AUSTRALIAN PRODUCT INFORMATION – DEMAZIN® ORIGINAL 6 HOUR RELIEF (CHLORPHENAMINE AND PSEUDOEPHEDRINE) TABLETS

1 NAME OF THE MEDICINE

Chlorphenamine maleate and pseudoephedrine sulfate

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each DEMAZIN Original 6 hour Relief tablet contains chlorphenamine maleate 4 mg and pseudoephedrine sulfate 60 mg.

Excipients with known effect:

- Lactose monohydrate

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Tablet

A round, convex, blue tablet plain on one side and score-line on the other.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

Relief of upper respiratory mucosal congestion and hypersecretion accompanying conditions such as the common cold, nasal allergy, hayfever, and sinusitis.

4.2 DOSE AND METHOD OF ADMINISTRATION

Adults and children 12 years and over:

One tablet every 6 hours, when necessary.

4.3 CONTRAINDICATIONS

- Hypersensitivity to chlorphenamine, pseudoephedrine or to other drugs of similar chemical structure or any of the other ingredients in this medicine.
- Severe or uncontrolled hypertension
- Severe coronary artery disease.
- Severe acute or chronic kidney disease/renal failure
- Taking monoamine oxidase inhibitors (MAOIs) or have taken MAOIs within the previous 14 days.
- Traditional antihistamines, such as chlorphenamine are contraindicated in patients taking an antihypertensive agent.

- Narrow angle glaucoma
- Stenosing peptic ulcer
- Symptomatic prostatic hypertrophy
- Bladder neck obstruction
- Pyloroduodenal obstruction.

DEMAZIN Original 6 hour relief should not be used in children under 12 years of age (see section 4.4 Paediatric use).

For additional information see Section 4.5 Interactions with other medicines and other forms of interaction.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Identified precautions

Use with caution in patients with the following conditions:

- Hypertension
- Hyperthyroidism
- Diabetes mellitus
- Coronary artery disease
- Ischaemic heart disease
- Glaucoma
- Prostatic hypertrophy
- Epilepsy.

Effects on sleep

Chlorphenamine may cause drowsiness and may increase the effects of alcohol. Drowsiness may continue the following day. Those affected should not drive or operate machinery. Alcohol should be avoided.

This medicine contains pseudoephedrine which may cause sleeplessness if taken up to several hours before going to bed.

Ischaemic colitis

Some cases of ischaemic colitis have been reported with pseudoephedrine. Pseudoephedrine should be discontinued, and medical advice sought if sudden abdominal pain, rectal bleeding or other symptoms of ischaemic colitis develop.

Posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS)

Cases of PRES and RCVS have been reported with the use of pseudoephedrine-containing product (see Section 4.8 Adverse Effects). The risk is increased in patients with severe or uncontrolled hypertension, or with severe acute or chronic kidney disease/renal failure (see Section 4.3 Contraindications).

Pseudoephedrine should be discontinued and immediate medical assistance sought if the following symptoms occur: sudden severe headache or thunderclap headache, nausea, vomiting, confusion,

seizures and/or visual disturbances. Most reported cases of PRES and RCVS resolved following discontinuation and appropriate treatment.

Ischaemic optic neuropathy

Cases of ischaemic optic neuropathy have been reported with pseudoephedrine. The product should be discontinued if sudden loss of vision or decreased visual acuity such as scotoma occurs.

Use in hepatic impairment

Use with caution in patients with impaired hepatic function.

Use in renal impairment

Use with caution in patients with impaired renal function.

Use in the elderly

Elderly patients (approximately 60 years and older) are more likely to experience dizziness, sedation and hypotension with medicines containing chlorphenamine.

Paediatric use

DEMAZIN Original 6 hour relief should not be used in children under 12 years of age.

Chlorphenamine may cause excitation in children.

Antihistamines should not be given to newborn or premature infants.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

The following interactions with pseudoephedrine have been noted:

- Antidepressant medication e.g. tricyclic antidepressants and monoamine oxidase inhibitors (MAOIs) – may cause a serious increase in blood pressure or hypertensive crisis.
- Other sympathomimetic agents, such as decongestants, appetite suppressants and amphetamine-like psychostimulants – may cause an increase in blood pressure and additive effects.
- Antihypertensives e.g. methyldopa and beta-blockers – pseudoephedrine may antagonise the effect of certain classes of antihypertensives and cause an increase in blood pressure.
- Urinary acidifiers enhance elimination of pseudoephedrine.
- Urinary alkalinisers decrease elimination of pseudoephedrine.

The following interactions with chlorphenamine have been noted:

- Central nervous system (CNS) depressants (alcohol, sedatives, opioid analgesics, hypnotics, barbiturates) may cause an increase in sedation effects.
- Monoamine oxidase inhibitors (MAOIs) and tricyclic antidepressants (TCAs) – may prolong and intensify the anticholinergic and CNS depressive effects.
- When taken concomitantly with phenytoin may cause a decrease in phenytoin elimination.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available.

Use in pregnancy – Pregnancy Category B2

Safe use of DEMAZIN preparations during pregnancy has not been established. Therefore, the product should be used only if the potential benefit justifies the potential risk to the foetus. Chlorphenamine maleate should not be used in the third trimester of pregnancy because newborn and premature infants may have severe reactions to antihistamines.

Use in lactation

It has been estimated that 0.5% to 0.7% of a single dose of pseudoephedrine ingested by the mother will be excreted in the breast milk over 24 hours.

