

## Package leaflet: Information for the patient

### Piriton® 4mg tablets (chlorphenamine maleate)

#### Please read right through this leaflet before you start using this medicine.

This medicine is available without prescription, but you still need to use Piriton tablets carefully to get the best results from them.

- Keep this leaflet, you may need to read it again.
- If you have any questions, or if there is anything you do not understand, ask your pharmacist.

#### In this leaflet:

1. What Piriton tablets do
2. Check before you take Piriton tablets
3. How to take Piriton tablets
4. Possible side effects
5. How to store Piriton tablets
6. Contents of the pack and other information

### 1. What Piriton tablets do

**Piriton tablets are used to treat the allergic symptoms of hayfever and other allergies.** The active ingredient is chlorphenamine maleate, an antihistamine which can help to relieve the symptoms of some allergies and itchy skin rashes. They can be used to treat the itchiness, redness, swelling, tenderness and irritation that can be caused by:

- hayfever and other allergies e.g. pet, house dust mite and mould spore allergies
- nettle rash and hives
- skin allergies
- reactions to food, food additives or medicines
- insect bites and stings

### 2. Check before you take Piriton tablets

#### Do not take Piriton tablets:

- if you have ever had an allergic reaction to chlorphenamine, any other antihistamines or any of the other ingredients (listed in Section 6).
- 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 coughs and colds.

#### Take special care with Piriton tablets

- Talk to your doctor before you start taking these tablets if you have **high blood pressure, epilepsy, an overactive thyroid, glaucoma, enlarged prostate, heart, kidney or liver disease, bronchitis, asthma** or other **similar respiratory problems**.
- This product may act as brain stimulant in children and occasionally in adults (see Section 4).
- Be careful when drinking alcohol** while using Piriton tablets. It can increase the effects of drinking.
- Piriton tablets contain lactose. If you have been told by your doctor that you have an **intolerance to some sugars**, contact your doctor before using Piriton tablets.

#### If you are taking other medicines

Talk to your doctor or pharmacist before taking these tablets if you are taking any prescribed medicines; particularly **phenytoin** (for epilepsy) or medicines for **anxiety** or to **help you sleep** or anticholinergic drugs (such as psychotropic medications and atropine).

#### Pregnancy and breast-feeding

**Talk to your doctor** before taking Piriton tablets if you are **pregnant or breast-feeding**.

#### Driving and operating machinery

This product may cause **dizziness, drowsiness** or **blurred vision**. **You should not drive or operate machinery** until you are sure you are not affected.

### 3. How to take Piriton tablets

#### Swallow the tablet with a drink of water

Adults and children aged 12 years and over:

Take 1 tablet every 4-6 hours (maximum 6 tablets in 24 hours).

Elderly: Take 1 tablet every 4-6 hours (maximum 3 tablets in 24 hours).

Children 6-12 years: Dose 0.1mg/kg. Take **half** a tablet every 4-6 hours (maximum 6 half tablets in 24 hours).

- The minimum dosage interval is 4 hours.**
- Do not take more than the recommended dose.**
- Do not give to children under 6 years.**
- If symptoms persist, consult your doctor.**

#### If you take too many tablets

Contact your doctor or casualty department. Do not drive if you have taken too many.

#### If you forget to take the tablet

Take your next dose at the usual time. Never take two doses together.

### 4. Possible side effects

Like all medicines, Piriton tablets can have side effects, but not everybody gets them. Children and older people are more prone to side effects.

#### Stop using this product and consult your doctor if you experience:

Allergic reaction which can be severe. Signs include:

- Raised and itchy rash (hives)
- Swelling, sometimes of the face or mouth causing difficulty in breathing
- Collapse

These reactions are rare.

#### Possible side effects:

Very Common (affects more than 1 in 10 people)

- drowsiness and sedation

Common (affects between 1 in 10 and 1 in 100 people)

- disturbance in concentrating, un-coordination, dizziness, headache
- blurred vision
- feeling or being sick, dry mouth
- fatigue

Very Rare (affects less than 1 in 10,000 people)

- low blood count, bruising
- hepatitis (severe stomach pain, nausea or vomiting and loss of appetite and/or jaundice (yellow colouring of the skin or the whites of the eyes))

**Other side effects may include:** allergic reactions, swelling of the skin, loss of appetite, confusion, excitation, irritability, nightmares, low blood pressure, thickening of phlegm, vomiting, abdominal pain, diarrhoea, indigestion or upset stomach, itchy skin, rash, sensitivity to the sun, muscle twitching, muscle weakness, difficulty passing water, chest tightness.

#### 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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine. HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2. Tel: +353 1 6764971, Fax: +353 1 6762517.

Website: [www.hpra.ie](http://www.hpra.ie) e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

## 5. How to store Piriton tablets

### **Keep this medicine out of the sight and reach of children.**

Do not use this medicine after the expiry date which is stated on the outer package and blisters after EXP. The expiry date refers to the last day of that month.

Store below 30°C.

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 protect the environment.

## 6. Contents of the pack and other information

### **What Piriton Tablets contain**

**Active ingredient:** Each tablet contains 4mg of chlorphenamine maleate.

**Other ingredients:** Lactose, maize starch, yellow iron oxide (E172), magnesium stearate and water.

### **What Piriton Tablets look like and contents of the pack**

Piriton are yellow, circular, biconvex tablets with a breakline on both sides. They are engraved with a 'P' to one side of the breakline, on one face.

The tablet can be divided into equal halves

Piriton Tablets are supplied in blister packs of 30 tablets.

### **Manufacturers**

Manufactured by: Haupt Pharma Wulfing GmbH, Bethelner Landstrasse 18, D-31028 Gronau/Leine, Germany  
or  
FAMAR Italia S.p.A. Via Zambelletti, 25 20021 — Baranzate (MILANO) — Italy

Procured from within the EU and repackaged by:  
Doncaster Pharmaceuticals Group Ltd., Kirk Sandall,  
Doncaster, DN3 1QR, UK.

PPA holder: Imbat Ltd., Unit L2, North Ring Business Park,  
Santry, Dublin 9.

Distributed by: Eurodrug Ltd., Unit L2, North Ring Business  
Park, Santry, Dublin 9.

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Blind or partially sighted?  
Is this leaflet hard to see or  
read?

Call +44 (0) 1302 365000  
(Regulatory)

Please be ready to give the  
following information:

Product name: Piriton 4mg  
Tablets

Reference PPA1151/266/001