APPROVED PROPOSED PROFESSIONAL INFORMATION

SCHEDULING STATUS: S2

1. NAME OF THE MEDICINE

RHINETON NON DROWSY

tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

RHINETON NON DROWSY

: Each tablet contains loratadine 10 mg.

Excipients with known effect:

Contains sugar: Lactose (78,25 mg per tablet).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets

White to off-white, uncoated, round, flat tablets with bevelled edges, debossed with 'R' on one side and '10' on the other.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

RHINETON NON DROWSY are indicated in adults for the relief of symptoms associated with perennial and /or seasonal allergic rhinitis, chronic urticaria and other allergic skin disorders.

4.2 Posology and method of administration

Posology

Adults

One RHINETON NON DROWSY orally once daily.

Special populations

Use in patients with hepatic failure or renal impairment:

In patients with hepatic failure or renal impairment, an initial dose of 5 mg once daily or 10 mg on alternate days is recommended.

Use in elderly patients:

Safety of RHINETON NON DROWSY in the elderly has not been established (see section 4.3).

Paediatric population

Safety and efficacy of RHINETON NON DROWSY in children under two years of age have not been established (see section 4.3).

Method of administration

RHINETON NON DROWSY are for oral administration.

RHINETON NON DROWSY can be taken with or without meal.

4.3 Contraindications

Hypersensitivity or idiosyncratic reaction to loratadine or to any of the excipients listed in section 6.1.

Safety of RHINETON NON DROWSY 10 in the elderly has not been established.

Safety and efficacy of RHINETON NON DROWSY 10 in children under two years of age have not been established.

RHINETON NON DROWSY are contraindicated in **pregnancy and lactation**

as the safety has not been established (see section 4.6).

4.4 Special warnings and precautions for use

RHINETON NON DROWSY lack 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.

RHINETON NON DROWSY should be administered with caution in patients with severe hepatic impairment because they may have a reduced clearance of loratadine. A lower initial dose of 5 mg once daily or 10 mg every other day is recommended in such patients.

RHINETON NON DROWSY should be discontinued at least two days (48 hours) prior to skin testing procedures, since it may prevent or diminish otherwise positive reactions to dermal reactivity indicators.

Geriatrics: See section 4.3

The use of RHINETON NON DROWSY **has been associated with the risk of weight gain (see section 4.8).**

Important information about excipients:

Lactose

RHINETON NON DROWSY contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicines and other forms of interaction

Medicine/laboratory test interactions

RHINETON NON DROWSY should be discontinued about two days prior to skin testing procedures, since it may prevent or diminish otherwise positive reactions to dermal reactivity indicators (see section 4.4).

When administered concurrently with alcohol, RHINETON NON DROWSY have no potentiating effects. However, concomitant consumption of excessive amounts of alcohol should be avoided (see section 4.4).

Caution should be exercised when other medicines known to inhibit hepatic microsomal enzymes are co-administered with RHINETON NON DROWSY. Medicines known to inhibit either P450 3A4 or P450 2D6 are quinidine, fluconazole or fluoxetine.

An 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 together with RHINETON NON DROWSY until definitive interaction studies can be completed or in the absence of formal interaction studies.

4.6 Fertility, pregnancy and lactation

Contraindicated in pregnancy and lactation (see section 4.3).

Fertility

There is no fertility data available.

4.7 Effects on ability to drive and use machines

RHINETON NON DROWSY lack significant sedative effects. However, a few patients treated with non-sedating antihistamines such as RHINETON NON DROWSY have experienced drowsiness. Therefore, it is prudent that caution should be exercised before driving or operating machinery; the effect of RHINETON NON DROWSY on a particular patient can be ascertained after the first few doses. This effect may be compounded by the simultaneous intake of alcohol or other central nervous system depressants.

