# PHARMANIAGA CHLORPHENIRAMINE TABLET

Chlorpheniramine Maleate (4mg)

#### What is in this leaflet

- 1. What Pharmaniaga Chlorpheniramine is used for
- 2. How Pharmaniaga Chlorpheniramine works
- 3. Before you use Pharmaniaga Chlorpheniramine
- 4. How to use Pharmaniaga Chlorpheniramine
- 5. While you are using Pharmaniaga Chlorpheniramine
- 6. Side effects
- Storage and disposal of Pharmaniaga Chlorpheniramine
- 8. Product description
- 9. Manufacturer and Product Registration Holder
- 10. Date of revision

# What Pharmaniaga Chlorpheniramine is used for

Pharmaniaga Chlorpheniramine is used to relieve allergic conditions which are responsive to antihistamines such as hay fever, urticaria (a red, raised itchy rash) and food allergies.

# How Pharmaniaga Chlorpheniramine works

Chlorpheniramine maleate works by preventing the effects of a substance called histamine, which is produced in the body as a result of an allergic reaction. Histamine can cause itching, sneezing, runny nose and watery eyes. In some cases, histamine can close up the air passage of the lungs and make breathing difficult.

### Before you use Pharmaniaga Chlorpheniramine

-When you must not use it Do not take Pharmaniaga Chlorpheniramine:

- if you have ever had an allergic reaction to chlorpheniramine, any other antihistamines or any of the other ingredient (listed at the end of the leaflet).
- if you are taking or have taken in the last two weeks monoamine oxidase inhibitors (MAOIs) prescribed for depression.
- if you are taking other medicines containing antihistamines, including products for the relief of cough and colds.
- i) Not suitable to be used for children below 2 years of age.
  ii) Use carefully and follow the advice from doctor or pharmacist for children aged 2 to 6 years.

### -Before you start to use it

Tell your doctor and pharmacist if you are allergic to any medicines.

Tell your doctor if you have or have ever had epilepsy, glaucoma (increased pressure in the eyeball), enlarged prostate, asthma or other similar respiratory problems.

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or breastfeeding. This medicine may inhibit breastfeeding. Small amounts of the medicine are distributed into breast milk. Use of this medicine is not recommended in breastfeeding women because of the risk of adverse effects such as unusual excitement or irritability in infants.

#### Children

Antihistamines voung children particularly mav produce excitation. Use is not recommended in newborn or premature infants because this age group has an increased susceptibility to anticholinergic side effects, such as central system nervous (CNS) excitation and an increased tendency towards convulsions.

## Elderly (60 years or older)

It is more likely to cause dizziness, sedation, confusion and low blood pressure in elderly. Medication should be discontinued if anticholinergic effects such as dryness of mouth and urinary retention (especially in males) continue to occur or are severe.

#### - Taking other medicines

Talk to your doctor or pharmacist before taking Pharmaniaga Chlorpheniramine if you are taking any prescribed medicines or medicines for anxiety or to help you to sleep, depression, anticholinergic or ototoxic (cause damage to the hearing) medications.

# How to use Pharmaniaga Chlorpheniramine

-How much to use

Adults and children over 12 years:

Take 4 mg 3 or 4 times a day (every 6 to 8 hours).

Children 6 – 12 years:

Take 2 mg 3 or 4 times a day (every 6 to 8 hours) or as directed by physician.

Children 2-5 years: Take 1 mg every 4-6 hours (maximum 6 mg daily).

# PHARMANIAGA CHLORPHENIRAMINE **TABLET**

Chlorpheniramine Maleate (4mg)

#### -When to use it

The minimum dosage interval is 4 hours. Do not take more than the recommended dose.

#### -How long to use it

This medicine is usually used for a short period of time. If symptoms persist, consult your doctor

-If you forget to use it
Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take extra medicine to make up the missed dose.

#### -If you take too much (overdose) Contact your doctor or go to nearest hospital your immediately. Do not drive if you have taken too many.

Symptoms of overdosage with chlorpheniramine varies. small children, the symptoms include hallucinations. excitement, ataxia (loss of full control of bodily movements), flushed face and fever. In some serious cases, a deepening coma with cardiorespiratory collapse (failure of heart to beat and eventually stops functioning) and death may occur.

In adults, the symptoms may include fever, flushed face. excitement leading to convulsions and postictal depression (depression syndrome after seizure episode) preceded by drowsiness and coma.

# While you are using Pharmaniaga Chlorpheniramine

# -Things you must do

Talk to your pharmacist or doctor if your symptoms do not improve.

Your pharmacist or doctor will assess your condition and decide if you should continue to take the medicine.

### -Things you must not do

Do not take Pharmaniaga Chlorpheniramine to treat any other complications unless told by your pharmacist or doctor.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not take more than the recommended dose unless told by your pharmacist or doctor.

### -Things to be careful of

This product may cause dizziness or drowsiness. You should not drive or operate any machineries until you are sure you are not affected.

This product may act as brain stimulant in children and occasionally in adults.

Be careful when drinking alcohol while using this product. It can increase the effects of drinking.

#### **Side effects**

Pharmaniaga Chlorpheniramine may have some side effects, but not everybody gets them. Children and older people are more prone to the side effects.

# Possible side effects:

- Drowsiness
- Lassitude (lack of energy)
- Disturbances in concentrating. dizziness. headache
- Fatigue
- Dizziness
- Insomnia
- **Irritability**
- Tremor
- Nightmare, hallucinations and euphoria.
- Convulsions, vertigo (a sensation of whirling and loss of balance), tinnitus (buzzing in the ears), dilated pupils, labyrinthitis (inflammation of the inner
- Dry mouth, nose and throat.
- Low blood count and brusing.

Other side effects may include: allergic reactions, swelling of the skin, anaphylactic reactions, irritability, nightmares, blood pressure, thickening of phlegm, vomiting, diarrhoea, itchy skin, rash, sensitivity to the sun, difficulty passing water, chest tightness.

This is not a complete list of the side effects. If you experience any significant effects after consuming this medicine, please consult your doctor pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting website <u>portal.bpfk.gov.my</u> (Consumers → Reporting)

# PHARMANIAGA CHLORPHENIRAMINE TABLET

Chlorpheniramine Maleate (4mg)

# Storage and disposal of Pharmaniaga Chlorpheniramine

-Storage

Protect from light. Keep out of the reach and sight of children.

Do not use this medicine after the expiry date which is stated on the outer package. Do not store above 25°C.

### -Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist on how to dispose of medicines which are no longer required. These measures will help to protect the environment.

## **Product description**

-What it looks like

Yellow, round tablet 6 mm in diameter, beveled-edge with logo on one side and scoreline on the other.

### Ingredients:

-Active ingredient:
Each tablet contains
Chlorpheniramine maleate 4mg,

-Inactive ingredients:

Sunset yellow lake, Cornstarch, Quinoline yellow lake, Lactose monohydrate, Magnesium stearate.

### -MAL Number:

Pharmaniaga Chlorpheniramine Tablet 4 mg: MAL20000681AZ

#### Manufacturer:

Pharmaniaga Manufacturing Berhad (60016-D), 11A, Jalan P/1, Kawasan Perusahaan Bangi, 43650 Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia.

#### **Product Registration Holder:**

Pharmaniaga Manufacturing Berhad (60016-D), 11A, Jalan P/1, Kawasan Perusahaan Bangi, 43650 Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia.

### Date: of revision:

20/10/2015

#### **Serial Number:**

BPFK(R4/1)150715/00198