PRODUCT INFORMATION

DEMAZIN 6 Hour Relief

PRODUCT DESCRIPTION

6 Hour Relief Tablets - Chlorpheniramine maleate 4 mg and pseudoephedrine sulfate 60 mg.

PHARMACOLOGY

Antihistamine plus decongestant. DEMAZIN preparations contain an antihistamine (chlorpheniramine) for prophylaxis and treatment of allergy symptoms and a decongestant (pseudoephedrine) for relief of nasal and sinus congestion.

INDICATIONS

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

CONTRAINDICATIONS

Hypersensitivity to chlorpheniramine, pseudoephedrine or to other drugs of similar chemical structure.

Traditional antihistamines, such as chlorpheniramine 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.

WARNINGS

Antihistamines should not be given to newborn or premature infants.

PRECAUTIONS

Chlorpheniramine

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 drug has been determined.
Should be used 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.

Might have the sedative effect potentiated by the concomitant use with alcohol, tricyclic antidepressants, barbiturates or other CNS depressants. MAOI's prolong and intensify the effects of antihistamines.

Are more likely to cause dizziness, sedation and hypotension in elderly patients (approximately 60 years and older).

May cause excitation in children.

**Pseudoephedrine**

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

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

**Use in Pregnancy** (Category B2)

Safety for 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. Chlorpheniramine 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 preparations are excreted in human milk, caution should be exercised when DEMAZIN preparation are administered to nursing mothers.

**ADVERSE REACTIONS**

Drowsiness, sedation, dizziness, ataxia, nausea and headache may occur. Disturbances of the cardiovascular, haematological, gastrointestinal and nervous system may occur.

**DOSAGE AND ADMINISTRATION**

**DEMAZIN 6 Hour Relief Tablets**

**Adults and children 12 years and over:**
One tablet every 6 hours, when necessary.
OVERDOSAGE

In the event of overdosage, emergency treatment should be started immediately. Contact the Poisons Information Centre (tel: 13 11 26) for the latest advice regarding treatment.

PRESENTATION

DEMAZIN 6 Hour Relief Tablets (blue, round, scored, marked with company logo): 12’s

POISON SCHEDULES

DEMAZIN 6 Hour Relief Tablets: S3

SPONSOR

Schering-Plough Pty Limited
Level 4, 66 Waterloo Road,
North Ryde, NSW 2113
AUSTRALIA

This Product Information has been approved by the TGA on: 4th February 2008 and 13th March 2008.
Date of most recent amendment: 29 June 2010

© Schering-Plough Pty Limited 2010