4.8 Undesirable effects

Tabulated list of adverse reactions

MedDRA System organ class	**Frequency**	**Adverse reactions**
Blood and lymphatic system disorders	Less frequent	Thrombocytopenia.
Immune system disorders	Less frequent	Hypersensitivity reactions (including skin rash, bronchospasm, angioedema and anaphylaxis) and cross sensitivity.
Psychiatric disorders	Frequent	Insomnia, nervousness.

	Less frequent	Depression.
Nervous system disorders	Frequent	Headache, somnolence, .
	Less frequent	Dizziness, convulsions, sweating, paraesthesias, extrapyramidal effects, tremor, sleep disturbances,
Cardiac disorders	Less frequent	Tachycardia, palpitations and dysrythmias, including ventricular and supraventricular dysrythmias; hypotension.
Ear and labyrinth disorders	Less frequent	Tinnitus.
Cardiac disorders	Less frequent	Tachycardia, palpitations and dysrythmias, including ventricular and supraventricular dysrythmias; hypotension.
Gastrointestinal disorders	Frequent	Increased appetite
	Less frequent	Nausea, vomiting, diarrhoea, dry mouth, gastritis, or epigastric pain, anorexia.
Hepato-biliary disorders	Less frequent	Abnormal hepatic functions, including jaundice and hepatitis.
Skin and subcutaneous tissue disorders	Less frequent	Rash, alopecia.
Musculoskeletal and connective tissue disorders	Less frequent	Myalgia.
General disorders and administration site conditions	Frequent	Fatigue.
Investigations	Frequency unknown	Weight increase.

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

Overdosage with loratadine may manifest in any of the symptoms described under section 4.8. There is no specific antidote for loratadine. In case of overdosage, treatment which is symptomatic and supportive should be started immediately.

Consider standard measures to remove any unabsorbed medicine in the stomach, such as adsorption by activated charcoal administered as a slurry with water. The administration of gastric lavage should be considered.

0,9 % Sodium chloride solution is the lavage solution of choice, particularly in children.

In adults tap water can be used; however, as much as possible of the amount administered should be removed before the next instillation. Sodium chloride or saline cathartics draw water into the bowel by osmosis and therefore, may be valuable for their action in rapid dilution of

bowel content.

Loratadine is not dialysable. After emergency treatment, the patient should continue to be under medical supervision.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 5.7.1 Antihistaminics.

Loratadine is a long acting tricyclic antihistamine with selective peripheral H_1-receptor antagonistic activity and no central sedative or anticholinergic effects. It acts by competing with histamine for H_1-receptor sites on effector cells. Loratadine thereby prevents, but does not reverse responses mediated by histamine alone.

5.2 Pharmacokinetic properties

Absorption

Loratadine is well absorbed from the gastro-intestinal tract after oral

administration.

Bioavailability is increased when administered with food.

Biotransformation

The major metabolite, descarboethoxyloratadine, has histamine-H_1 blocking activity. Reported half-lives for loratadine and descarboethoxyloratadine are 8 $\pm$ 6 hours and 18 $\pm$ 6 hours respectively.

Distribution

Loratadine is about 97 % bound to plasma proteins; descarboethoxyloratadine is less extensively bound (73-77 %). The volume of distribution is about 120 ± 80 l/kg. Loratadine and its metabolites are detected in breast milk, but do not appear to cross the blood-brain barrier to a significant extent.

Elimination

Loratadine and its metabolites are excreted in the urine and faeces.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate

Maize starch

Pregelatinized starch

Magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C, protected from moisture.

6.5 Nature and contents of container

Blister strips of clear, colourless PVC/PVDC film with aluminium foil backing containing 10 tablets.

Cartons contain 10 and 30 tablets.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Ranbaxy Pharmaceuticals (Pty) Ltd.

a Sun Pharma company

14 Lautre Road, Stormill, Ext. 1

Roodepoort, 1724

South Africa

8. REGISTRATION NUMBERS

36/5.7.1/0231

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24 October 2003

10. DATE OF REVISION OF THE TEXT

15 August 2022

Namibia:
NS1 Reg. no.: 08/5.7.1/0020