CURRENT

PATIENT INFORMATION LEAFLET

Chlorphenamine Maleate

PLEASE READ THIS LEAFLET CAREFULLY BEFORE YOU START TAKING THIS MEDICINE

What is in your medicine?
The active ingredient in this medicine is Chlorphenamine Maleate. This is the new name for Chlorpheaniramine Maleate. The ingredient itself has not changed.

This medicine contains Chlorphenamine Maleate, available in tablets of 4 mg and the excipients lactose, maize starch, povidone, E104, magnesium stearate and sodium starch glycollate. Chlorphenamine Maleate is available in containers of 100, 500 and 1,000 tablets, and in blister packs of 10 and 30 tablets.

How does Chlorphenamine work?
Chlorphenamine is a phenothiazine derivative with antihistamine action and is useful in controlling allergic conditions.

The Manufacturer is:
DDSA Manufacturing Ltd., Chatfield Road, off York Road, London SW11 3SE.

The Product Licence Holder is:
Chelonia Healthcare Limited, 11 Boumpoulinas, 3rd Floor, 1060 Nicosia, Cyprus

What are Chlorphenamine tablets for?
Chlorphenamine is used to control the symptoms of allergic conditions which include urticaria, hayfever, food allergy, drug and serum reactions, insect bites, nasal inflammation with running nose and fluid build-up in the tissues below the skin.

Check before you take Chlorphenamine Maleate tablets
Before taking this medicine, tell your doctor if you have ever had any unusual or allergic reactions to Chlorphenamine or any other ingredients of Chlorphenamine Maleate tablets, or other antihistamine medicines, or medicines of the phenothiazine group.
Also tell your doctor or pharmacist if you are allergic to any other substances such as foods, preservatives or dyes.
You should not take this medicine if you have taken monoamine oxidase inhibitor medicines during the previous 14 days.
It is important that you tell your doctor if you are pregnant, or likely to become pregnant, or if you are breast feeding.
The presence of other medical problems may affect the use of this medicine. Make sure, therefore, to tell your doctor or pharmacist if you have any other medical problems, especially: epilepsy, glaucoma, enlargement of the prostate gland, difficulty passing urine, blockage between the stomach and intestines, liver disease or any bronchial conditions, thyrotoxicosis, blood pressure, heart disease or bronchial asthma. The effects of alcohol may be increased by this medicine.

Use in pregnancy
Safety for use during pregnancy has not been established, and Chlorphenamine should only be used when it is clearly needed, and when the potential benefit outweighs the potential unknown risks to the unborn baby when taken during the last 3 months of pregnancy. Chlorphenamine Maleate may result in reactions in the newborn or premature babies. Small amounts of Chlorphenamine Maleate are excreted in breast milk. Use by nursing mothers is not recommended because of the risk of adverse effects in the infant. Chlorphenamine may stop lactation.

Can you take Chlorphenamine Maleate with other medicines?
You can take these tablets with other medicines, but there are some medicines that can interfere with Chlorphenamine. It is very important to tell your doctor or pharmacist about all the medicines that you are taking, whether or not any medicines were prescribed by your doctor or bought without a prescription from the pharmacy or elsewhere. This includes monoamine oxidase inhibitors which should **not** be taken within 14 days of using Chlorphenamine Maleate, medicines that have been prescribed for sleep such as nitrazepam; for anxiety such as chlordiazepoxide and carbamazepine or phenytoin.

When and how to take Chlorphenamine Maleate tablets
The tablets should be taken by mouth.
Adults: 4 mg (1 tablet) three or four times daily.
Children: Below 6 years: Not recommended.
6-12 years: 2 mg (½ tablet) three or four times daily.
Elderly: The dosage as in adults but the elderly are prone to confusional and other nervous system effects.

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What to do if too many tablets are taken at the same time

If you accidentally take more tablets than recommended, contact your doctor or hospital casualty department at once.

What to do if you miss a dose

If you miss a dose, skip the missed dose and go back to your regular dosage schedule. Do not double the dose. If you feel that this medicine is not working as well after you have taken it for a short time (1-2 weeks) do not increase the dose, instead check with your doctor.

What side effects can Chlorphenamine Maleate tablets have?

Because Chlorphenamine causes drowsiness, dizziness, blurred vision and difficulty in co-ordination, which can hamper the ability to drive and to use machines, you should not drive or operate machinery while taking Chlorphenamine Maleate tablets. The tablets produce sedation varying from slight drowsiness to deep sleep. Other side-effects include: Inability to concentrate, a feeling of weakness (lassitude), blurred vision, stomach upset such as nausea, vomiting, diarrhoea, heart burn, abdominal pain, dryness of the mouth, headache, dizziness, difficulty in passing water, difficulty in producing tears, constipation, twitching, tremor, changes in heartbeat, low blood pressure, loss of appetite, hepatitis (including jaundice), different forms of anaemia.

Allergic reactions are rare but include scaling and flaking of the skin, nettle rash (urticaria), sensitivity to sunlight, spasm of the windpipe, fluid under the skin and around certain organs, and anaphylaxis which may cause tightness of the chest resulting in difficulty breathing, with swelling of the face, neck and skin around the eyes. Muscular weakness, incoordination, convulsions, buzzing in the ears, irritability, confusion, depression and nightmares may also occur on rare occasions. Children may become unusually excitable and the elderly are prone to confusion.

Storing your medicine

You must keep the medicine in a safe place where children cannot get it. Your medicine could harm them.

Keep your medicine in a dry place below 25°C and protect it from light.

Keep the tablets in the container in which they were given to you.

On the label you will find the words "Expiry Date" followed by numbers indicating the day, month and year. This is the date when the medicine is no longer fit for use. Do not use the medicine after this date.

A reminder

This leaflet does not contain the complete information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist who have access to additional information.

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This leaflet was revised in November 2004