Professional Information

SCHEDULING STATUS

S2

1. NAME OF THE MEDICINE

RHINETON SYRUP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml contains:

Chlorpheniramine maleate 2 mg

Preservatives:

Methyl hydroxybenzoate 0,12 % *m/v*

Propyl hydroxybenzoate 0,016 % *m/v*

Contains Sugar:

Liquid glucose 1,6 g/5 ml

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Syrup

A grape-red coloured syrup with a grape flavour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of conditions responsive to antihistaminic therapy.

4.2 Posology and method of administration

Posology

Adults

5 ml - 20 ml daily in divided doses.

Children

1-2 years

2,5 ml ($^1/_2$ medicine measure) orally twice daily.

2-5 years

2,5 ml ($^1/_2$ medicine measure) orally every 4 to 8 hours to a maximum of 15 ml daily.

6-12 years

5 ml (1 medicine measure) orally every 4 to 8 hours to a maximum of 30 ml daily.

Method of administration

Oral administration.

4.3 Contraindications

RHINETON SYRUP is contra-indicated in:

- In neonates and lactation (see Section 4.6).
- Paediatrics – Not recommended for newborn or premature infants because it causes anticholinergic side effects such as excitation of the central nervous system and increased tendency towards convulsions.
- Epilepsy.
- Acute attacks of asthma.

4.4 Special warnings and precautions for use

This medicine may lead to drowsiness and impaired concentration that may be aggravated by simultaneous intake of alcohol and other central nervous system depressants. Patients should be advised, particularly in the initiation therapy, against taking charge of vehicles or machinery or performing potentially hazardous tasks where loss of concentration could lead to accidents.

Avoid use of alcohol or CNS depressants.
Inform your physician if taking other medications (see Section 4.5).
Drowsiness may occur (see Section 4.4).
Geriatrics – Dizziness, confusion and hypotension is more likely to occur in geriatric patients taking antihistamines.

Except under special circumstances RHINETON SYRUP should not be used when the following medical problems exist and the risk benefit should also be considered: Bladder neck obstruction, prostatic hypertrophy, hypokalaemia, closed angle-glaucoma and open angle glaucoma.

RHINETON SYRUP contains 1.6 g of liquid glucose per 5 ml. This should be taken into account in patients with diabetes mellitus.

Patients with rare glucose-galactose malabsorption should not take this medicine.

RHINETON SYRUP contains methyl hydroxybenzoate and propyl hydroxybenzoate which may cause allergic reactions (possibly delayed).

4.5 Interaction with other medicines and other forms of interaction

- Sedating antihistamines may enhance the sedative effects of the CNS depressants including alcohol, barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives, and antipsychotics.
- Sedating antihistamines have an additive antimuscarinic action with other antimuscarinic drugs, such as atropine and some antidepressants (both tricyclics and MAOI's).

4.6 Fertility, pregnancy and lactation

Pregnancy: RHINETON SYRUP should not be administered during the early months of pregnancy because of foetal abnormalities in studies in animals.

Breast-feeding mothers: Use of **RHINETON SYRUP** is not recommended; it may cause unusual excitement or irritability in nursing 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
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
Nervous system disorders*	Frequent	Sedation, somnolence,
		disturbance in attention, abnormal coordination, dizziness, headache
Eye disorders	Frequent	Blurred vision
Ear and labyrinth disorders	Frequency unknown	Tinnitus
Cardiac disorders	Frequency unknown	Palpitations, tachycardia, arrythmias
Vascular disorders	Frequency unknown	Hypotension
Respiratory, thoracic and mediastinal disorders	Frequency unknown	Thickening of bronchial secretions
Gastrointestinal disorders	Frequent	Nausea, dry mouth
	Frequency unknown	Vomiting, abdominal pain, diarrhoea, dyspepsia
Hepato-biliary disorders	Frequency unknown	Hepatitis, including jaundice
Skin and subcutaneous tissue disorders	Frequency unknown	Exfoliative dermatitis, rash, urticaria, photosensitivity

Musculoskeletal and connective tissue disorders	Frequency unknown	Muscle twitching, muscle weakness
Renal and urinary disorders	Frequency unknown	Urinary retention
General disorders and administration site conditions	Frequent	Fatigue
	Frequency unknown	Chest tightness

*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

Anticholinergic effects – clumsiness or unsteadiness, severe drowsiness, severe dryness of mouth, nose, or throat, flushing or redness of face, shortness of breath or troubled breathing, cardiac arrhythmias, central nervous system depression and stimulation, hypotension. There is no antidote for overdose with antihistamines. Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and Class: A 5.7.1 Antihistaminics

Pharmacotherapeutic group: Antihistamines for systemic use,

ATC code: R06AB02

PHARMACOLOGICAL ACTION:

Chlorpheniramine maleate acts by competing with histamine for H_1-receptor sites on effector cells. It thereby prevents, but does not reverse, responses mediated by histamine alone.

5.2 Pharmacokinetic properties

Well absorbed from the gastrointestinal tract. Following oral administration, peak plasma concentrations are achieved in 2 – 3 hours and effects usually last 4 – 6 hours. It has a plasma half-life of about 4 – 8 hours. Widely distributed throughout the body, including central nervous system, and is excreted as metabolites in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Blackcurrant colour LS1904/18
- Citric acid anhydrous
- Glycerin
- Grape concord 1524
- Liquid glucose
- Methyl hydroxybenzoate (0,12 % *m/v*)
- Propyl hydroxybenzoate (0,016 % *m/v*)
- Purified water
- Raspberry red H1277
- Sodium cyclamate
- Sodium saccharin

- Xanthan gum.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at or below 25 °C in a cool place.

Protect from light.

Keep well closed.

6.5 Nature and contents of container

50ml and 100ml in long round amber PVC bottles, fitted with a white LDPE snap on cap.

50 ml, 100 ml and 200 ml amber glass bottles, fitted with a white Polypropylene screw on cap.

50 ml, 100 ml and 200 ml HDPE bottles, fitted with a white screw on cap.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

RANBAXY PHARMACEUTICALS (PTY) LTD.

14 LAUTRE ROAD

STORMILL EXT.1

ROODEPOORT 1724

SOUTH AFRICA

8. REGISTRATION NUMBER(S)

41/5.7.1/0780

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

09 December 2008

10. DATE OF REVISION OF THE TEXT

10 November 2022