

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS:

**S2**

### **ALLERGEX® TABLETS (4 mg)**

Chlorphenamine maleate

Contains sugar: Lactose monohydrate 119,80 mg

**Read all of this leaflet carefully because it contains important information for you.**

ALLERGEX TABLETS is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use ALLERGEX TABLETS carefully

to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share ALLERGEX TABLETS with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

### **What is in this leaflet**

1. What ALLERGEX TABLETS is and what it is used for.
2. What you need to know before you take ALLERGEX TABLETS.
3. How to take ALLERGEX TABLETS.
4. Possible side effects.
5. How to store ALLERGEX TABLETS.
6. Contents of the pack and other information.

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### 1. What ALLERGEX TABLETS is and what it is used for

ALLERGEX TABLETS is used for the treatment of allergic and anaphylactic conditions such as hay fever, vasomotor rhinitis (allergy in the nose when the small blood vessels in the nose dilate causing nasal congestion), urticaria (itchy rash that appears on the skin), angioedema (swelling under the skin), drug reactions, contact dermatitis (itchy rash caused by direct contact with a substance), atopic dermatitis (itchy, red and dry skin), insect bites, pruritus (itching) and pruritus vulvae (itching of the female genital area).

### 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ALLERGEX TABLETS

#### Do not take ALLERGEX TABLETS:

- If you are hypersensitive (allergic) to chlorphenamine maleate or any of the other ingredients of ALLERGEX TABLETS (listed in section 6).
- If you suffer from recurrent seizures (Epilepsy).
- If you suffer from acute attacks of asthma.
- ALLERGEX TABLETS should not be administered to Premature infants and newborn babies.

#### Warnings and precautions

#### Take special care with ALLERGEX TABLETS:

- The use of this medicine leads to drowsiness which is worsened 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.
- If you consume other central nervous system depressants e.g. sedatives and tranquilizers (sleeping tablets which result in a calming effect). This may lead to drowsiness and impaired concentration.
- If you suffer from prostatic hypertrophy (enlarged prostate).

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- If you suffer from increased pressure in the eye (glaucoma).
- If you suffer from urinary retention (unable to empty your bladder)
- ALLERGEX TABLETS may suppress positive skin test results and should be stopped several days before the test.

Do not take ALLERGEX TABLETS if you are on monoamine oxidase Inhibitor therapy (medicines used for depression). The anticholinergic (dry mouth, constipation) and drowsiness effects of ALLERGEX TABLETS may be intensified.

### **Other medicines and ALLERGEX TABLETS:**

Always tell your health care provide if you are taking any other medicine . (This includes all complementary or traditional medicines)

- Medicines that cause depression of the central nervous system (such as those used for insomnia or anxiety).
- Medicines to treat epilepsy (phenytoin)
- Medicines used to treat depression, Parkinson's disease, or other diseases
- Medicines that stop the action of the enzyme monoamine oxidase (antidepressants).

### **Pregnancy, breastfeeding and fertility:**

If you are pregnant or breastfeeding your baby, think you may be pregnant or planning to have a baby, please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

Safety of ALLERGEX TABLETS in pregnancy, fertility and breastfeeding has not been established.

**Driving and using machines**

ALLERGEX TABLETS may make you sleepy and reduce your level of concentration or alertness. Do not drive or operate any tools or machines as this medicine may interfere with your ability to do these safely.

Taking this medicine with alcohol and other medicines to treat depression may worsen these effects.

It is not always possible to predict to what extent ALLERGEX TABLETS may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ALLERGEX TABLETS affects them.

**Children and adolescents**

The use of ALLERGEX TABLETS in children under 6 years of age is not recommended.

**ALLERGEX TABLETS contains lactose**

Patients with the rare hereditary conditions of lactose or galactose intolerance should not take ALLERGEX TABLETS.

ALLERGEX TABLETS contains lactose which has an effect on the control of your blood sugar if you have diabetes mellitus.

**3. HOW TO TAKE ALLERGEX TABLETS**

Do not share this medicine with any other person.

Always take ALLERGEX TABLETS exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

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### **The usual dose is:**

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.

Children up to 6 years: Use is not recommended.

### **If you take more ALLERGEX TABLETS than you should:**

- In the event of overdosage, consult your doctor or pharmacist even if you do not notice the symptoms. If neither is available, contact the nearest hospital or poison control centre.
- Symptoms of overdosage include Central Nervous System (CNS) stimulation and antimuscarinic effects, including impaired balance (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. Low blood pressure (hypotension) may also occur. Elderly patients are more susceptible to the CNS depression and hypotensive effects even at therapeutic levels.

### **If you forget to take ALLERGEX TABLETS**

Do not take a double dose to make up for forgotten individual doses. If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose, do not take the dose that you missed.

#### 4. POSSIBLE SIDE EFFECTS

ALLERGEX TABLETS can have side effects.

Not all side effects reported for ALLERGEX TABLETS are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking ALLERGEX TABLETS, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop taking ALLERGEX TABLETS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, and mouth or throat, which may cause difficulty in swallowing or breathing.
- rash
- fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to ALLERGEX TABLETS. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department if you notice any of the following:

- chest tightness
- angina
- changes in the way your heart beats
- difficulty breathing
- signs of recurrent infections such as fever or sore throat,

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- less urine than is normal for you,
- yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

### **Frequent side effects**

- sedation (calming or relaxing state)
- incoordination
- dizziness
- Blurred vision
- Headache
- Nausea (feeling that one is about to vomit)

### **Frequency unknown**

- vomiting (to be sick)
- diarrhoea (frequent or loose watery stools)
- constipation
- Increased appetite
- Stomach pain
- dry mouth
- allergic reactions and cross sensitivity to related medicines
- anorexia (loss of appetite)
- muscle weakness
- painful urination
- tachycardia (increased heart rate)
- tremors (shaking)

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- convulsions (an episode of spasm(s) and reduced consciousness)
- tightness of the chest
- hypotension (low blood pressure)
- tinnitus (ringing in the ears)

### **Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ALLERGEX TABLETS .

You may also report side effects to Adcock Ingram Limited using the following email: [Adcock.AEReports@adcock.com](mailto:Adcock.AEReports@adcock.com) .

### **5. HOW TO STORE ALLERGEX TABLETS**

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

KEEP OUT OF REACH OF CHILDREN

Store in the original package/container

Keep the container tightly closed

Store in outer carton until required for use.

Do not store in a bathroom

Do not use after the expiry date stated on the label/carton/bottle.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)



## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

### What ALLERGEX TABLETS contains:

#### Each tablet contains:

The active substance is: Chlorpheniramine maleate 4mg

Other Ingredients are: colour yellow A1C, hydroxy propyl methyl cellulose E5, lactose monohydrate, magnesium stearate , pregelatinised starch .

### What ALLERGEX TABLETS looks like and contents of the pack:

ALLERGEX TABLETS are yellow, round, normal convex tablet, scored on one side and embossed with "A "on the reverse side.

It is packaged in 10's, 30's and 100's in blister or securitainers and 1 000's in securitainers or HDPE containers with screw caps and induction seals.

Not all packs and packs sizes are marketed.

### Holder of Certificate of Registration

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