

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

HISTIN TABLET

Chlorpheniramine Maleate BP 4mg (maximum 12mg daily).

Read this leaflet carefully before you start taking this medicine. · Keep this leaflet. You may need to read it again before, during or after use of this

- medicine. . If you have any further questions, ask your health care provider. • This medicine has been prescribed for you only. Do not pass it on to others. It may harm
- them, even if their symptoms are the same as yours. If any of the side effects become serious, or if you notice any side effects not listed in this eaflet, please inform your health care provider.

- In this leaflet: 1. What Histin Tablet is and what it is used for
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1. WHAT HISTIN TABLET IS AND WHAT IT IS USED FOR

This medicine contains Chlorpheniramine 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 hay fever, 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 USE HISTIN TABLET.

Do not use HISTIN TABLET if you:

- Are allergic to Chlorpheniramine 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 lunas)

Other medicines and Chlorpheniramine

- 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 Chlorpheniramine
- · Anticholinergic drugs (e.g. Atropine and hyoscine) may increase the action of
- Chlorpheniramine Betahistine, a drug used to treat vertigo and hearing disturbances. The effects may be
- reduced if taken with Chlorpheniramine · Lopinavir (may increase plasma concentration of Chlorpheniramine)

Chlorpheniramine with food, drink and alcohol

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

Pregnancy and breast feeding

You must consult your doctor before taking Chlorpheniramine 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.

3. HOW TO USE HISTIN TABLET

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

Not recommended for children under 6 years of age.

Elderly: The elderly is more likely to experience neurological anticholinergic effects. Consideration should be given to using a lower daily dose (e.g., a maximum of 12 mg in any 24 hours).

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 nharmacist

4. POSSIBLE SIDE EFFECTS

Like all medicines, Chlorpheniramine 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 Chlorpheniramine. 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 co- ordination 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)

5. HOW TO STORE HISTIN TABLET

- 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 30°C.
 Keep the container tightly closed.
- · Store in the original container.

6. FURTHER INFORMATION.

Each tablet of Histin contains 4mg of Chlorpheniramine maleate

What HISTIN looks like and contents of the pack 10 x 10 tablet packed in an ALU/PVC blister placed in an inner carton with insert. 1 x 1000 in a jar with insert

Supplier and Manufacturer Fidson Healthcare Plc,

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