1.5.5 Proposed Clean Patient Information Leaflet

SCHEDULING STATUS:

S2

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

DEMAZIN® NS

5 mg loratadine (micronized) and 120 mg pseudoephedrine sulphate

READ ALL OF THIS LEAFLET CAREFULLY BECAUSE IT CONTAINS IMPORTANT INFORMATION FOR YOU DEMAZIN ND is available with or without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use DEMAZIN ND carefully to get the best results from it.

•Keep this leaflet. You may need to read it again

•Do not share DEMAZIN ND with any other person

•Ask your pharmacist if you need more information or advice

•You must see a doctor if your symptoms worsen or do not improve after 14 days.

WHAT DEMAZIN ND CONTAINS

Each DEMAZIN ND contains 5 mg loratadine (micronized) 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 (pseudoephedrine) in the core is delayed to ensure a long-lasting effect.

The other ingredients are: 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.

WHAT DEMAZIN ND IS USED FOR

DEMAZIN ND is a tablet that has a two active ingredients.

Loratadine belongs to a class of medicines known as antihistamines. Antihistamines help to reduce allergic symptoms by preventing the effects of a substance called histamine, which is produced in the body.

Pseudoephedrine sulphate is an orally active vasoconstrictor (agent that causes narrowing of blood vessels therefore a decrease in blood flow) which produces a sustained shrinkage of congested upper respiratory mucous membranes.

DEMAZIN ND relieves symptoms of the nose and eyes due to upper respiratory mucosal congestion, such as allergic and vasomotor (controlling of the muscular walls of the blood vessels) rhinitis (runny nose and/or watery eyes).

BEFORE YOU TAKE DEMAZIN ND

DEMAZIN ND should not be used:

If you are hypersensitive (allergic) to loratadine or to any of the other ingredients of DEMAZIN ND or to adrenergic agents or to other drugs of similar chemical structure.

If you are receiving monoamine oxidase inhibitors, or within 14 days of stopping such treatment.

If you suffer from narrow angle glaucoma, urinary retention, severe hypertension or coronary artery disease and hyperthyroidism, consult your health care practitioner before taking DEMAZIN ND.

TAKE SPECIAL CARE WITH DEMAZIN ND:

The safe use of DEMAZIN ND in children under twelve years of age has not been established.

The safe use of DEMAZIN ND in the elderly has not been established.

If you suffer from glaucoma), stenosing peptic ulcer, pyloroduodenal obstruction, prostatic hypertrophy, urinary tract obstruction, cardiovascular disease, increased intraocular pressure or diabetes mellitus, contact a health care practitioner before taking DEMAZIN ND S.

DEMAZIN ND may cause central nervous system stimulation, excitability and convulsions or cardiovascular collapse with accompanying hypotension.

If you are 60 years of age or older, DEMAZIN ND are also more likely to cause adverse reactions such as confusion, hallucination, convulsions, central nervous system depression and death. Consequently, you should exercise caution when taking a long-action formulation.

If you suffer from severe liver impairment you should be administered a lower initial dose because you may

have reduced clearance of loratadine; an initial dose of one DEMAZIN ND daily is recommended.

Pseudoephedrine sulphate has been abused. At high doses, people 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.

Taking DEMAZIN ND with food and drink

DEMAZIN ND may be taken with or without a meal.

Pregnancy and breast-feeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machinery

DEMAZIN ND lack significant sedative effects. However some people may suffer sedation. Test your response before driving or performing complicated tasks. You can suffer sedation if you take alcohol or other central nervous system depressant at the same time as taking DEMAZIN ND S.

TAKING OTHER MEDICINES WITH DEMAZIN ND

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

•If you are scheduled to have any skin tests for allergies you should not take DEMAZIN ND for two days before having these tests, because this medicine may affect testresults.

•DEMAZIN ND progressively inhibits the activity of the heart isoenzyme MB, the inhibition becomes complete

over six hours.

•If you take monoamine oxidase inhibitors, hypertensive reactions including hypertensive crisismay occur.

•Ketoconazole, erythromycin or cimetidine can enhance the plasma concentrations ofloratadine.

•Do not take DEMAZIN ND together with other medicines known to slow or stopliver metabolism.

