1.5.5 Proposed Professional Information

Proposed Professional Information

SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

RHINETON (4 mg tablet)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each **RHINETON** tablet contains

Chlorpheniramine maleate 4mg

Contains sugar: Lactose monohydrate 103,645 mg per tablet

3. PHARMACEUTICAL FORM

Tablet

Yellow, round, biconvex tablet, with a diameter of 7,20 mm, and a score on the one side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

RHINETON is indicated for symptomatic treatment of perennial and seasonal allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis and mild, uncomplicated allergic skin manifestations of urticaria and angioedema. **RHINETON** is also indicated as therapy for anaphylactic reactions adjunctive to adrenaline and other standard measures after the acute manifestations have been controlled. Skin conditions such as allergic eczema, atopic dermatitis, insect bites and drug reactions are often relieved by **RHINETON**.

4.2 Posology and method of administration

Posology

Adults and children 12 years or older: One 4 mg **RHINETON** tablet every 4 to 6 hours, up to a maximum of 24 mg in 24 hours.

Children 6 to 12 years: 2 mg (Half a **RHINETON** tablet) every 4 to 6 hours, up to a maximum of 12 mg in 24 hours.

Children up to 6 years: Use is not recommended.

Method of administration

Oral administration.

4.3 Contraindications

RHINETON is contra-indicated in:

- **RHINETON** should not be used in patients with known hypersensitivity to the chlorpheniramine or any of the excipients of **RHINETON** (listed in section 6.1).
- Patients receiving MAO inhibitor therapy. The anticholinergic properties of chlorpheniramine are intensified by monoamine oxidase inhibitors (MAOIs).

4.4 Special warnings and precautions for use

This medicine may lead to drowsiness and impaired concentration, which may be aggravated by the simultaneous intake of alcohol or other central nervous system depressants eg. sedatives and tranquillizers. 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.

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.

RHINETON may cause paradoxical hyperexcitability, nervousness, irritability and insomnia. Do not give this product to children who have breathing problems such as chronic bronchitis, or who have glaucoma, without first consulting the child's doctor. **RHINETON** may cause drowsiness: Sedatives and tranquillizers may increase the drowsiness effect. Do not give this product to children who are taking sedatives and tranquillizers, without first consulting the child's doctor.

RHINETON should be used with caution in patients with narrow angle glaucoma, stenosing peptic ulcer, pyloroduodenal obstruction, prostatic hypertrophy or bladder neck obstruction, cardiovascular disease including hypertension, in those with increased intraocular pressure or hyperthyroidism. Caution should be used when the following medical conditions exist: severe cardiovascular disorders, epilepsy and during an acute attack of asthma.
Antihistamines may cause dizziness, sedation and hypotension in patients over 60 years of age.

RHINETON contains 103,645 mg lactose monohydrate per tablet.

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

- 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.
- Positive skin tests may be suppressed by antihistamines; therefore treatment with antihistamines should be stopped several days before the test.
- The action of anticoagulants may be inhibited by antihistamines

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety in pregnancy has not been established.

Breastfeeding

May inhibit lactation due to anticholinergic effects. Small amounts of antihistamines entering breast milk may cause drowsiness or excitement and / or irritability in infants.

RHINETON is contra-indicated in newborn and premature infants.

4.7 Effects on ability to drive and use machines

The anticholinergic properties of chlorphenamine may cause drowsiness, dizziness, blurred vision and psychomotorimpairment, which can seriously hamper the patients' ability to drive and use machinery.

4.8 Undesirable effects

System Organ Class	**Frequency**	**Adverse reaction**
Blood and lymphatic system disorders	Frequency unknown	Haemolytic anaemia, blood dyscrasias, agranulocytosis, leukopenia, thrombocytopenia.
Immune system disorders	Frequency unknown	Allergic reaction, angioedema, anaphylactic reactions.
Metabolism and nutrition disorders	Frequency unknown	Anorexia.

