Professional Information

SCHEDULING STATUS

S2

PROPRIETARY NAME AND DOSAGE FORM

DEMAZIN® ND

COMPOSITION:

Active Ingredients:

Each DEMAZIN ND contains 5 mg loratadine (micronised) in the tablet coating and 120 mg pseudoephedrine sulphate, equally distributed between the tablet coating and the barrier-coated core. The two active components in the coating are quickly liberated while the release of decongestant in the core is delayed to ensure a long-lasting effect.

Inactive ingredients: Acacia, calcium sulphate, carnauba wax, lactose, magnesium stearate, maize starch, microcrystalline cellulose, neutral soap, oleic acid, povidone, rosin, sucrose, talc, titanium dioxide, white wax and zein.

Contains sugars: Lactose monohydrate 17 %, Sucrose 19 %

CATEGORY AND CLASS:

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

PHARMACOLOGICAL ACTION:

Loratadine is a long-acting, tricyclic antihistamine with selective peripheral H1-receptor antagonist activity.

Pseudoephedrine sulphate is an orally active vasoconstrictor which produces sustained shrinkage of congested upper respiratory mucosa through a sympathomimetic action

INDICATIONS:

DEMAZIN® ND are indicated for the relief of nasal and ocular symptoms of upper respiratory mucosal congestion, as in allergic and vasomotor rhinitis.

CONTRAINDICATIONS:

DEMAZIN® ND are contraindicated in patients who have shown sensitivity or idiosyncrasy to either of its active components, to adrenergic agents or to other drugs of similar chemical structure and in patients receiving monoamine oxidase inhibitors, or within 14 days of stopping such treatment.

DEMAZIN ND should not be used in patients with severe or uncontrolled hypertension.

DEMAZIN ND is contraindicated in patients with severe acute or chronic kidney disease or failure.

Narrow angle glaucoma, urinary retention, coronary artery disease and hyperthyroidism are relative contra-indications.

The safe use of DEMAZIN ND in children under 12 years of age, or in pregnant or lactating mothers has not been established. [SEE HUMAN REPRODUCTION]

Safety in the elderly has not been established.

WARNINGS AND SPECIAL PRECAUTIONS:

DEMAZIN ND contains sugar, patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose galactose malabsorption should not take DEMAZIN ND.

Special Precautions

In patients 60 years of age or older, sympathomimetics are also more likely to cause adverse reactions such as confusion, hallucination, convulsions, central nervous system depression and death. Consequently, caution should be exercised when administering a repeat-action formulation to elderly patients.

Sympathomimetics should be given with caution in patients with glaucoma, stenosing peptic ulcer, pyloroduodenal obstruction, prostatic hypertrophy, urinary tract obstruction, cardiovascular disease, increased intraocular pressure or diabetes mellitus and in patients older than 60 years of age.

Patients with severe liver impairment should be administered a lower initial dose because they may have reduced clearance of loratadine; an initial dose of one DEMAZIN ND daily is recommended.

Pseudoephedrine sulphate has been abused. At high doses subjects commonly experience an elevation of mood, decreased appetite and a sense of increased physical energy, mental capacity and alertness. Anxiety, irritability and loquacity also have been experienced. With continued use, tolerance develops; the user increases the dose and ultimately toxicity occurs. Depression may follow rapid withdrawal.

Acute generalized exanthematous pustulosis (AGEP), a form of severe skin reaction, may occur with pseudoephedrine-containing products in isolated cases. If signs and symptoms such as fever, erythema, or small (generalized) pustules are observed, patients should discontinue to use the drug and consult their physician.

Pseudoephedrine is associated with risks of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS). These are rare conditions that can involve reduced blood supply to the brain, potentially causing serious, life-threatening complications. Discontinue treatment immediately if any symptoms of PRES or RCVS, such as a sudden severe headache, feeling sick, vomiting, confusion, seizures and visual disturbances occur.

Effects on Ability to Drive and Use Machinery

Loratadine lacks significant sedative effects.

Patients should, however, be warned that a small number of individuals may experience sedation. It is therefore advisable to determine individual response before driving or performing complicated tasks. This effect may be compounded by the simultaneous intake of alcohol or other central nervous system depressants.

MEDICINE/LABORATORY TEST INTERACTIONS:

Antihistamines should be discontinued approximately 48 hours prior to skin testing procedures since these medicines may prevent or diminish otherwise positive reactions to dermal reactivity indicators.

The in vitro addition of pseudoephedrine to sera containing the cardiac isoenzyme MB of serum

creatine phosphokinase progressively inhibits the activity of the enzyme. The inhibition becomes complete over 6 hours.

When sympathomimetics are given to patients receiving monoamine oxidase inhibitors, hypertensive reactions including hypertensive crisis may occur.

