PROFESSIONAL INFORMATION

SCHEDULING STATUS

S2

PROPRIETARY NAME AND DOSAGE FORM

DEMAZIN® Syrup

COMPOSITION

Each 5 ml contains:

Active Ingredients: Chlorpheniramine maleate 1,25 mg and phenylephrine hydrochloride 2,5 mg.

Inactive ingredients: Dye FD and C yellow no. 6, dye FD and C blue no. 1, dye FD and C green no. 3, benzaldehyde, glycerin, hydrochloric acid, levomenthol, peach flavour, purified water, propylene glycol, sucrose and vanillin flavour.

Preservatives: Methylparaben 0, 05 % *m/v* and Propylparaben 0, 01 % *m/v*

Contains sugar: Sucrose 2,75 mg/5 ml

Contains no alcohol

CATEGORY AND CLASS

A.5.8 Preparations for the common cold including nasal decongestants and antihistaminics

PHARMACOLOGICAL ACTION

Chlorpheniramine maleate is a histamine H1 receptor antagonist that competes reversibly with histamine for H1 receptor sites on effector cells. It suppresses those symptoms due to histamine release. Antihistamines have anticholinergic properties and have a drying effect on the nasal mucosa.

PROFESSIONAL INFORMATION

Phenylephrine hydrochloride is a sympathomimetic agent with mainly direct effects on adrenergic receptors. It has predominantly alpha adrenergic activity and is without significant stimulating effects on the central nervous system at usual doses. Its pressor activity is weaker than that of ephedrine.

INDICATIONS

DEMAZIN Syrup provides relief of nasal congestion and other symptoms associated with sinusitis, hay fever, nasal allergies or other respiratory allergies.

CONTRAINDICATIONS

Sensitivity to any of the ingredients is a contraindication for the use of DEMAZIN Syrup.

DEMAZIN Syrup is contraindication in children under 2 years of age.

DEMAZIN Syrup should not be given to patients receiving monoamine oxidase inhibitors or within 14 days of termination of such treatment.

Safety in pregnancy and lactation has not been established. Phenylephrine is best avoided in pregnancy, because of the potential promotion of uterine contractility and peripheral vasoconstriction, with the possibility of foetal hypoxia. Chlorpheniramine maleate may inhibit lactation due to anticholinergic effects. Small amounts of antihistamines entering breast milk may cause drowsiness or excitement and/ or irritability in infants.

Severe hypertension or ischaemic heart disease.

PROFESSIONAL INFORMATION

WARNINGS AND SPECIAL PRECAUTIONS

Effects on Ability to Drive and Use Machines:

This medicine may lead to drowsiness and impaired concentration, which may be aggravated by the simultaneous intake of alcohol or other central nervous system depressant agents e.g. sedatives and tranquillisers. Caution should be used when driving a motor vehicle or operating machinery or performing potentially dangerous tasks, where loss of concentration may lead to accidents.

DEMAZIN Syrup should be used with caution in patients with hyperthyroidism; cardiovascular disease such as ischaemic heart disease, arrhythmia or tachycardia; occlusive vascular disorders, including arteriosclerosis, hypertension or aneurysms; diabetes mellitus, closed-angle glaucoma, prostatic hypertrophy, phaeochromocytoma, emphysema or chronic bronchitis and porphyria.

DEMAZIN Syrup should not be taken for more than 7 days. After 5 to 7 days tachyphylaxis may occur and the product loses effect. If symptoms do not improve, or are accompanied by fever, consult a doctor.

Exceeding the recommended dosage may result in nervousness, dizziness, sleeplessness, tremors or cardiac arrhythmia. This may also occur in sensitive individuals at small doses.

DEMAZIN Syrup is not recommended in newborn or premature infants. This age group has an increased susceptibility to anticholinergic side effects such as central nervous system excitation and an increased tendency towards convulsions.

DEMAZIN Syrup may cause paradoxical hyperexcitability, nervousness, irritability and insomnia.

PROFESSIONAL INFORMATION

Do not administer DEMAZIN Syrup to children who have breathing problems such as chronic bronchitis, or who have glaucoma, without first consulting the child's doctor.

DEMAZIN Syrup may cause drowsiness; sedatives and tranquillisers may increase the drowsiness effect. Do not give this product to children who are taking sedatives and tranquillisers, without first consulting the child's doctor.

Elderly patients are especially susceptible to dizziness, sedation, confusion, hypotension and anticholinergic effects such as dry mouth and urinary retention.

Long term use of antihistamines may decrease salivary flow and contribute to development of caries, periodontal disease, oral candidiasis and discomfort.

INTERACTIONS

Medicine Interactions:

All sedatives and alcohol potentiate the central nervous system depressant effects of the antihistamines.

Tricyclic antidepressants or maprotiline potentiate anticholinergic effects if taken with antihistamines.

Monoamine oxidase inhibitors will potentiate both the drowsiness effect and the anticholinergic effects if taken with antihistamines. Concurrent use is not recommended.

