Package leaflet: Information for the patient
Chlorphenamine 10 mg/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. See section 4.

What is in this leaflet:

1. What Chlorphenamine is and what it is used for

Chlorphenamine 10 mg/ml Solution for Injection (i.e. injection) contains the active ingredient chlorphenamine maleate which is an antihistamine.

Chlorphenamine is indicated in adults, and children (aged 1 month to 18 years) for the treatment of acute allergic reactions.

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.

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 of this medicine (listed in section 6)
- if you are in a **pre-coma** state
- if you 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**, raised pressure within the eye or **glaucoma**, 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).

Other medicines and Chlorphenamine
Tell your doctor 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 medicine contains less than 1 mmol sodium (23 mg) per 1 ml, that is to say 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 10 mg – 20 mg (1 or 2 ampoules), up to a maximum of 40 mg (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			0.25 mg/kg
1 to 5 years	2.5 mg to 5 mg	OR	0.20 mg/kg
6 to 12 years	5 mg to 10 mg	OR	0.20 mg/kg
12 to 18 years	10 mg to 20 mg	OR	0.20 mg/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:

Frequency Not Known (cannot be estimated from the available data)

- 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
- 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, 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.

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.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.

Do not store above 25ºC. 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 use this medicine if you notice any discolouration of the solution or any particles in the solution.

Once opened this medicine should be used immediately.

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.
Each 1 ml ampoule contains 10 mg of chlorphenamine maleate.

The **other ingredients** are: sodium chloride and water for injections (*see section 2 'Chlorphenamine contains sodium'*).

What Chlorphenamine looks like and contents of the pack
Chlorphenamine is a clear, colourless, sterile solution for injection, supplied in glass ampoules.

Contents: 5 glass ampoules per box.

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Evolan Pharma AB
P.O.Box 120
SE-182 12 Danderyd
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