# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Chlorphenamine 10 mg/ml Solution for injection

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipient with known effect

Each 1 ml of solution contains 0.13 mmol (3.0 mg) of sodium. Please refer to section 4.4 for further details.

For the full list of excipients, see section 6.1.

## 3 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 260 – 320 mOsm/Kg.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Chlorphenamine is indicated in adults, and children (aged 1 month to 18 years) 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.

## 4.2 Posology and method of administration

Posology

*Adults*

The usual dose of chlorphenamine injection for adults is 10 mg to 20 mg, but not more than 40 mg should be given within a 24-hour period.

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 10 mg to 20 mg of chlorphenamine injection should be given by the subcutaneous route. This can be repeated to a total of 40 mg 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 10 mg.

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 | | | 0.25 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 |

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 0.2 ml chlorphenamine injection to 2 ml with sodium chloride 0.9% injection produces a solution containing chlorphenamine 1 mg/ml. The diluted product should be used immediately.

Method of administration

Intramuscular

Subcutaneous

Intravenous

When administered intravenously the injection should be given slowly over a period of one minute in order to avoid hypotension or central nervous system stimulation.

## 4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

The anticholinergic properties of chlorphenamine are intensified by monoamine oxidase inhibitors (MAOIs). Chlorphenamine injection is therefore contraindicated in patients who have been treated with MAOIs within the last fourteen days.

## 4.4 Special warnings and precautions for use

Chlorphenamine, in common with other drugs having anticholinergic effects, should be used with caution in epilepsy; raised intra-ocular pressure including glaucoma; prostatic hypertrophy; severe hypertension or cardiovascular disease; bronchitis; bronchiectasis and asthma; hepatic disease and thyrotoxicosis. Children and the elderly are more likely to experience the neurological anticholinergic effects.

This medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially 'sodium-free'.

## 4.5 Interaction with other medicinal products and other forms of interaction

Concurrent use of chlorphenamine and hypnotics or anxiolytics may potentiate drowsiness. Concurrent use of alcohol may have a similar effect.

Chlorphenamine inhibits phenytoin metabolism and can lead to phenytoin toxicity.

The anticholinergic effects of chlorphenamine are intensified by MAOIs (see section 4.3).

## 4.6 Fertility, pregnancy and lactation

Pregnancy

There are no or limited amount of data (less than 300 pregnancy outcomes) from the use of Chlorphenamine in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3). As a precautionary measure, it is preferable to avoid the use of Chlorphenamine during pregnancy. Use during the third trimester may result in reactions in neonates.

Breastfeeding

Small amounts of antihistamines are excreted in breast milk. Use by nursing mothers is not recommended because of the risks of adverse effects in the infants. Antihistamines may inhibit lactation.

Fertility

There are no human data available on fertility.

## 4.7 Effects on ability to drive and use machines

The anticholinergic properties of chlorphenamine may cause drowsiness, blurred vision and psychomotor impairment, which can seriously hamper the patient's ability to drive and use machinery.

## 4.8 Undesirable effects

The following effects have been reported and are listed below by system organ class:

| System Organ Class (SOC) | Frequency | Adverse Event |
|---|---|---|
| Blood and lymphatic system disorders | Not known* | Haemolytic anaemia and other blood dyscrasias |
| Cardiac disorders | Not known* | Palpitations |
| Ear and labyrinth disorders | Not known* | Tinnitus |

| | | |
|---|---|---|
| Eye disorders | Not known* | Blurred vision |
| Gastrointestinal disorders | Not known* | Nausea, vomiting, diarrhoea, dry mouth, painful dyspepsia |
| General disorders and administration site conditions | Not known* | Irritability, lassitude, stinging or burning sensation at the site of injection |
| Hepatobiliary disorders | Not known* | Hepatitis including jaundice |
| Immune system disorders | Not known* | Hypersensitivity, anaphylactic reaction |
| Metabolism and nutrition disorders | Not known* | Anorexia |
| Musculoskeletal and connective tissue disorders | Not known* | Twitching, muscular weakness, incoordination |
| Nervous system disorders | Not known* | Headaches, dizziness, inability to concentrate, sedation (most common side effect varying from slight drowsiness to deep sleep), CNS stimulation (as a result of rapid intravenous injection) |
| Psychiatric disorders | Not known* | Depression, nightmares, paradoxical excitation in children, confusional psychosis in the elderly |
| Renal and urinary disorders | Not known* | Urinary retention |
| Respiratory, thoracic and mediastinal disorders | Not known* | Thickening of bronchial secretions |
| Skin and subcutaneous tissue disorders | Not known* | Exfoliative dermatitis, photosensitivity, skin reactions, urticaria |
| Vascular disorders | Not known* | Transitory hypotension (as a result of rapid intravenous injection) |

* cannot be estimated from the available data

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

### 4.9 Overdose

The estimated lethal dose of chlorphenamine is 25 mg to 50 mg/kg body weight. Symptoms and signs include sedation, paradoxical stimulation of the CNS, toxic psychosis, seizures, apnoea, convulsions, anticholinergic effects, dystonic reactions and cardiovascular collapse including arrhythmias.

Symptomatic and supportive measures should be provided with special attention to cardiac, respiratory, renal and hepatic functions, and fluid and electrolytic balance. If overdosage is by the oral route, treatment should include gastric lavage or induced emesis. Following these measures activated charcoal and cathartics may be administered to minimise absorption.

Treat hypotension and arrhythmias vigorously. CNS convulsions may be treated with iv diazepam. Haemoperfusion may be used in severe cases.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antihistamines for systemic use, substituted alkylamines.

ATC code: R06AB04

Antihistamines, including chlorphenamine, used in the treatment of allergy act by competing with histamine for $H_1$- receptor sites on cells and tissues. Chlorphenamine also has anticholinergic activity.

The mechanism by which chlorphenamine exerts its anti-emetic, anti-motion sickness and anti-vertigo effects is not precisely known but may be related to its central actions. Further, most antihistamines, including chlorphenamine, cross the blood-brain barrier and probably produce sedation largely by occupying $H_1$-receptors in the brain.

### 5.2 Pharmacokinetic properties

Following IV administration, the apparent steady-state volume of distribution of chlorphenamine is approximately 3L/kg in adults and 3.8L/kg in children.

Chlorphenamine is approximately 70% bound to plasma proteins.

In adults with normal renal and hepatic function, the terminal elimination half-life of chlorphenamine reportedly ranges from 12 to 43 hours.

The systemic exposure per mg dose is lower in children than adults and the elimination half-life

may be shorter.

### 5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the Summary of Product Characteristics.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Sodium chloride

Water for injections

### 6.2 Incompatibilities

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

### 6.3 Shelf life

Unopened: 3 years

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

### 6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

### 6.5 Nature and contents of container

Chlorphenamine injection is presented in 1ml amber, neutral glass (Type I, Ph. Eur.) ampoules. It is supplied in boxes of 5 ampoules.

### 6.6 Special precautions for disposal

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 1 mg/ml. For example, 0.2 ml chlorphenamine injection may be diluted to 2 ml with sodium chloride 0.9% injection immediately prior to administration.

See section 4.2 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 section 6.3 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.

## 7 MARKETING AUTHORISATION HOLDER

Synchrony Pharma Limited

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London

EC1Y 8YZ

United Kingdom

## 8 MARKETING AUTHORISATION NUMBER(S)

PL 39280/0010

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

11/09/2025

## 10 DATE OF REVISION OF THE TEXT

11/09/2025