine oxidase inhibitors will potentiate both the drowsiness effect and the anticholinergic effect if taken with ALLERGEX TABLETS. Concurrent use is not recommended. (See Section 4.4)

Interactions with laboratory tests

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

Interactions with food, drink and alcohol

The sedative effect of alcohol may be enhanced by ALLERGEX TABLETS.

4.6 Fertility, pregnancy and lactation

Fertility

Safety in fertility has not yet been established.

Pregnancy

Safety in pregnancy has not yet been established.

Breastfeeding

Safety in lactation has not yet been established.

4.7 Effects on ability to drive and use machines

This medicine may lead to drowsiness, dizziness, blurred vison and impaired concentration that may be aggravated by simultaneous intake of alcohol or other central nervous system depressants. Patients should be advised, particularly at the initiation of therapy, against taking charge of vehicles or machinery or performing potentially hazardous tasks where loss of concentration could lead to accidents.

4.8 Undesirable side effects

System Organ Class	***Frequency***	***Undesirable effect***
Nervous system disorders	Frequent	Sedation, lassitude, incoordination, dizziness, headache
Eye disorders	Frequent	Blurred vision
Gastrointestinal disorders	Frequent	Nausea
	Frequency unknown	Vomiting, diarrhoea or constipation, Increased appetite, epigastric pain and dry mouth
Immune system disorders	Frequency unknown	Allergic reaction and cross sensitivity to related medicines may be produced
Metabolism and nutritional disorders	Frequency unknown	Anorexia
Musculoskeletal and connective tissue disorders	Frequency unknown	Muscular weakness
Renal and urinary disorders	Frequency unknown	Difficulty in micturition and dysuria
Cardiac disorders	Frequency unknown	Tachycardia, tremors, and convulsions
Respiratory, thoracic and mediastinal disorders	Frequency unknown	Tightness of the chest
Vascular disorders	Frequency unknown	Hypotension

Ear and labyrinth disorders	Frequency unknown	Tinnitus

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important.

It allows continued monitoring of the benefit/risk balance of the medicine. Health care

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.

You may also report side effects 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 tremor, convulsions, dilated pupils, dry mouth, flushed face and hyperpyrexia. Deepening coma, cardiorespiratory collapse and death may occur.

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

Treatment: Symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

A 5.7.1 Medicines affecting autonomic functions – Antihistamines

Mechanism of action

ALLERGEX TABLET is an antihistamine.

ATC code: R06AB02

ALLERGEX TABLETS contain the antihistamine, chlorpheniramine maleate.

ALLERGEX TABLETS competes reversibly with histamine for H1 receptor sites on effector cells. They suppress those symptoms due to histamine release.

Antihistamines have anticholinergic properties and have a drying effect on the nasal mucosa.

5.2 Pharmacokinetic properties

Chlorpheniramine is well absorbed from the gastrointestinal tract, following oral administration. The effects develop within 30 minutes, are maximal within 1 to 2 hours and last 4 to 6 hours. The plasma half-life has been estimated to be 12 to 15 hours.

Chlorpheniramine is metabolised to the monodesmethyl and didesmethyl derivatives.

About 22% of an oral dose is excreted unchanged in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Colour yellow AIC
- Hydroxy propyl methyl cellulose E5
- Lactose monohydrate
- Magnesium stearate
- Pregelatinized Starch

6.2 Incompatibilities

Not applicable

6.3 Shelf life

Two years.

6.4 Special precautions for storage

Store at or below 30 ºC in airtight containers. Protect from light.

6.5 Nature and contents of container

10’s , 30’s and 100’s in blister or securitainers and 1000’s in securitainers or HDPE containers with screw caps and induction seals.

Not all packs and pack sizes are marketed.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION

Adcock Ingram Limited

1 New Road,

Erand Gardens,

Midrand,

1685

Customer Care: 0860 ADCOCK /232625

8. REGISTRATION NUMBERS:

C668 (Act 101 of 1965)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1976

10. DATE OF REVISION OF THE TEXT

08 March 2024

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Botswana: BOT1803276