1.3.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S2

PROPRIETARY NAME AND DOSAGE FORM

RINEX DIFFUCAPS (capsule)

RINEX SYRUP

RINEX PED (syrup)

COMPOSITION

RINEX DIFFUCAPS

Each RINEX DIFFUCAPS capsule contains:

Chlorphenamine maleate	12 mg
Phenylpropanolamine hydrochloride	30 mg
Phenylephrine hydrochloride	20 mg

Excipients:

Colour FD & C Blue No. 2 (C.I. No. 73015), erythrosine (C.I. No. 45430), gelatin, lactose monohydrate, maize starch, povidone, shellac, stearic acid, sucrose, sunset yellow (C.I. No. 15985), talc

Contains sugar: Sucrose 159,15 mg, lactose monohydrate 6,00 mg

RINEX SYRUP

Each 5 ml of RINEX SYRUP contains:

Chlorphenamine maleate	4 mg
Phenylpropanolamine hydrochloride	5 mg
Phenylephrine hydrochloride	5 mg

Excipients:

Carmoisine W.S. (C.I. No. 14720), citric acid monohydrate, ethanol (96 %) rebate, flavor essence cherry No. 1, flavour vanilla No. 1, nipasept, monosodium glutamate, saccharin sodium, sodium cyclamate, sorbitol (70 %) solution.

Contains alcohol: 4,50 % *v/v*

Preservative: Nipasept 0,12 % *m/v*

Contains sugar : Sorbitol (70 %) solution 3,5 ml

Contains sweetener: Sodium cyclamate 40 mg, saccharin sodium 4 mg

RINEX PED

Each 5 ml of RINEX PED contains:

Chlorphenamine maleate	2 mg
Phenylpropanolamine hydrochloride	2,50 mg
Phenylephrine hydrochloride	2,50 mg

Excipients:

Carmoisine W.S (C.I. No. 14720), citric acid monohydrate, flavour cherry essence No. 1, flavour vanilla essence No. 1, nipasept, monosodium glutamate, saccharin sodium, sodium cyclamate, sorbitol (70 %) solution.

Alcohol free

Preservative: Nipasept 0,12 % *m/v*

Contains sugar: Sorbitol (70 %) solution 3,504 ml

Contains sweetener: Sodium cyclamate 40 mg, saccharin sodium 4 mg

CATEGORY AND CLASS

A 5.8 Preparation for the common cold, including nasal decongestants

PHARMACOLOGICAL ACTION

The combination has antihistaminic and sympathomimetic properties.

Chlorphenamine is an antihistamine with sedative properties.

Phenylephrine is a sympathomimetic amine which acts directly on alpha-adrenergic receptors. It is without significant stimulating effects on the central nervous system at usual doses.

Phenylpropanolamine is a sympathomimetic amine which acts directly by displacing noradrenaline from pre-synaptic stores. It has some direct effects on both alpha- and beta-adrenergic receptors with predominantly alpha-adrenergic activity.

The sympathomimetic amines have alpha-adrenergic receptor stimulating properties on the mucosa of the respiratory tract producing vasoconstriction.

INDICATIONS

RINEX is indicated for:

- The symptomatic relief of nasal congestion due to the common cold and flu, hay fever, allergic rhinitis, other upper respiratory allergies, or associated with sinusitis.
- Relief of Eustachian tube congestion as an adjunct to treatment of middle ear infection.

CONTRAINDICATIONS

- Hypersensitivity to any of the active ingredients or excipients in RINEX (see COMPOSITION).
- During acute attacks of asthma.

- Patients on a monoamine oxidase inhibitor for depression (e.g. tranylcypromine) or within two weeks of stopping treatment.
- Safety in pregnancy and lactation has not been established (see HUMAN REPRODUCTION).
- Patients with hypertension, hyperthyroidism or cardiovascular disease, such as ischaemic heart disease.
- RINEX PED syrup and RINEX SYRUP are contraindicated in children under six years of age.
- RINEX DIFFUCAPS is contraindicated in children under twelve years of age.

WARNINGS AND SPECIAL PRECAUTIONS

RINEX should not be taken for more than seven 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, tremulousness or cardiac dysrhythmia. This may also occur in sensitive individuals at small doses.

RINEX should be used with caution in patients with:

- Occlusive vascular disease including arteriosclerosis and aneurysms.
- Closed-angle glaucoma.
- Phaeochromocytoma.

Severe hypertensive episodes leading to intracranial haemorrhage have followed phenylpropanolamine ingestion. Patients should be informed of the dangers of exceeding the recommended dose; in particular the increased risk of serious adverse events such as hypertensive crisis and haemorrhagic stroke. Patients with cardiovascular disease, hypertension or hyperthyroidism should not use the RINEX products (see CONTRAINDICATIONS). In addition, RINEX may aggravate conditions such as diabetes, glaucoma or prostatic enlargement. Patients on mono-amine oxidase inhibitors (e.g. tranylcypromine) should not use RINEX (see CONTRAINDICATIONS).

