PROFESSIONAL INFORMATION

SCHEDULING STATUS

S2

1 NAME OF THE MEDICINE

DEMAZIN SYRUP, 1,25 mg and 2,5 mg, syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains 1,25 mg chlorphenamine maleate and 2,5 mg phenylephrine hydrochloride.

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

Contains sugar: (sucrose) 550 mg/ml. Alcohol free.

For full list of excipients, see **section 6.1**.

3 PHARMACEUTICAL FORM

Syrup

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

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Posology

Adults: 10 ml every three or four hours.

Paediatric population

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.

Refer to section 4.4.

Elderly population

Dose reduction may be required **(refer to section 4.4)**.

Method of administration

Take orally.

4.3 Contraindications

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

DEMAZIN SYRUP is contraindicated 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.

Not recommended for use in pregnancy and lactation **(refer section 4.6)**.

Severe hypertension or ischaemic heart disease.

4.4 Special warnings and precautions for use

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 may cause paradoxical hyperexcitability, nervousness, irritability and insomnia.

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.

Contains sucrose which may have an effect on the glycaemic control of patients with diabetes mellitus.

Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrase-isomaltase insufficiency should not take DEMAZIN SYRUP.

Co-administration with any substrate for alcohol dehydrogenase such as ethanol may induce adverse effects in children less than 5 years old.

Medical monitoring is required in patients with impaired renal or hepatic functions because various adverse events attributed to propylene glycol have been reported such as renal dysfunction (acute tubular necrosis), acute renal failure and liver dysfunction.

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

Paediatric population

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.

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.

4.5 Interaction with other medicines and other forms of interaction

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.

Reversal of the action of antihypertensive agents may occur and therefore special care is advisable in patients receiving antihypertensive therapy. Interactions with alpha- and betablockers may be complex and can produce hypertensive crisis.

Interactions are possible with guanethidine, reserpine, tricyclic antidepressants, digoxin and alphamethyldopa.

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 medicines 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 chlorphenamine maleate may prevent or diminish otherwise positive reactions to dermal reactivity indicators.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

Pregnancy

Phenylephrine is best avoided in pregnancy, because of the potential promotion of uterine contractility and peripheral vasoconstriction, with the possibility of foetal hypoxia (see section **4.3 Contraindications**).

Breastfeeding

Chlorphenamine 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 (see section **4.3 Contraindications**).

Fertility

No data available.

4.7 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.

4.8 Undesirable 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.

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.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

See section **4.8 Undesirable 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.

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

ATC code: R01BA53 Phenylephrine, combinations

Mechanism of action

Chlorphenamine maleate is a histamine H_1 receptor antagonist that competes reversibly with histamine for H_1 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.

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose

Glycerin

Propylene glycol

Methylparaben

Propylparaben

Levomenthol

Vanillin flavour

Benzaldehyde

Peach flavour

Dye FD and C blue no. 1

Dye FD and C green no. 3

Dye FD and C yellow no. 6

Hydrochloric acid

Purified water

6.2 Incompatibilities

None known.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at or below 25 ºC.

6.5 Nature and contents of container

Amber glass bottles of 100 ml.

6.6 Special precautions for disposal <and other handling>

No special requirements

7 HOLDER OF CERTIFICATE OF REGISTRATION

iNova Pharmaceuticals (Pty) Ltd

15E Riley Road

Bedfordview

2007

8 REGISTRATION NUMBER(S)

C535 (Act 101/1965)

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Old medicine

10 DATE OF REVISION OF THE TEXT

27 January 2023

NAMIBIA

Scheduling Status: NS1

Registration Number: 14/5.8/0376

BOTSWANA

Scheduling Status: S2

Registration Number: BOT1703220A