

Package leaflet: Information for the patient

Chlorphenamine 10mg/ml Solution for Injection (Chlorphenamine Maleate)

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Chlorphenamine is and what it is used for
2. What you need to know before Chlorphenamine is given
3. How Chlorphenamine is given
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

Chlorphenamine 10mg/ml Solution for Injection contains the active ingredient chlorphenamine maleate which is an antihistamine. These medicines inhibit the release of histamine into the body that occurs during an allergic reaction. This product relieves some of the main symptoms of a severe allergic reaction.

This injection is usually given to you by your doctor or someone else trained to give it to you.

2. What you need to know before Chlorphenamine is given

You MUST NOT be given Chlorphenamine if you:

- are **allergic** to chlorphenamine maleate or any of the other ingredients in the product (*see section 6: Contents of the pack and other information*)
- are in a **pre-coma** state
- have had monoamine oxidase inhibitor (MAOI) **antidepressive treatment** within the past 14 days.

Warnings and precautions

Talk to your doctor or nurse before you are given this medicine if you:

- are being treated for an **overactive thyroid** or **enlarged prostate gland**
- have **epilepsy, glaucoma** or raised pressure within the eye, very **high blood pressure, heart disease, liver disease, asthma** or other chest diseases.

Children and the elderly are more likely to experience certain side effects (see section 4: Possible side effects).

Other medicines and Chlorphenamine

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

The following **affect** the way Chlorphenamine works:

- MAOIs – these **must not** be given with Chlorphenamine.

Chlorphenamine may **increase** the effects of the following:

- drugs that treat anxiety or help you to sleep
- psychotropic drugs (that change perception or behaviour)
- atropine (used as eye drops to dilate the pupils, or given as an injection to treat low heart rate in emergencies)
- phenytoin (used to treat epilepsy).

Chlorphenamine with alcohol

Do not consume alcohol whilst being treated with Chlorphenamine. It may cause the effects of the medicine to be increased, making you more drowsy. It may also cause the effect of the alcohol to be increased.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you are given this medicine.

Chlorphenamine **must not** be given during pregnancy or breast-feeding unless your doctor believes it is essential.

Driving and using machines

Chlorphenamine may cause drowsiness and make you sleepy. **Do not** drive or operate machinery until you know how this product affects you.

Chlorphenamine contains sodium

This medicinal product contains less than 1mmol sodium (23mg) per 1ml (essentially “sodium-free”).

3. How Chlorphenamine is given

This injection is usually given to you by your doctor or someone else trained to give it to you. You will be given the injection beneath your skin, into a muscle, or directly into a vein.

Adults: the usual dose is 10mg - 20mg (1 or 2 vials), up to a maximum of 40mg (4 vials) in 24 hours.

Children: the dose will be calculated by the doctor, according to the child's age or body weight:

Age	Dose		
1 month to 1 year			0.25mg /kg
1 to 5 years	2.5mg to 5mg	OR	0.20mg /kg
6 to 12 years	5mg to 10mg	OR	0.20mg /kg
12 to 18 years	10mg to 20mg	OR	0.20mg /kg

The doctor may dilute Chlorphenamine with sodium chloride 0.9% to make it easier to measure and inject the small amounts required for children.

When administered into a vein, the injection should be given slowly over a period of one minute to avoid a fall in blood pressure (hypotension) or central nervous system stimulation (giddiness).

If you are given too much Chlorphenamine

This product will be given to you under medical supervision. It is therefore unlikely that you will be given too much. However, if you feel unwell, you should tell your doctor immediately.

Symptoms of overdose include sedation, seizures, stopping of breathing (apnoea), convulsions, abnormal and sustained muscle contractions (dystonic reactions), mental disturbances and heart failure (cardiovascular collapse).

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The most common side effect is sedation, which can range from slight drowsiness to deep sleep.

The following side effects have been reported:

- allergic reactions (skin reactions including redness and scaling of the skin, itching of raised bumps on the skin, sensitivity to light)
- a stinging or burning feeling at the site of injection, high fever
- nausea, vomiting, or diarrhoea
- feeling dizzy, weak, tired, unable to concentrate
- rapid or irregular heart beat, chest tightness, fall in blood pressure
- dryness of the mouth, thickening of the phlegm in the airways (this may make it more difficult to cough up phlegm), headache, loss of appetite, indigestion, abdominal pain, liver problems including jaundice (this can cause yellowing of the skin and whites of the eyes), difficulty passing urine
- muscular twitching, weakness and incoordination, tremor, seizures, ringing in the ears, blurred vision, irritability, depression, nightmares, inability to sleep, nervousness
- blood abnormalities.

Children and the elderly are more likely to experience the side effects which relate to the nervous system (these may affect the mind, nerves, muscles, and the senses). Elderly people may become confused and children may become agitated or excitable.

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet.

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 IMB Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.imb.ie; e-mail: imbpharmacovigilance@imb.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Chlorphenamine

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

Store below 25°C. Keep the ampoules in the outer carton in order to protect from light.

Do not use this medicine after the expiry date which is stated on the carton after 'EXP'. The expiry date refers to the last day of that month.

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 Chlorphenamine contains

The **active substance** is: chlorphenamine maleate (also known as chlorpheniramine maleate). The **other ingredients** are: sodium chloride and water (*see end of section 2*).

What Chlorphenamine looks like and contents of the pack

Chlorphenamine is supplied in glass vials. Each 1ml vial contains 10mg chlorphenamine maleate (clear, colourless, sterile solution). Contents: 5 glass vials per box.

Marketing Authorisation Holder

Archimedes Pharma UK Ltd.
250 South Oak Way, Green Park
Reading, Berkshire RG2 6UG
UK
(send all enquiries to this address).

Manufacturer


Haupt Pharma Wülfing GmbH
Bethelner Landstrasse 18
31028 Gronau
Germany

PA 0757/003/001

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YELLOWDOT DESIGN Artwork Technical Specifications

DESCRIPTION: Chlorphenamine 10mg/ml PIL - IRE
INTERNAL CODE No.:
CUTTERGUIDE REF.:
VERSION No.: 6.7
DATE: 07/02/2014
YELLOWDOT REF: 12073
REASON FOR CHANGE: Amend text under "Reporting of
side effects" (BS 07/02/2014)

SIZE: 250mm high x 144mm wide
COLOURS: Black 
TEXT SIZE: 8.5pt
LEADING: 9pt (3.175mm)
FONTS: ITC New Baskerville, Symbol