

## Patient information leaflet

# CHLORPHENAMINE 4MG TABLETS

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4
- You must talk to a doctor if you do not feel better or if you feel worse.

### In this leaflet:

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

## 1. What Chlorphenamine is and what it is used for

This medicine contains Chlorphenamine maleate which belongs to a group of medicines called antihistamines, which act to relieve the symptoms of allergies.

It can be used to relieve the symptoms of allergic reactions including hayfever, raised, red itchy skin (symptoms of urticaria, which is often known as hives or nettle rash), allergic reactions to foods or medicines, insect bites, runny nose and swelling of the face or throat due to fluid build up and itching caused by chickenpox.

## 2. What you need to know before you take Chlorphenamine

**Do NOT take Chlorphenamine if you:**

- are allergic to Chlorphenamine or any other antihistamines or any of the other ingredients of this medicine (listed in section 6). This medicine contains sunset yellow E110 and can cause allergic type reaction, including asthma (allergy tends to be more common in people who are sensitive to aspirin)
- have taken monoamine oxidase inhibitor (MAOI) antidepressant treatment in the past 14 days
- have known brain damage or epilepsy
- are comatose or in pre-comatose state

### Warnings and precautions

Talk to your doctor or pharmacist before taking these tablets if you have:

- raised pressure inside your eyes including glaucoma
- an enlarged prostate
- an overactive thyroid

- very high blood pressure
- liver or heart disease
- asthma, bronchitis or bronchiectasis (chronic inflammation of the airways that carry air to the lungs)

### Other medicines and Chlorphenamine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, especially:

- medicine containing **phenytoin** for epilepsy
- drugs to treat anxiety
- **sedatives** - all drugs that have a sedative effect are likely to increase the sedative effects of Chlorphenamine
- anticholinergic drugs (e.g. **atropine** and **hyoscine**) may increase the action of chlorphenamine
- **betahistine**, a drug used to treat vertigo and hearing disturbances. The effects may be reduced if taken with Chlorphenamine
- **lopinavir** (may increase plasma concentration of chlorphenamine)

### Chlorphenamine with food, drink and alcohol

Alcohol should be avoided, as chlorphenamine may increase the sedative effects of alcohol

### Pregnancy and breast feeding

You must consult your doctor before taking Chlorphenamine if you are pregnant, trying to become pregnant or breast feeding.

### Driving and using machines

This medicine may make you drowsy and may cause blurred vision and impaired movement. If affected in this way you should not drive or operate machinery.

### Chlorphenamine tablets contain lactose & sunset yellow (E110)

**Lactose** - These tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking these tablets.

**Sunset yellow (E110)** - This colouring agent may cause allergic reactions.

## 3. How to take Chlorphenamine

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The tablets should be swallowed with a glass of water.

### Dosage

**Adults:** 4mg (one tablet) every 4 to 6 hours (maximum 24mg daily).

**Children aged 6-12 years:** 2mg (Equivalent to half a tablet) every 4 to 6 hours (maximum 12mg daily).

**Not recommended for children under 6 years of age.**

**Elderly:** As for adults. Talk to your doctor or pharmacist before taking this medicine as you

may be more likely to get side effects including confusion and you may need to take a lower dose.

#### **If you take more tablets than you should**

If you or anyone else has taken too many tablets, contact your nearest hospital casualty department or doctor immediately. Take any remaining tablets with you to show the doctor.

#### **If you forget to take a dose**

Do not take a double dose to make up for forgotten individual doses.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### **4. Possible side effects**

Like all medicines, Chlorphenamine tablets can cause side effects, although not everybody gets them.

If you experience any of the following side effects, stop taking the medicine and tell your doctor **immediately**:

- difficulty breathing, raised and itchy skin, swelling of the face, lips, tongue or throat (severe allergic reaction)

#### **Other side effects**

\*Drowsiness is the most common side effect of Chlorphenamine. It may cause you to fall asleep, or sleepiness

Other common side effects include:

- feeling tired, blurred vision, dizziness
- Headache, inability to concentrate, lack of coordination
- feeling Sick (nausea), being sick, diarrhoea

Uncommon side effects include:

- sleeping difficulties, nervousness, very high fever, convulsions and shaking or tremors
- loss of appetite, heartburn, stomach pain, dry mouth
- difficulty passing urine

Rarer side effects include:

- ringing in the ears
- other allergic reactions including skin peeling, itchy red skin rash, sensitivity to light
- changes in heart rate, palpitations, low blood pressure (you may feel faint), tightness of the chest
- thickening of bronchial secretions (which may cause a cough or phlegm)
- hepatitis including yellowing of the skin or whites of the eyes caused by liver or blood problems
- reduction in red blood cells which can make the skin pale yellow and cause weakness or breathlessness and other blood dyscrasias
- muscle weakness, twitching
- depression, \*irritability and \*nightmares
- \*excitation may occur in children
- \*confusion in the elderly

\*Children and elderly adults are more susceptible to neurological anticholinergic effects and paradoxical excitation (e.g. increased energy, restlessness, nervousness).

#### **Reporting of side effects:**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Chlorphenamine**

#### **Keep all medicines out of the sight and reach of children**

- Do not take this medicine after the expiry date which is stated on the label after "EXP" The expiry date refers to the last day of that month.
- Do not store above 25°C.
- Keep the container tightly closed.
- Store in the original container.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

### **6. Contents of the pack and other information**

#### **What Chlorphenamine tablets contain**

- **The active substance** is Chlorphenamine. Each tablet contains 4mg of Chlorphenamine maleate.
- **The other ingredients** are lactose monohydrate, maize starch, magnesium stearate and the colours quinoline yellow (E104) and sunset yellow (E110).

*See end of section 2 for further information on lactose and sunset yellow (E110).*

#### **What Chlorphenamine tablets look like and contents of the pack:**

- Chlorphenamine 4mg tablets are yellow, circular normal convex tablets with a break line embossed C/4 on one face and PV on the reverse.
- Pack sizes for Chlorphenamine are 30, 100, 250, 500 & 1000 tablets in container packs. Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder and Manufacturer:**

Pharmvit Ltd, 177 Bilton Road, Perivale, Greenford, Middlesex UB6 7HQ.

**Telephone: 0208 997 5444**

**Fax: 0208 997 5433**

To request a copy of this leaflet in large print or audio format or additional copies, please contact the licence holder at the address (or telephone, fax) above.

PL 04556 / 0040



Reference: 00400815/02

This leaflet was last revised in August 2015