Anticholinergics or medicines with anticholinergic activity will be potentiated if used concurrently with antihistamines.

An increased risk of arrhythmias may occur if DEMAZIN Syrup is given to patients receiving cardiac glycosides, quinidine or tricyclic antidepressants.

PROFESSIONAL INFORMATION

Reversal of the action of antihypertensive agents may occur and therefore special care is advisable in patients receiving antihypertensive therapy. Interactions with alpha- and beta-blockers may be complex and can produce hypertensive crisis.
Interactions are possible with guanethidine, reserpine, tricyclic antidepressants, digoxin and alpha-methyldopa.

DEMAZIN Syrup should be avoided or used with caution in patients undergoing anaesthesia with cyclopropane, halothane or other halogenated anaesthetics as they may induce ventricular fibrillation.

The warning signs of damage caused by ototoxic drugs such as aminoglycoside antibiotics may be masked.

Medicine and laboratory test interactions:
The use of DEMAZIN Syrup should be discontinued several days prior to skin testing procedures since chlorpheniramine maleate may prevent or diminish otherwise positive reactions to dermal reactivity indicators.

HUMAN REPRODUCTION:

Safety in pregnancy and lactation has not been established. **[SEE CONTRAINDICATIONS]**

DOSAGE AND DIRECTIONS FOR USE

Children: **Two to three years:** 2,5 to 5 ml every three or four hours.

Three to six years: 5 to 10 ml every three or four hours.

Adults: 10 ml every three or four hours.

PROFESSIONAL INFORMATION

SIDE EFFECTS

Antihistamines:

Central Nervous System: Sedation, dizziness, fatigue, lassitude, incoordination, tremors, confusion, blurred vision, diplopia, tinnitus, euphoria, nervousness, tingling and weakness of the hands, irritability, nightmares, insomnia, hallucinations and convulsions.

Anticholinergic Effects: Dryness of the mouth and respiratory passages, thickening of mucous, cough, increased sweating, urinary retention or frequency, dysuria. Headache, tight chest, palpitations, tachycardia and hypotension.

Gastrointestinal Disturbances: Loss of appetite, nausea, vomiting, epigastric distress and diarrhoea. Reduction in tone and motility of the gastrointestinal tract, resulting in gastric reflux and constipation.

Hypersensitivity Reactions: Allergic dermatitis, drug fever and photosensitisation.

Blood Disorders: Agranulocytosis, haemolytic anaemia, leukopenia and thrombocytopenia.

Caution should be used when the following medical conditions exist: Severe cardiovascular disorders, epilepsy and during an acute attack of asthma.

Oral Nasal Decongestants:

Insomnia, fear, anxiety, restlessness, tremor, confusion, irritability, weakness and psychotic states. Nausea and vomiting may occur and appetite may be reduced.

Vasoconstriction with resultant hypertension. The rise in blood pressure may produce cerebral haemorrhage and pulmonary oedema. Tachycardia or bradycardia, cardiac

arrhythmias, palpitations and cardiac arrest may result. Hypotension with dizziness and fainting and flushing may occur.

Anginal pains may be precipitated in patients with angina pectoris.

Difficulty in micturition and urinary retention, dyspnoea, altered metabolism, including disturbances of glucose metabolism, sweating and hypersalivation. Headache is also common.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

See "**SIDE EFFECTS"**

Overdosage Information: In the event of overdosage, emergency treatment should be started immediately.

Manifestations: Symptoms include drowsiness or paradoxical excitement, ataxia, tremors, athetosis, hallucinations and convulsions. Fixed, dilated pupils with flushed face, sinus tachycardia, dyspnoea, urinary retention, dry mouth and fever. Terminally there may be deepening coma and cardiorespiratory collapse.

Severe increase in blood pressure may occur. Treatment with alpha-adrenergic blocking agents to reduce blood pressure should be instituted if myocardial ischaemia or encephalopathy is provoked.

Central excitatory effects constitute the greatest danger, particularly in children who are more likely to exhibit central nervous system stimulation. Adults more frequently exhibit central nervous system depression and the aged are particularly prone to experience hypotension.

PROFESSIONAL INFORMATION

Treatment: The stomach should be emptied by emesis or lavage. There is no specific antidote and treatment is symptomatic and supportive.

IDENTIFICATION

A clear, blue syrup with an aromatic odour and sweet taste, free from foreign matter.

PRESENTATION

Amber glass bottles of 100 ml.

STORAGE INSTRUCTIONS

Store at or below 25 ºC.

Keep out of reach of children.

REGISTRATION NUMBER

C535 (Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Bayer (Pty) Ltd

27 Wrench Road, Isando, 1600, South Africa

1968/011192/07

DATE OF PUBLICATION OF THIS PROFESSIONAL INFORMATION

Date on the registration certificate: Old medicine

Date of the most recently revised professional information: 30 March 2012

Manufactured by Schering-Plough, France for Bayer (Pty) Ltd.