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: Chlorphenamine Maleate 10 mg

Excipient(s) with known effect: 2.9 mg/ml sodium (as sodium chloride).

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for Injection. (Injection)
Clear colourless sterile solution for injection.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Posology

Adults
The usual dose is 10 mg to 20 mg, with a maximum dose of 40 mg in 24 hours.

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 a rapid effect is desired, as in anaphylactic reactions, the intravenous route is recommended in addition to emergency therapy as per current standard clinical practice guidelines e.g. with adrenaline (epinephrine), corticosteroids, oxygen and supportive therapy as required.

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.
Pre-coma states.

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

In common with other drugs having anticholinergic effects, chlorphenamine should be used with caution in epilepsy, prostatic hypertrophy, glaucoma, hepatic disease, bronchitis, bronchiectasis, thyrotoxicosis, raised intra-ocular pressure, severe hypertension or cardiovascular disease and bronchial asthma.

Children and the elderly are more likely to experience the neurological anticholinergic effects.

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

4.5 Interaction with other medicinal products and other forms of interaction

Chlorphenamine may have an additive effect when used concurrently with hypnotics and anxiolytics causing potentiation of drowsiness. A similar additive effect will result from concurrent usage of alcohol with chlorphenamine, with the effects of alcohol being increased.

The effects of anti-cholinergics, e.g. some psychotropic drugs and atropine, may be potentiated by this product giving rise to tachycardia, mouth dryness, gastrointestinal disturbances e.g. dyskinesia, colic, urinary retention and headache.

As monoamine oxidase inhibitor therapy intensifies the anticholinergic effects of chlorphenamine, concurrent therapy is contraindicated.

Chlorphenamine inhibits phenytoin metabolism and can lead to phenytoin toxicity.

4.6 Fertility, pregnancy and lactation

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.

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.

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, blood disorder
Cardiac disorders	Not known*	Palpitations, tachycardia, arrhythmia

Ear and labyrinth disorders	Not known*	Tinnitus
Eye disorders	Not known*	Vision blurred
Gastrointestinal disorders	Not known*	Nausea, vomiting, diarrhoea, dry mouth, abdominal pain, dyspepsia
General disorders and administration conditions	Not known*	Fatigue, chest discomfort, irritability, hyperpyrexia, injection site pain
Hepatobiliary disorders	Not known*	Hepatitis, jaundice
Immune system disorders	Not known*	Hypersensitivity, anaphylactic reaction
Metabolism and nutrition disorders	Not known*	Decreased appetite
Musculoskeletal and connective tissue disorders	Not known*	Muscle twitching, muscular weakness
Nervous system disorders	Not known*	Sedation, disturbance in attention, headache, dizziness, coordination abnormal, tremor, convulsion, CNS stimulation (as a result of rapid intravenous injection)
Psychiatric disorders	Not known*	Depression, nightmare, agitation, senile psychosis, insomnia, nervousness
Renal and urinary disorders	Not known*	Urinary retention
Respiratory, thoracic and mediastinal disorders	Not known*	Increased viscosity of bronchial secretion
Skin and subcutaneous tissue disorders	Not known*	Dermatitis exfoliative, photosensitivity reaction, skin reaction, urticaria
Vascular disorders	Not known*	Hypotension

*cannot be estimated from the available data

Any drowsiness, giddiness or hypotension following intravenous injection is usually transitory.

The following populations may be more susceptible to certain undesirable effects:

Paediatric population
Children are more likely to experience the neurological anticholinergic effects. Paradoxical excitation (agitation) in children can occur.

Elderly population
The elderly are more likely to experience the neurological anticholinergic effects. Confusional psychosis in the elderly can occur.

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

4.9 Overdose

The estimated lethal dose of Chlorphenamine Injection is 25 mg/kg 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 electrolyte 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

Chlorphenamine maleate is a potent antihistamine (H_1-receptor antagonist). Antihistamines diminish or abolish the actions of histamine in the body by competitive reversible blockade of histamine 1 receptor sites on tissues.

Chlorphenamine also has anticholinergic activity.

5.2 Pharmacokinetic properties

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

This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.

6.3 Shelf life

3 years unopened.

The product should be administered immediately after opening ampoule.

6.4 Special precautions for storage

Do not store above 25°C. Keep the ampoules in the outer carton in order to protect from light.

6.5 Nature and contents of container

Chlorphenamine injection is presented in 1 ml Type I glass ampoules. It is supplied in boxes of 5 ampoules.

6.6 Special precautions for disposal and other handling

Use in the paediatric population:
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. The diluted product should be used immediately (see section 4.2).

No special requirements for disposal.

7 MARKETING AUTHORISATION HOLDER

Evolan Pharma AB
PO Box 120
182 12 Danderyd
Sweden

8 MARKETING AUTHORISATION NUMBER

PA2262/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10 June 1995

Date of last renewal: 10 June 2010

10 DATE OF REVISION OF THE TEXT

November 2023