PACKAGE LEAFLET: INFORMATION FOR THE USER
Chlorphenamine 10mg/ml Solution for Injection
Chlorphenamine maleate
(Referred to as Chlorphenamine throughout this leaflet)

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 pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. 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
2. What you need to know before you are given Chlorphenamine
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 YOU ARE GIVEN CHLORPHENAMINE

You MUST NOT be given Chlorphenamine if you:
- are **allergic** to chlorphenamine or any of the other ingredients of this medicine (listed in section 6)
- 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 before you are given Chlorphenamine 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.**

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
- 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.

Chlorphenamine contains sodium
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.

Use in children and adolescents: 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.

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 medicine, ask your doctor or pharmacist.

INFORMATION FOR THE HEALTHCARE PROFESSIONAL

Chlorphenamine 10mg/ml Solution for Injection
Please refer to the Summary of Product Characteristics (SmPC) for further details on this product.

Qualitative and Quantitative Composition
Each 1ml of solution contains 10mg of chlorphenamine maleate.

Excipient with known effect:
Each 1ml of solution contains 0.13mmol (3.1mg) of sodium.

Pharmaceutical Form
Solution for injection
Clear, colourless sterile solution for injection.
The pH of the solution is 4.0 - 5.2 and the osmolality is 261 - 319 mOsm/Kg.

Therapeutic Indications
Chlorphenamine injection is indicated for acute urticaria, control of allergic reactions to insect bites and stings, angioneurotic oedema, drug and serum reactions, desensitisation reactions, hayfever, vasomotor rhinitis, severe pruritus of non-specific origin.

Posology and method of administration

Adults:
The usual dose of chlorphenamine injection for adults is 10mg to 20mg, but not more than 40mg should be given within a 24-hour period. The injection may be given by the subcutaneous, intramuscular or intravenous route.

When a rapid effect is desired, as in anaphylactic reactions, the intravenous route is recommended in addition to emergency therapy with adrenaline (epinephrine), corticosteroids, oxygen and supportive therapy as required. In this case chlorphenamine injection should be injected slowly over a period of one minute, using the smallest adequate syringe. Any drowsiness, giddiness or hypotension which may follow is usually transitory.

In the event of a blood transfusion reaction, a dose of 10mg to 20mg of chlorphenamine injection should be given by the subcutaneous route. This can be repeated to a total of 40mg within a 24-hour period, or oral forms of chlorphenamine may be given until the symptoms subside.

Chlorphenamine injection may be helpful in the prevention of delayed reactions to penicillin and other drugs when given separately by intramuscular injection immediately prior to administration of the other drug. The usual dose is 10mg.

Chlorphenamine injection cannot, however, be relied on to prevent anaphylactic reactions in patients known to be allergic to a particular drug.

Paediatric population:
The dose for children should be calculated, based on either the child's age or their body weight, using the following table:

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

Extra care should be taken when preparing the injection for children under 1 year due to the small volumes that are required. Dilution of chlorphenamine injection with sodium chloride intravenous infusion (0.9% w/v) should facilitate preparation. For example, diluting 0.2ml chlorphenamine injection to 2ml with sodium chloride 0.9% injection produces a solution containing chlorphenamine 1mg/ml.
For instruction on dilution of the product before administration, see "Special precautions for disposal".

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:
- 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.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting systems listed below:

United Kingdom:
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

Malta:
ADR Reporting,
Website: www.medicinesauthority.gov.mt/adrportal

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.
- This medicinal product does not require any special storage conditions.
- This medicine should be used immediately after opening. Once opened, any unused contents should be discarded.
- After dilution: Chemical and physical in-use stability has been demonstrated for 24 hours at 5°C in polypropylene syringes. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.
- This medicine should not be used after the expiry date which is stated on the carton and inner label after 'EXP'. The expiry date refers to the last day of that month.
- Medicines should not be thrown away via wastewater or household waste. Your doctor or nurse will dispose of medicines no longer required. 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). Each 1ml of solution contains 10mg chlorphenamine 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 a clear, colourless sterile solution for injection, supplied in 1ml clear, neutral glass (Type I) ampoules. It is available in packs of five ampoules.

Marketing Authorisation Holder
Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, United Kingdom

Manufacturer
CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, United Kingdom

Other sources of information
To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:
0800 198 5000 (UK only).

Please be ready to give the following information:

Product name	Reference number
Chlorphenamine 10mg/ml Solution for Injection	29831/0585

This is a service provided by the Royal National Institute of Blind People.

For Malta please call +44 1978 669272.

This medicinal product is authorised in the Member States of the EEA under the following names:
United Kingdom and Malta:
Chlorphenamine 10mg/ml Solution for Injection

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For shelf-life and storage conditions after dilution of the medicinal product, see "Shelf life" and "Special precautions for storage".

Pharmaceutical Particulars
List of excipients
Sodium chloride
Water for Injections

Incompatibilities
In the absence of incompatibility studies, this product must not be mixed with other medicinal products.

Shelf life
Unopened: 36 months

The injection should be given immediately after opening the ampoule. Once opened, any unused portion should be discarded.

After dilution: Chemical and physical in-use stability has been demonstrated for 24 hours at 5°C in polypropylene syringes.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

Special precautions for storage
This medicinal product does not require any special storage conditions.

For storage conditions after dilution of the medicinal product, see "Shelf life".

Nature and contents of container
Chlorphenamine injection is presented in 1ml clear, neutral glass (Type I) ampoules. It is supplied in boxes of 5 ampoules.

Special precautions for disposal and other handling
Use in the paediatric population
Due to the small volumes that are required for children under one year of age, chlorphenamine injection may be diluted with sodium chloride 0.9% injection to produce a solution containing chlorphenamine 1mg/ml. For example, 0.2ml chlorphenamine injection may be diluted to 2ml with sodium chloride 0.9% injection immediately prior to administration. See the information under "Posology and method of administration" for details of paediatric dosing.

The diluted solution should be inspected visually for particulate matter and discoloration prior to administration. In the event of either being observed, discard the medicinal product. Only clear solution should be used. See the information under "Shelf-life" for details regarding the shelf-life of the diluted solution.

This medicinal product is for single use only.

If the entire reconstituted content of the ampoule is not required, any unused solution should be discarded in accordance with local requirements.

Marketing Authorisation Holder
Wockhardt UK Ltd
Ash Road North
Wrexham
LL13 9UF
United Kingdom

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