•DEMAZIN ND reduce the antihypertensive effects of methyldopa, mecamylamine,reserpine and veratrum alkaloids.

•Increased arrhythmias may occur when taken together with digitalis.

•The effect of beta-adrenergic blockers may also be reduced.

•Antacids increase the rate of pseudoephedrine absorption, while kaolin decreases theabsorption rate.

HOW TO TAKE DEMAZIN ND

Do not share medicines prescribed for you with any other person.

•Always take DEMAZIN ND exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

•The usual dose is one DEMAZIN ND a day for adults and children over twelveyears of age only.

•Do not chew the tablets

•You should take DEMAZIN ND for as long as it takes to clear your symptoms,but do not take it for longer than 14 days.

If you have the feeling that DEMAZIN ND are too strong or too weak, talk to your doctor or pharmacist.

If you take more DEMAZIN ND than you should

If you take an overdose of DEMAZIN ND, you may have symptoms which 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, dilated pupils; flushing; hyperthermia and gastro-intestinal symptoms).

If you take large doses, DEMAZIN ND 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 people may develop cardiac arrhythmias,

circulatory collapse, convulsions, coma and respiratory failure.

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

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take DEMAZIN ND:

If you forget to take your dose on time, take it as soon as possible, then go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with DEMAZIN ND is stopped:

There should be no symptoms from stopping taking DEMAZIN ND, if you experience some

consult your doctor or pharmacist.

POSSIBLE SIDE-EFFECTS

Like all medicines, DEMAZIN ND can have side-effects. Contact a doctor or pharmacist if you have any reaction to DEMAZIN ND that continues, is bothersome or that you think is serious.

Table 1:The following side-effects have been reported and the frequencies are unknown:	
Immune System disorders	Hypersensitivity (allergic) reactions including bronchospasm (Sudden constriction of the small airways of the lung that can cause wheezing and shortness of breath) , angioedema (rapid swelling of the skin and submucosal tissues) and anaphylaxis (Serious, life-threatening allergic reaction)

Neurological	Nervousness, dizziness, fatigue, arthralgia (severe joint pain), confusion, hyperkinesias (extreme restlessness in children), hypoesthesia, paraethesia (pins and needles), tremor, vertigo, flushing, increased sweating, agitation, apathy, depression, euphoria, migraine, asthenia (weakness), malaise, rigors, anxiety (feelings of dread or danger) , insomnia (difficulty sleeping or falling asleep)
Gastro-intestinal	Nausea, abdominal distress, anorexia, thirst, increased appetite, dyspepsia, eructation (belching), haemorrhoids, tongue discolouration, tongue disorder, vomiting, dehydration
Cardiovascular	Tachycardia, hypertension, palpitation, supraventricular tachyarrhythmias, postural hypotension (low blood pressure)
Respiratory	Pharyngitis, rhinitis, change in bowel habits, bronchospasm, coughing, dyspnoea, epistaxis (nose bleeds), nasal congestion, sneezing, nasal irritation
Renal and urinary disorders	Dysuria, micturition disorder, nocturia, polyuria, urinary retention
General	Paroneiria, weight increase, back pain, leg cramps, anaphylaxis,
Eye disorders	Dysphonia, eye disorders
Ear, Nose, Throat	Earache, tinnitus, taste abnormality
Hepato-biliary	Transient hepatic function, abnormal hepatic function
Skin and subcutaneous tissue	Acne, pruritis, rash, urticaria, alopecia
Productive system	Decreased libido

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

Not all side-effects reported for DEMAZIN ND are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

STORING AND DISPOSING OF DEMAZIN ND S

Store all medicines out of the reach and sight of children.

Store at or below 25°C in a dry place away from moisture.

Do not freeze. (Do not store in a bathroom or a refrigerator).

Keep the blister card in the carton until you need to take the tablets.

Do not use this product after the expiry date that appears on the package.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF DEMAZIN ND S:

Blister packs of 6 tablets.

IDENTIFICATION OF DEMAZIN ND S

White to off-white, biconvex, coated tablets.

REGISTRATION NUMBER

27/5.8/0373

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF REGISTRATION HOLDER

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2007

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