Chlorphenamine is excreted in breast milk.

Therefore, DEMAZIN is not recommended for breastfeeding mothers.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

May cause drowsiness. Patients should be warned against engaging in mechanical operations which require alertness, such as driving a motor vehicle, until response to the medicine has been determined. Alcohol should be avoided.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Drowsiness, dizziness, ataxia, and nausea may occur. Adverse drug reactions identified during post-marketing experience are detailed in the table below.

Adverse effects of pseudoephedrine include:

- cardiovascular stimulation – elevated blood pressure, tachycardia or arrhythmias
- central nervous system (CNS) stimulation – restlessness, insomnia, anxiety, tremors and (rarely) hallucinations
- skin rashes and urinary retention
- ischaemic colitis (frequency unknown)
- weakness
- myadriasis.

Children and the elderly are more likely to experience adverse effects than other age groups.

Adverse reactions with chlorphenamine:

- CNS stimulatory effects of chlorphenamine may include anxiety, hallucinations, appetite stimulation, muscle dyskinesias and activation of epileptogenic foci.
- CNS depressive effects of chlorphenamine include sedation and impaired performance (impaired driving performance, poor work performance, incoordination, reduced motor skills, and impaired information processing). Performance may be impaired in the absence of sedation and may persist the morning after a night-time dose.
- High doses of chlorphenamine may cause nervousness, tremor, insomnia, agitation, and irritability.

- Side effects of chlorphenamine associated with cholinergic blockage include dryness of the eyes, mouth and nose, blurred vision, urinary hesitancy and retention, constipation, and tachycardia.

Adverse drug reactions identified during post-marketing experience with pseudoephedrine and chlorphenamine appear in the following table. The frequency category was estimated from spontaneous reporting rates.

Adverse events that have been observed during clinical trials and/or post-marketing use are ranked under the following frequency: Very common (≥1/10), common (≥1/100 and <1/10), uncommon (≥1/1000 and <1/100), rare (≥1/10,000 and <1/1,000), very rare (<1/10,000).

System Organ Class Frequency Category	 Adverse Event Preferred Term
Immune System Disorders	
Very rare	Anaphylactic reaction, Hypersensitivity
Psychiatric Disorders	
Very rare	Anxiety, Euphoric mood, Restlessness, Insomnia, Hallucinations, Hallucination, visual
Nervous System Disorders	
Very rare	Cerebrovascular accident*, Headache, Paraesthesia, Psychomotor hyperactivity (in the paediatric population), Tremor
Unknown	Posterior Reversible Encephalopathy Syndrome, Reversible Cerebral Vasoconstriction Syndrome
Eye disorders	
Unknown	Ischaemic optic neuropathy
Cardiac Disorders	
Very rare	Arrhythmia, Myocardial infarction*, Palpitations, Tachycardia
Gastrointestinal Disorders	
Very rare	Abdominal discomfort, Colitis ischaemic, Diarrhoea, Vomiting
Skin and Subcutaneous Tissue Disorders	
Very rare	Pruritus, Acute generalised exanthematous pustulosis, Angioedema, Pruritic rash, Rash, Urticaria, Fixed eruption
Renal and Urinary Disorders	
Very rare	Dysuria, Urinary retention
General disorders and administration site conditions	
Very rare	Feeling jittery, Anxiety
Investigations	
Very rare	Blood pressure increased

* These events have been reported very rarely in post-marketing safety. A recent post-authorisation safety study (PASS) did not provide any evidence of increased risk of myocardial infarction or cerebrovascular accident associated with the use of vasoconstrictors for nasal decongestion, including pseudoephedrine.

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration 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 at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Antihistamine plus decongestant.

DEMAZIN contains an antihistamine (chlorphenamine) for prophylaxis and treatment of allergy symptoms and a decongestant (pseudoephedrine) for relief of nasal and sinus congestion.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

No data available.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

- Brilliant blue FCF
- Lactose monohydrate
- Magnesium stearate
- Maize starch
- Povidone.

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 25^{0}C. Protect from moisture.

6.5 NATURE AND CONTENTS OF CONTAINER

Blister pack: 12's and 4's (sample pack).

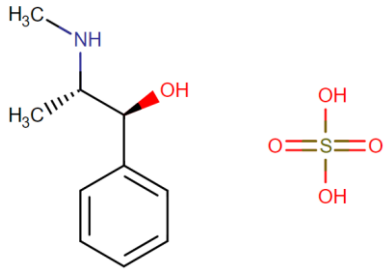
6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

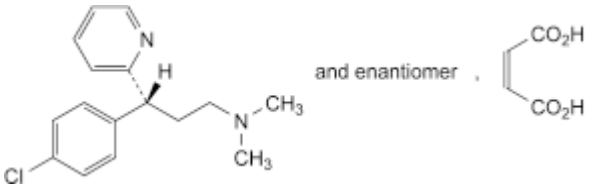
6.7 PHYSICOCHEMICAL PROPERTIES

Chemical structure

Pseudoephedrine sulfate



Chlorphenamine maleate



CAS number

Pseudoephedrine sulfate: 7460-12-0

Chlorphenamine maleate: 113-92-8

7 MEDICINE SCHEDULE (POISONS STANDARD)

Schedule 3

8 SPONSOR

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9 DATE OF FIRST APPROVAL

4th February 2008

10 DATE OF REVISION

15 December 2025

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
4.3, 4.4, 4.5, 4.6 & 4.8	Text reformatting and updates to safety information