Psychiatric disorders	Frequency unknown	Confusion*, excitation*, irritability*, nightmares*, depression, hallucinations, incoordination, lassitude, tremors.
Nervous system disorders*	Frequent	Sedation, somnolence, Disturbance in attention, abnormal coordination, dizziness, headache
	Frequency Unknown	Euphoria, nervousness, insomnia, tingling, convulsions.
Eye disorders	Frequent	Blurred vision, diplopia.
Ear and labyrinth disorders	Frequency unknown	Tinnitus.
Cardiac disorders	Frequency unknown	Palpitations, tachycardia, arrhythmias, extrasystoles
Vascular disorders	Frequency unknown	Hypotension
Respiratory, thoracic and	Frequency unknown	Thickening of bronchial secretions, dryness of the mouth and respiratory

mediastinal disorders		passages, cough, tightness of chest, wheezing, nasal stuffiness.
Gastrointestinal disorders	Frequent	Nausea
	Frequency unknown	Vomiting, abdominal pain, diarrhoea, dyspepsia, loss of appetite, epigastric distress, reduction in tone and motility of the gastro-intestinal tract, resulting in gastric reflux and constipation.
Hepato-biliary disorders	Frequency unknown	Hepatitis, including jaundice.
Skin and subcutaneous tissue disorders	Frequency unknown	Exfoliative dermatitis, rash, urticaria, photosensitivity, allergic dermatitis, fever.
Musculoskeletal and connective tissue disorders	Frequency unknown	Muscle twitching, muscle weakness.
Renal and urinary disorders	Frequency unknown	Urinary retention or frequency, dysuria, difficult urination.
Reproductive system and breast disorders	Frequency unknown	Early menses.
	Frequent	Fatigue.

General disorders and administration site conditions	Frequency unknown	Chest tightness, excessive perspiration, chills, dryness of mouth nose and throat, anaphylactic shock

*Children and the elderly are more susceptible to neurological anticholinergic effects and paradoxical excitation (eg. increased energy, restlessness, nervousness).

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/

4.9 Overdose

Symptoms include drowsiness or paradoxical excitement, ataxia, tremors, athetosis, hallucinations and convulsions; hyperpyrexia may also occur. Fixed dilated pupils with a flushed face, sinus tachycardia, dyspnoea, urinary retention, dry mouth and fever. Terminally there may be deepening coma and cardiorespiratory collapse.

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: In the event of overdosage, emergency treatment should be started immediately. The stomach should be emptied by emesis. There is no specific antidote and treatment is symptomatic and supportive. Stimulants (analeptic agents) should not be used.

Hyperpyrexia, especially in children, may require treatment with tepid water, sponge baths or hypothermic blanket.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class**:** A.5.7.1. Antihistaminics.

Pharmacotherapeutic group**:** Antihistamines for systemic use,

ATC code: R06AB02

RHINETON tablets contain the antihistamine, chlorpheniramine maleate. RHINETON competes reversibly with histamine for H1 receptor sites on effector cells. They suppress those symptoms due to histamine release. Antihistamines have anticholinergic properties and have a drying effect on the nasal mucosa.

5.2 Pharmacokinetic properties

Chlorpheniramine is well absorbed from the gastro-intestinal tract, following oral administration. The effects develop within 30 minutes, are maximal within 1 to 2 hours and last 4 to 6 hours. The plasma half-life has been estimated to be 12 to 15 hours.

Chlorpheniramine is metabolised to the monodesmethyl and didesmethyl derivatives. About 22% of an oral dose is excreted unchanged in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Lactose monohydrate,
- Magnesium stearate,
- Microcrystalline cellulose,
- Purified talc,
- Quinolone yellow lake,
- Sodium lauryl sulphate.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store below 25°C. Protect from light.

6.5 Nature and contents of container

Containers of 30, 100 and 1000 tablets.

Patient ready packs of different pack sizes.

6.6 Special precautions for disposal

No special requirements for disposal

7. HOLDER OF CERTIFICATE OF REGISTRATION

RANBAXY PHARMACEUTICALS (PTY) LTD.

14 LAUTRE ROAD

STORMILL EXT.1

ROODEPOORT 1724

SOUTH AFRICA

8. REGISTRATION NUMBER(S)

36/5.7.1/0166

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24 October 2003

10. DATE OF REVISION OF THE TEXT

04 May 2023