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

1 NAME OF THE MEDICINE

Chlorphenamine maleate and pseudoephedrine sulfate

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each DEMAZIN 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.

Traditional antihistamines, such as chlorphenamine are contraindicated in patients taking an antihypertensive agent or an antidepressant medication containing a monoamine oxidase inhibitor (MAOI).

Sympathomimetic agent decongestants, such as pseudoephedrine are contraindicated in patients with severe hypertension, coronary heart disease and also in patients receiving MAOI therapy (and for 14 days after cessation of MAOI therapy).

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

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Identified precautions

Chlorphenamine

Use with caution in patients with narrow angle glaucoma, stenotic peptic ulcer, pyloroduodenal obstruction and urinary bladder obstruction due to symptomatic prostatic hypertrophy and narrowing of the bladder neck. (See also section 4.5 Interactions with other medicines and other forms of interactions and section 4.7 Effect on ability to drive and use machines).

Pseudoephedrine

Use with caution in patients with a history of hypertension, coronary artery disease, narrow angle glaucoma, diabetes, hyperthyroidism or prostatic hypertrophy.

In some patients pseudoephedrine may cause side effects of sympathomimetic origin such as nausea, dizziness, weakness, tachycardia, insomnia, palpitations and mydriasis.

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.

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 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 sedative effect of chlorphenamine may be potentiated by the concomitant use with alcohol, tricyclic antidepressants, barbiturates or other CNS depressants.

MAOI's prolong and intensify the effects of antihistamines.

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

As it is not known whether the components of DEMAZIN are excreted in human milk, caution should be exercised when DEMAZIN is administered to nursing 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.

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Drowsiness, sedation, dizziness, ataxia, nausea and headache may occur. Disturbances of the cardiovascular, haematological, gastrointestinal (ischaemic colitis – frequency unknown) and nervous system may occur.

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 25^0C. Protect from moisture.

6.5 NATURE AND CONTENTS OF CONTAINER

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

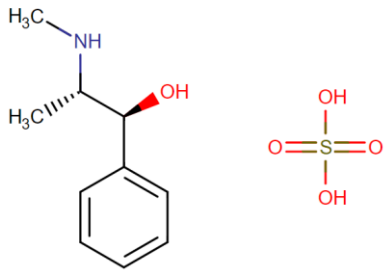
6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

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

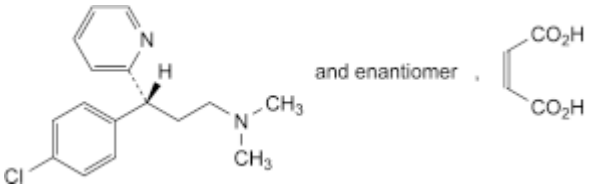
6.7 PHYSICOCHEMICAL PROPERTIES

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

iNova Pharmaceuticals (Australia) Pty Ltd
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9 DATE OF FIRST APPROVAL

4th February 2008

10 DATE OF REVISION

20 September 2019

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
All	PI format
4.4 & 4.8	Inclusion of precaution and adverse effect for ischaemic colitis
8	New sponsor