RINEX should be used with care in conditions such as narrow angle glaucoma, urinary retention and prostatic hypertrophy.

RINEX may also suppress positive skin results and should thus be stopped several days before the test.

RINEX should be used with caution in patients who may be hyper susceptible to the effects of sympathomimetics, particularly those with hyperthyroidism. Great care is also needed in patients with cardiovascular disease such as ischaemic heart disease; dysrhythmias or tachycardia; occlusive vascular disorders, including arteriosclerosis, hypertension, or aneurysms.

Reversal of action of many antihypertensive agents occurs in patients given sympathomimetics, and therefore special care is advisable in patients receiving antihypertensive therapy (see INTERACTIONS).

Effects on ability to drive and use machines

The use of RINEX may cause drowsiness and impaired concentration, which is aggravated by the simultaneous intake of alcohol and other central nervous system depressants; patients affected should not drive or operate machinery.

Excipients

RINEX DIFFUCAPS contains sucrose and lactose monohydrate which may have an effect on the glycaemic control of patients with diabetes mellitus. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, Lapp lactase deficiency, glucose-galactose malabsorption, fructose intolerance or sucrase-isomaltase insufficiency should not take RINEX DIFFUCAPS.

RINEX SYRUP and RINEX PED contain sorbitol and may have a laxative effect.

Patients with the rare hereditary condition of sorbitol intolerance should not take RINEX SYRUP and RINEX PED.

INTERACTIONS

Alcohol: Potentiates sedation.

Antihypertensive agents including alpha- and beta-blockers: Reversal of action of antihypertensive agents.

Cardiac glycosides, quinidine or tricyclic antidepressants: Increased risk of dysrhythmias may occur in patients.

Halothane, or other halogenated anaesthetics: May induce ventricular fibrillation.

Hypnotics and anxiolytics: May cause potentiation of drowsiness.

Monoamine oxidase inhibitors, atropine and tricyclic antidepressants: Enhancement of antimuscarinic effects.

Phenytoin: Chlorphenamine, as contained in RINEX, inhibits phenytoin metabolism leading to phenytoin toxicity.

Central nervous system depressants, including alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and tranquilisers: Enhancement of sedative effects.

Interactions are possible with reserpine, tricyclic antidepressants, digoxin and alpha-methyldopa.

HUMAN REPRODUCTION

Safety in pregnancy and lactation has not been established.

Phenylephrine hydrochloride is best avoided in pregnancy, because of the potential promotion of uterine contractility and peripheral vasoconstriction, with the possibility of foetal hypoxia.

DOSAGE AND DIRECTIONS FOR USE

DO NOT EXCEED THE RECOMMENDED DOSE.

RINEX DIFFUCAPS

Adults and children 12 years and older: One capsule every 8 to 12 hours.

Do not chew the capsule or the content.

RINEX SYRUP

NOT FOR CHILDREN UNDER 6 YEARS OF AGE.

Adults and children 12 years and older: One medicine measure (5 ml) 3 to 4 times daily.

Children 6 to 12 years: Half a medicine measure (2,5 ml) 3 to 4 times daily.

RINEX PED syrup

NOT FOR CHILDREN UNDER 6 YEARS OF AGE.

Children 6 to 12 years: One medicine measure (5 ml) 3 to 4 times daily.

SIDE EFFECTS

Chlorphenamine

Blood and the lymphatic system disorders

Less frequent: Agranulocytosis, leucopenia and haemolytic anaemia

Psychiatric disorders

Less frequent: Depression, nightmares, irritability

Frequency unknown: Euphoria

Nervous system disorders

Frequent: Sedation varying from slight drowsiness to deep sleep, and including lassitude, dizziness

Less frequent: Incoordination, headache, impaired concentration

Eye disorders

Less frequent: Blurred vision

Ear and labyrinth disorders

Less frequent: Tinnitus

Cardiac disorders

Less frequent: Palpitation, tachycardia, dysrhythmia

Vascular disorders

Less frequent: Hypotension

Respiratory, thoracic and mediastinal disorders

Less frequent: Increased viscosity of bronchial secretions

Gastrointestinal disorders

Less frequent: Nausea, vomiting, diarrhoea or constipation, anorexia or increased appetite, abdominal pain, dyspepsia, dryness of the mouth and epigastric pain

Hepato-biliary disorders

Less frequent: Hepatitis, jaundice

Skin and subcutaneous tissue disorders

Less frequent: Allergic reactions including exfoliative dermatitis and cross-sensitivity to related medicines may occur, photosensitivity and skin reactions such as urticaria

Musculoskeletal, connective tissue and bone disorders

Less frequent: Muscular weakness, twitching

Renal and urinary disorders

Less frequent: Urinary retention

Frequency unknown: Difficulty in micturition, dysuria

General disorders and administrative site conditions

Less frequent: Tightness of the chest

Paradoxical central nervous system stimulation may occur, especially in children, with insomnia, nervousness, tachycardia, tremors and convulsions

