

**SCHEDULING STATUS** S2

**ALLERGEX® ELIXIR (2mg/ 5 ml)**

Chlorphenamine 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

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

**ALLERGEX ELIXIR** is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use **ALLERGEX ELIXIR** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share **ALLERGEX ELIXIR** with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

**What is in this leaflet**

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

**1. WHAT ALLERGEX TABLETS IS AND WHAT IT IS USED FOR**

**ALLERGEX ELIXIR** is an antihistamine that is used to relieve or prevent allergic symptoms. redness, swelling, tenderness and irritation. **ALLERGEX ELIXIR** is used for the treatment of allergic and anaphylactic conditions such as hay fever, vasomotor rhinitis (allergy in

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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, atopic dermatitis, insect bites, pruritus and pruritus vulvae.

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

### Do not take ALLERGEX ELIXIR

- If you are hypersensitive (allergic) to chlorphenamine maleate or any of the other ingredients of ALLERGEX ELIXIR (listed in section 6).
- If your child is a premature infant or neonate
- If your child is under 2 years of age
- If you are experiencing acute attacks of asthma

### Warnings and precautions

#### Take special care with ALLERGEX ELIXIR

- If you have narrow angle glaucoma, urinary retention and prostatic hypertrophy.
- This medicine may cause some people to become drowsy or less alert than they are normally.
- Make sure you know how to react to **ALLERGEX ELIXIR** before you drive, use machines, or do anything else that could be dangerous if you are not alert.
- **ALLERGEX ELIXIR** may add to the effects of alcohol and other CNS depressants (medicines that slow down the nervous system, possibly causing drowsiness). Some examples of CNS depressants are sedatives, tranquilizers, or sleeping medicine; prescription pain medicine or narcotics; barbiturates, medicine for seizure, muscle relaxants or anaesthetics.

### Other medicines and ALLERGEX ELIXIR

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

- Monoamine oxidase inhibitors, antimuscarinic medicines such as atropine and antidepressants -  
\*Side-effects, such as dryness of the mouth, with antihistamines may be more likely to occur.
- Central nervous system (CNS) depressants (medicines that cause drowsiness) – Effects, such as drowsiness, of CNS depressants including alcohol, barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives and antipsychotics may be worsened.

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- Before you have any skin tests for allergies, tell your doctor in charge that you are taking this medicine. The results of the test may be affected by this medicine.

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

The safety of **ALLERGEX ELIXIR** has not been studied in pregnant women.

- Use is not recommended in nursing mothers as babies are susceptible to the side-effects of **ALLERGEX ELIXIR**, such as unusual excitement or irritability.
- If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before taking this medicine.

### **Driving and using machinery**

It is not always possible to predict to what extent **ALLERGEX ELIXIR** 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 ELIXIR** affects them.

### **ALLERGEX ELIXIR contains sucrose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

### **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.

### 3. HOW TO TAKE ALLERGEX ELIXIR

Do not share medicines prescribed for you by any other person. Always take ALLERGEX ELIXIR 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.

The usual dose is:

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 measures 3 to 4 times daily

#### **If you take more ALLERGEX ELIXIR than you should**

Overdosage may lead to death, especially in infants and children in whom the following symptoms occur: ataxia (incoordination), excitement, hallucinations, muscle tremors, convulsions (seizures), dryness of mouth, dilated pupils (widened pupils), flushed or red face and extremely high fever. In adults the usual symptoms are drowsiness, coma and convulsions (seizures). Low blood pressure may occur. Elderly patients are usually more sensitive to the effects of **ALLERGEX ELIXIR**.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

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

Do not take/ receive 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.

#### **If you stop taking ALLERGEX ELIXIR**

Take **ALLERGEX ELIXIR** for as long as your doctor recommends. Don't stop unless your doctor advises you to.

### 4. Possible side-effects

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**ALLERGEX ELIXIR** can have side effects. Not all side effects reported for **ALLERGEX ELIXIR** are included in this leaflet. Should your general health worsen or if you experience untoward effects while taking **ALLERGEX ELIXIR**, please consult your health care provider for advice.

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

- Allergic reactions
- Raised and itchy rash (hives)
- Swelling, sometimes of the face or mouth can cause difficulty breathing
- Fainting

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

Tell your doctor if you notice any of the following:

### Frequent side effects

- sedation (calming or relaxing state)
- blurred vision
- tachycardia (rapid heart rate that could be regular or irregular)
- nausea (feeling that one is about to vomit)

### Side effects with an unknown frequency

- serious blood disorders
- allergic reactions
- cross-sensitivity to medicines (allergic reactions to similar medicines)
- increased appetite
- incoordination (inability to use different parts of the body smoothly together)
- dizziness
- headache
- tinnitus (ringing in the ears)
- tremors (involuntary, rhythmic shaking or trembling of a body part)
- convulsions (loss of consciousness)

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- hypotension (low blood pressure)
- chest tightness
- vomiting (to be sick)
- diarrhoea (frequent or loose watery stools)
- constipation
- epigastric pain (feeling of discomfort or aching in the upper abdomen)
- difficulty in emptying urine from bladder
- dysuria (discomfort, pain or burning when urinating)
- muscle weakness

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

### 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 information on the safety of ALLERGEX ELIXIR.

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

[Adcock.AEReports@adcock.com](mailto:Adcock.AEReports@adcock.com)

### 5. HOW TO STORE ALLERGEX ELIXIR

Store at or below 25 °C in a cool place

Protect from light

KEEP OUT OF REACH OF CHILDREN

### 6. CONTENTS OF THE PACK AND OTHER INFORMATION

#### What ALLERGEX ELIXIR contain:

The active substance is chlorpheniramine maleate

The other ingredients are glycerol (E 422), ethanol 96 %, oil of aniseed 339601, oil of coriander 420913, oil of cloves 400606, oil of cassia 100091, oil of orange Valencia LR 12772, colour red F1127

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C.I 14720/42090, sucrose/sucrose solution, methylparaben (0,12 % *m/v*), propylparaben (0,016 % *m/v*), purified water.

### **What ALLERGEX ELIXIR looks like and contents of the pack**

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

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

100 ml Amber PVC bottle with 24 mm white snap-on cap

200 ml PVC bottle medical round with 31 mm L.L.D.P.E closures snap on pilfer

200 ml Amber glass 28 mm MEDROPP GENERIC bottle with white polypropylene 28 mm cap with liner

### **Holder of Certificate of Registration**

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

Customer Care: 0860 ADCOCK / 232625

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