Chlorphenamine 10mg/ml Solution for Injection should be given by the subcutaneous route as required. The usual dose is 10mg to 20mg (1 or 2 ampoules), up to a maximum of 40mg within 24 hours. For children, the dose will be calculated by the child’s age or their body weight, using the smallest adequate syringe. See below for details.

### Pediatric population:

<table>
<thead>
<tr>
<th>Age</th>
<th>Dose (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 month to 1 year</td>
<td>0.25mg/kg</td>
</tr>
<tr>
<td>1 to 5 years</td>
<td>2.5mg to 5mg or 0.20mg/kg</td>
</tr>
<tr>
<td>6 to 12 years</td>
<td>5mg to 10mg or 0.20mg/kg</td>
</tr>
</tbody>
</table>

### Extra care should be taken when preparing the injection:

- For children under 1 year due to the small volumes that may be required.
- When administering to an infant, the injection should be given slowly over a period of one minute to avoid a fall in blood pressure (hypotensive or violent systemic reaction).

### Symptoms of overdose

- Include sedation, seizures, blood pressure (hypotension) or central nervous system stimulation.

### What you need to know before you are given Chlorphenamine

- You MUST NOT be given Chlorphenamine if you:
  - Have had an allergic reaction to Chlorphenamine or any of the other ingredients in this medicinal product.
  - Have an underlying condition which may be aggravated by Chlorphenamine.

### Other medicines and Chlorphenamine

- You should not be given Chlorphenamine if you are taking:
  - Drugs that treat anxiety or help you to sleep (benzodiazepines, tranquilizers).
  - Phenothiazines (like chlorpromazine).
  - Drugs that are used to treat high blood pressure or high cholesterol levels (angiotensin-converting enzyme [ACE] inhibitors or angiotensin II antagonists).

- If you have any further questions on the use of this medicinal product, you should talk to your doctor or pharmacist.

### Package leaflet: Information for the user

- You will be given Chlorphenamine by your doctor or someone else trained to give it to you. You will be given the injection slowly over a period of one minute to avoid a fall in blood pressure (hypotensive or violent systemic reaction).

### Qualitative and Quantitative Composition

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".

### Pharmaceutical form

- Chlorphenamine 10mg/ml Solution for Injection is a clear, colourless sterile solution for injection.

### INFORMATION FOR THE HEALTHCARE PROFESSIONAL

- Chlorphenamine 10mg/ml Solution for Injection is indicated for acute urticaria, hayfever, vasomotor rhinitis, control of allergic reactions to insect bites and stings, desensitisation reactions, and for pruritus of non-specific origin.

- The dose for children should be calculated, based on their age or their body weight, using the smallest adequate syringe.

- The dose for children is 10mg to 20mg of chlorphenamine injection should be given slowly over a period of one minute to avoid a fall in blood pressure (hypotension) or violent systemic reaction.

### Changes in detail:

- Regulatory text amends.
- Size/Layout: Regulatory
- Typefaces: Myriad Pro Regular / Italic / Semibold / Bold / Black

### CONTROL:

- Version changes due to change in:
  - Regulatory
  - Non-Regulatory

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- Wockhardt UK
4. POSSIBLE SIDE EFFECTS

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

The most common side effects in adults, which can range from slight dizziness to deep sleep:

The following side effects have been reported:
- a sensation of hearing, feeling at the tip of the nose, and the feeling of being drunk
- nausea, vomiting, or diarrhoea
- a stinging or burning feeling at the site of injection
- dryness of the mouth, headache, anorexia, indigestion, abdominal pain, loss of appetite including nausea, difficulty passing urine
- muscle abnormalities
- cardiovascular disorders, including the heart, damaged vision, tinnitus, depression, agitation, sleep disturbance
- allergies reactions (itching reactions, itching of raised bumps in the skin, sensitivity to light)
- local abnormalities

Elderly people may become confused and children may become hyperactive.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist.

This includes possible side effects not listed in this leaflet. You can also report side effects directly to the national reporting systems linked below.

United Kingdom:

Yellow Card Scheme
Website: www.medicines.gov.mt/adrportal
Website: www.mhra.gov.uk/yellowcard
Yellow Card Scheme
For reporting side effects you can help provide more information.

5. HOW TO STORE CHLORPHENAMINE

- Keep out of the sight and reach of children.
- This medicinal product does not require any special precautions for storage.
- 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. It must be used immediately even in case storage times and conditions prior to use are not the responsibility of the user.
- This medicine should not be thrown away via household waste or household waste. Your doctor or nurse will dispose of the medicinal product, see “Shelf life” and “Special precautions for storage”.
- Medicines should not be thrown away via wastewater, or household waste. Your doctor or nurse will dispose of the medicinal product, see “Shelf life”.
- All medicines should not be flushed down the toilet, or household waste.
- Older people may become confused and children may become hyperactive.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist.

This includes possible side effects not listed in this leaflet. You can also report side effects directly to the national reporting systems linked below.

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Yellow Card Scheme
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Yellow Card Scheme
For reporting side effects you can help provide more information.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Chlorphenamine contains:
- The active substance in Chlorphenamine maleate solution hydrochloride is Chlorphenamine maleate.
- Each tablet is stated on the carton and inner label after use and is stated after labelling "GRIP". This is the expiry date when the tablet is released and enter into the tablet. This is the expiry date when the tablet is released and enter into the tablet.
- Medicines should not be thrown away via wastewater, or household waste. Your doctor or nurse will dispose of the medicinal product, see “Shelf life”.
- All medicines should not be flushed down the toilet, or household waste.
- Older people may become confused and children may become hyperactive.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist.

This includes possible side effects not listed in this leaflet. You can also report side effects directly to the national reporting systems linked below.

Malta:

Website: www.medicinesauthority.gov.mt/adrportal
Website: www.mhra.gov.uk/yellowcard
Yellow Card Scheme
For reporting side effects you can help provide more information.

What Chlorphenamine looks like and contents of the pack:

Chlorphenamine is a clear, colourless solution for injection, supplied in boxes of 5 ampoules.

Pharmaceutical Particulars

Each 1ml of solution contains chlorphenamine maleate 1mg/ml. Each 1ml of solution contains chlorphenamine maleate 10mg/ml. Each 1ml of solution contains chlorphenamine maleate 30mg/ml. Each 1ml of solution contains chlorphenamine maleate 40mg/ml.

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- The active substance in Chlorphenamine maleate solution hydrochloride is Chlorphenamine maleate.
- Each 1ml of solution contains chlorphenamine maleate 1mg/ml. Each 1ml of solution contains chlorphenamine maleate 10mg/ml. Each 1ml of solution contains chlorphenamine maleate 30mg/ml. Each 1ml of solution contains chlorphenamine maleate 40mg/ml.

Special precautions for disposal and other handling:

Side effects reported for children under the age of 12 years and adults:
- The diluted solution should be inspected visually for impurities before administration. See the information under “Special precautions for storage” for details of the diluted solution.
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