Phenylpropanolamine

Psychiatric disorders

Frequency unknown: Fear, anxiety, restlessness, tremor, insomnia, confusion, irritability, weakness and psychotic states

Gastrointestinal disorders

Frequency unknown: Nausea, vomiting, appetite may be reduced, hypersalivation

Metabolism and nutritional disorders

Frequency unknown: Altered metabolism including disturbances of glucose metabolism

Phenylephrine

Psychiatric disorders

Frequent: Nervousness, irritability, restlessness, and excitability

Frequency unknown: Fear, anxiety, tremor, insomnia, confusion, weakness and psychotic

states

Nervous system disorders

Frequent: Headache, dizziness, insomnia

Eye disorders

Frequency unknown: Mydriasis, acute angle closure glaucoma

Cardiac disorders

Frequency unknown: Tachycardia or bradycardia, cardiac dysrhythmias, angina pain, palpitations, cardiac arrest

Vascular disorders

Frequent: Increased blood pressure

Frequency unknown: Hypotension with dizziness, fainting and flushing may occur, haemorrhagic stroke, flushing, sweating, vasoconstriction

Respiratory, thoracic and mediastinal disorders

Frequency unknown: Dyspnoea

Gastrointestinal disorders

Frequent: Nausea, vomiting, diarrhoea

Frequency unknown: Appetite may be reduced, hypersalivation

Metabolism and nutritional disorders

Frequency unknown: Altered metabolism including disturbances of glucose metabolism

Skin and subcutaneous tissue disorders

Frequency unknown: Allergic reactions such as rash, urticaria, allergic dermatitis, hypersensitivity reactions, including cross-sensitivity with other sympathomimetics

Renal and urinary disorders

Frequency unknown: Difficulty in micturition, urinary retention, dysuria.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS

Chlorphenamine

The main symptoms of overdosage with chlorphenamine in infants and children include ataxia, excitement, hallucinations, muscle tremor, convulsions, dilated pupils, dry mouth, flushed face and hyperpyrexia. Deepening coma, cardiorespiratory collapse and death may occur within 18 hours. In adults, the usual symptoms are drowsiness, coma and convulsions. Hypertension may also occur. Elderly patients are more susceptible to these central nervous

system depressant and hypotensive effects even at therapeutic doses.

Phenylpropanolamine

Overdosage with phenylpropanolamine may cause giddiness, headache, nausea, vomiting, sweating, thirst, palpitations, difficulty in micturition, muscular weakness and tremors, anxiety, restlessness and insomnia. Overdosage may also cause psychoses, hallucinations 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.

Phenylephrine

Overdosage with phenylephrine may cause headache, hypertension, palpitations and vomiting. 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. Unless contraindications exist, the stomach should be emptied by gastric lavage. Further treatment is symptomatic and supportive.

IDENTIFICATION

RINEX DIFFUCAPS:

Transparent, hard gelatin capsule, with a clear body and orange cap, containing blue and white pellets.

RINEX SYRUP:

A clear, red liquid with a strong cherry and vanilla odour.

RINEX PED:

A clear, red liquid with a strong cherry and vanilla odour.

PRESENTATION

RINEX DIFFUCAPS:

10 capsules are packed into clear, transparent, PVC blister strips with an aluminium backing. The blister strips are packed into an outer cardboard carton with a leaflet.

RINEX SYRUP:

100 ml of syrup is filled into an amber, round, glass bottle and capped with a white, polypropylene screw-cap with an expanded polyethylene liner. The bottle is then labelled and packed, together with a leaflet, into an outer cardboard carton.

RINEX PED:

100 ml of syrup is filled into an amber, round, glass bottle and capped with a white, polypropylene screw-cap with an expanded polyethylene liner. The bottle is then labelled and packed, together with a leaflet, into an outer cardboard carton.

200 ml of syrup is filled into an amber, round, roll on pilfer proof, glass bottle with a screw-

neck finish and capped with a 28 mm, round, flat-topped, white, polypropylene, screw-on child-lock cap with an expanded polyethylene liner and a translucent polyethylene tamper evident band. The bottle is then labelled and packed, together with a leaflet, into an outer unit cardboard carton.

Not all packs and pack sizes are necessarily marketed.

STORAGE INSTRUCTIONS

Store at or below 25 °C, in a well-closed container.

Protect from light.

Keep in original packaging until required for use.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

RINEX DIFFUCAPS: N/5.8/67

RINEX SYRUP: M/5.8/0125

RINEX PED: Q/5.8/0087

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

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

Date of registration:

RINEX DIFFUCAPS: 22 July 1981

RINEX SYRUP: 06 September 1979

RINEX PED: 19 July 1983

Date of the most recent amendment to the professional information as approved by the Authority: 02 March 2012

Namibia:	NS1
RINEX DIFFUCAPS:	90/5.8/001628
RINEX SYRUP:	90/5.8/001630
RINEX PED:	90/5.8/001629

ZA_RINECOMB_1203_05