Package leaflet: Information for user

Piriton Allergy 4mg Tablets

Chlorphenamine Maleate

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

This medicine is available without prescription, but you still need to use Piriton tablets carefully to get the best results from them. Always use this medicine exactly as described in this leaflet or as your pharmacist 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. 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.
- 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 and what they are used for
- 2. What you need to know 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 and what they are used for

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
- chickenpox

2. What you need to know 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, chronic lung disease or other similar respiratory problems.
- This product may act as brain stimulant in children and occasionally in adults (see Section 4).
- Do not drink alcohol whilst using this product.
- If you have been told by your doctor that you have an **intolerance to some sugars**, contact your doctor before using Piriton tablets.
- Avoid use in elderly people with confusion.

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 breastfeeding

Talk to your doctor before taking Piriton tablets if you are pregnant or breastfeeding.

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.
- Do not use for more than 2 weeks without consulting a 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

Difficulty urinating.

These reactions are rare.

Possible side effects:

Very Common (may affect more than 1 in 10 people)

drowsiness and sedation

Common (may affect up to 1 in 10 people)

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

Very Rare (may affect up to 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store tablets

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date (EXP) on the outer package and blisters. The expiry date refers to the last day of that month. Store below 30°C. Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Contents of the pack and other information

Active ingredient Each tablet contains Chlorphenamine Maleate 4 mg.

Other ingredients Lactose monohydrate, maize starch, pre-gelatinised maize starch, magnesium stearate and the colouring agent yellow iron oxide (E172).

Piriton tablets 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 Piriton tablets are supplied in packs of 30, 45, 60 or 500 tablets. Not all pack sizes may be marketed.

The product authorisation holder is

Haleon Ireland Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.

The manufacturer is: Haleon Alcala, S.A., Ctra. de Ajalvir, km. 2,500 - 28806 Alcalá de Henares, Madrid - Spain, or FAMAR Italia S.p.A. Via Zambeletti, 25 20021 - Baranzate (MILANO) - Italy'.

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