Increase in plasma concentrations of loratadine have been reported after concomitant use with ketoconazole, erythromycin or cimetidine in controlled clinical trials, but without clinically significant changes (including electrocardiographic). Other medicines known to inhibit hepatic metabolism should be co-administered with caution until definitive interaction studies can be completed.

Sympathomimetics reduce the antihypertensive effects of methyldopa, mecamylamine, reserpine and veratrum alkaloids. Increased arrhythmias may occur in conjunction with digitalis. The effect of beta-adrenergic blockers may also be reduced. Antacids increase the rate of pseudoephedrine absorption, while kaolin decreases the absorption rate.

HUMAN REPRODUCTION:

Safety use of DEMAZIN ND in pregnancy and lactating mothers has not been established.

DOSAGE AND DIRECTIONS FOR USE:

Adults and children over 12 years of age

One DEMAZIN ND twice daily, without chewing the tablet.

The duration of treatment should be determined by the duration of symptoms and should not exceed 14 days.

SIDE EFFECTS:

Table 1: The following side-effects have been reported and the frequencies are unknown:	
Immune system disorders	Hypersensitivity reactions including bronchospasm, angioedema and anaphylaxis
Psychiatric disorders	Depression, confusion, decreased libido, hyperkinesia, agitation, apathy, euphoria, insomnia,

Nervous system disorders	Nervousness, dizziness, thirst, hypoesthesia, paraesthesia, tremor, increase in sweating, migraine, malaise, central nervous stimulation, excitability, convulsions, rigors, anxiety, paroneiria, taste abnormality
Eye disorders	Eye disorders
Ear and labyrinth disorders	Vertigo, earache, tinnitus,
Cardiac disorders	Tachycardia, postural hypotension, palpitation, hypertension, supraventricular tachyarrythmias, cardiovascular collapse
Vascular disorders	Flushing, hypertension
Respiratory, thoracic and mediastinal disorders	Pharyngitis, rhinitis, bronchospasm, coughing, dyspnoea, nasal congestion, sneezing, nasal irritation, epistaxis.
Gastro-intestinal disorders	Vomiting, nausea, abdominal distress, change in bowel habits, dyspepsia, haemorrhoids, taste abnormality, tongue discolouration, tongue disorder, eructation, dehydration
Hepato-biliary disorders	Transient abnormal hepatic function, abnormal hepatic function
Skin and subcutaneous tissue disorders	Pruritus, rash, urticaria, acne, alopecia
Musculoskeletal and connective tissue disorders	Arthralgia, back pain, leg cramps, asthenia
Renal and urinary disorders	Dysuria, micturition disorder, nocturia, polyuria, urinary retention,
General disorders and administrative site conditions	Dysphonia, increased appetite, anorexia, increased weight, epistaxis, asthenia malaise, fatigue, rigors, excitability

From post-marketing experience, isolated cases of acute generalized exanthematous pustulosis (AGEP), a form of severe skin reaction, have been reported with pseudoephedrine-containing products.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See “SIDE EFFECTS”.

Overdosage Information: In the event of overdosage, general symptomatic and supportive treatment should be started immediately and maintained for as long as necessary.

Manifestations: They may vary from central nervous system depression (sedation, apnoea, diminished mental alertness, cyanosis, coma, cardiovascular collapse) to stimulation (insomnia, hallucination, tremors or convulsions) to death. Other signs and symptoms may be euphoria, excitement, tachycardia, palpitations, thirst, perspiration, nausea, dizziness, tinnitus, ataxia, blurred vision and hypertension or hypotension. Stimulation is particularly likely in children, as are atropine-like signs and symptoms (dry mouth, fixed and dilated pupils, flushing, hyperthermia and gastrointestinal symptoms).

In large doses sympathomimetics may give rise to giddiness, headache, nausea, vomiting, sweating, thirst, tachycardia, precordial pain, palpitations, difficulty in micturition, muscular weakness and tenseness, anxiety, restlessness and insomnia. Many patients can present a toxic psychosis with delusions and hallucinations. Some may develop cardiac arrhythmias, circulatory collapse, convulsions, coma and respiratory failure.

The Oral LD50 values for this combination product were greater than 525 and 1 839 mg/kg in mice and rats, respectively.

Treatment: Treatment is symptomatic and supportive.

IDENTIFICATION;

White to off-white, biconvex, coated tablets.

PRESENTATION;

Blister packs of 6 tablets.

STORAGE INSTRUCTIONS:

Store at or below 25 °C. Protect from moisture.

Keep out of reach of children.

REGISTRATION NUMBER:

27/5.8/0373

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

iNova Pharmaceuticals (Pty) Ltd

15E Riley Road

Bedfordview

2007

DATE OF PUBLICATION OF THIS PROFESSIONAL INFORMATION:

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