

Chlorphenamine 10mg/ml Solution for Injection

(Chlorphenamine Maleate)

Read all of this leaflet carefully before you start taking this medicine.

- Please keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you suffer from any side effect that gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Chlorphenamine is and what it is used for
2. Before Chlorphenamine is given
3. How Chlorphenamine is given
4. Possible side effects
5. How to store Chlorphenamine
6. Further 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. Before Chlorphenamine is given

You MUST NOT be given Chlorphenamine if you:

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

Take special care with Chlorphenamine

You should tell your doctor before you are given this product if you:

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

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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
- alcohol
- psychotropic drugs (that change perception or behaviour)
- atropine
- phenytoin, for epilepsy.

Pregnancy and breast-feeding

Tell your doctor before using any medicine.

Chlorphenamine **must not** be given during pregnancy or breastfeeding 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.

Important information about some of the ingredients

This medicinal product contains less than 1mmol sodium (23mg) per dose of up to 4ml, i.e. it is 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, or into a muscle, or directly into a vein.

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

Continued, please turn over

If you are given more Chlorphenamine than you should

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) and heart failure (cardiovascular collapse).

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

4. Possible side effects

Like all medicines, Chlorphenamine 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:

- a stinging or burning feeling at the site of injection
- giddiness or drowsiness if the drug is injected too quickly into a vein (this usually passes)
- 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, headache, anorexia, indigestion, abdominal pain, liver problems including jaundice, difficulty passing urine
- muscular incoordination, ringing in the ears, blurred vision, irritability, depression, nightmares
- allergic reactions (skin reactions, itching of raised bumps on the skin, sensitivity to light)
- blood abnormalities.

Elderly people may become confused and children may become excitable.

If any of these side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

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 the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Chlorphenamine

Keep out of the sight and reach of children.
Store below 25°C and protect from light.
Do not use after the date shown as 'EXP' on the carton.
Use immediately after opening. For single use only.
Discard any unused contents immediately after use.
Use immediately after dilution.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Chlorphenamine contains

The **active substance** is: chlorphenamine maleate.

The **other ingredients** are: sodium chloride (*see also end of section 2*), water, hydrochloric acid (for pH adjustment) and sodium hydroxide (for pH adjustment).

What Chlorphenamine looks like and contents of the pack

Chlorphenamine is supplied in glass ampoules. Each ampoule contains 10mg chlorphenamine maleate (in 1ml of clear, colourless sterile solution for injection).
Contents: 5 glass ampoules per box.

Marketing Authorisation Holder

Macarthy's Laboratories Ltd
T/A Martindale Pharma
Bampton Road,
Harold Hill, Romford,
Essex, RM3 8UG,
United Kingdom

Manufacturer

Demo S.A.
21st km National Road
Athens-Lamia
Krioneri Attiki
14568, Greece

This leaflet was last revised: July 2018