

**REGAL PHARMACEUTICALS LIMITED  
NAIROBI, KENYA**

**1.5.3 PATIENT INFORMATION LEAFLET (PIL)**

**APPLICATION FOR REGISTRATION OF RINALIN SYRUP -  
RWANDA FOOD AND DRUGS AUTHORITY.**

# RINALIN

## CHLORPHENIRAMINE MALEATE SYRUP AND TABLETS

### Presentation:

Rinalin syrup is a yellow coloured, liquid containing Chlorpheniramine maleate BP 2mg per 5ml. Rinalin tablets are yellow coloured, round, flat faced, scored on one side, each containing Chlorpheniramine maleate BP 4 mg

### Pharmacological Actions:

Chlorpheniramine maleate is a H<sub>1</sub> receptor antagonist which inhibits most responses of smooth muscle to histamine. It blocks the action of histamine that results in increased capillary permeability and formation of oedema and wheal. It blocks the effects of Ach at nicotinic receptor sites. It reduces secretion in both the upper and lower respiratory tracts. This effect in the nasopharynx may provide some symptomatic relief of acute rhinitis associated with coryza or hay fever.

### Indications:

Rinalin is indicated for the symptomatic control / relief of all allergic conditions responsive to antihistamines like:

- Hay fever
- Vasomotor rhinitis
- Urticaria
- Angioedema
- Food allergy
- Drug and serum reactions
- Insect bites and stings

### Precautions:

Rinalin may cause drowsiness, dizziness, blurred vision and psychomotor impairment. So, persons affected should not drive or operate machinery. Caution is required when there is concurrent usage of alcohol.

In common with other drugs having anticholinergic effects, Rinalin should be used with caution in epilepsy, prostatic hypertrophy, glaucoma, hepatic disease, bronchitis, bronchiectasis, thyrotoxicosis, raised intra-ocular pressure, severe hypertension or cardiovascular disease and bronchial asthma.

Rinalin should only be used in pregnancy when clearly needed and when the potential benefits to the mother outweighs the risks to the foetus. Usage during the third trimester should be avoided.

Use by lactating mothers is not recommended because of the risks of adverse effects in the infant. Antihistamines may inhibit lactation.

### Side Effects:

The most common side effect is sedation, varying from slight drowsiness to deep sleep and including lassitude, dizziness and inco-ordination.

Other common side effects include dryness of mouth, thickened respiratory tract secretions and tightness of the chest, blurred vision, urinary retention, and constipation.

Gastro-intestinal disturbances such as nausea, vomiting, diarrhoea, increased gastric reflux or epigastric

### Dose

#### Rinalin Syrup:

##### Children: 6 - 12 years:

One 5ml spoonful every four to six hours

##### Children: 2 - 6 Years:

Consult a healthcare professional before use.

Half a 5ml spoonful every four to six hours

##### Children Below 2 Years:

Not recommended.

#### Rinalin Tablets:

##### Adults and Children

##### Over 12 years:

1 tablet every four to six hours

##### Or as directed by a doctor

DO NOT EXCEED THE STATED DOSE

If symptoms persist, seek medical advice

### Contra-indications:

Patients with a history of hypersensitivity to antihistamines or to any of the constituents.

Patients that have had monoamine oxidase inhibitor therapy within the previous 14 days.

pain are also common side effects. Less frequent side effects include arrhythmias, tachycardia and palpitations.

### Overdosage:

Symptoms and signs of overdosage include sedation, paradoxical stimulation of CNS, seizures, apnoea, convulsions, dystonic reactions and cardiovascular collapse.

Symptomatic and supportive measures should be provided, with attention to cardiac, respiratory, renal and hepatic functions and electrolyte balance. Gastric lavage or induced emesis should be included as treatment. Activated charcoal should be administered to minimise absorption.

Hypotension and arrhythmias should be treated vigorously and I.V. Diazepam and Phenytoin used for CNS convulsions.

### Storage:

Store below 25°C, in a dry and dark place.

Keep out of reach of children.

### Legal Category:

Pharmacy sale (P)

### Package Quantities:

Rinalin Syrup: 60ml, 100ml, 5 litres

Rinalin Tablets: 1000's

Ref: P07R02/2



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#### **1.5.4 MOCK-UPS AND SPECIMENS**

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