For the use of Registered Medical Practitioner of Hospital or a Laboratory only

Chlorphenamine Injection BP 10mg/ml

COMPOSITION
Each ml contains:

Chlorphenamine Maleate	BP	10mg
Phenol (As preservative in Vials only)	BP	0.5% w/v
Water for Injection	BP	q.s.

CLINICAL PHARMACOLOGY
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.
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.

INDICATION AND USAGE
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.

CONTRA-INDICATION
Hypersensitivity to the active substance or to any of the excipients listed.
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.

DRUG INTERACTIONS
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.

WARNINGS AND PRECAUTIONS
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 1 ml, that is to say essentially 'sodium-free'.

SIDE 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*	
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

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.

OVERDOSE
The estimated lethal dose of chlorphenamine is 25mg to 50mg/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.

DOSAGE & MODE 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.

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. 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.

STORAGE CONDITION
Protected from light.

KEEP OUT OF REACH OF CHILDREN

PRESENTATION
1ml Ampoules & 10ml Vial packed in cardboard carton along with pack insert.

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