REGAL PHARMACEUTICALS LIMITED
NAIROBI, KENYA

1.5.1 SUMMARY OF PRODUCT CHARACTERISTICS

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

SUMMARY OF PRODUCT CHARACTERISTICS

RINALIN SYRUP

Table of Contents

1. Name of the medicinal product

a) Proprietary name of a medicine

Rinalin Syrup

b) Approved generic name(s)

Chlorpheniramine Maleate

2 Qualitative and quantitative composition

Each 5ml contains Chlorpheniramine Maleate B.P 2mg

3 Pharmaceutical form Dosage form

Syrup

4 Clinical particulars

4.1 Therapeutic indication(s)

Rinalin is indicated for the symptomatic control /relief of

all allergic conditions responsive to antihistamine like hay fever, vasomotor rhinitis, urticaria, angioedema, food allergy, drug and serum reactions and insect bites and stings.

4.2 Posology and method of administration

Method of administration: oral.

Adults and children over 12 years: 1 tablet 4 to 6 hourly. Maximum daily dose: 6 tablets (24mg) in any 24 hours.
Elderly: The elderly are more likely to experience neurological anticholinergic effects. Consideration should be given to using a lower daily

4.3 Contra-indications

Rinalin is contra-indicated in patients who are hypersensitive to antihistamines or to any of the syrup ingredients.
The anticholinergic properties of chlorpheramine are intensified by monoamine oxidase inhibitors (MAOIs). The syrup is therefore contra-indicated in patients who have been treated with MAOIs within the last fourteen days

4.4 Special warnings and precautions for use

Chlorpheramine, in common with other drugs having anticholinergic effects, should be used with caution in epilepsy; raised intra-ocular pressure including glaucoma; prostatic hypertrophy; severe hypertension or cardiovascular disease; bronchitis, bronchiectasis or asthma; hepatic impairment; renal impairment.
Children and the elderly are more likely to experience the neurological anticholinergic effects and paradoxical excitation (e.g. Increased energy, restlessness, nervousness).
The anticholinergic properties of chlorpheramine may cause drowsiness, dizziness, blurred vision and psychomotor impairment in some patients which may seriously affect ability to drive and use machinery.
The effects of alcohol may be increased and therefore concurrent use should be avoided. Should not be used with other antihistamine containing products, including antihistamine containing cough and cold medicines.
Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interactions

Concurrent use of chlorpheramine and hypnotics or anxiolytics may cause an increase in sedative effects; therefore medical advice should be sought before taking chlorpheramine concurrently with these medicines.

Chlorpheramine inhibits phenytoin metabolism and can lead to phenytoin toxicity.

The anticholinergic effects of chlorpheramine are intensified by MAOIs (see Contra- indications).

4.6 Pregnancy and lactation

Pregnancy

There are no adequate data from the use of chlorpheramine maleate in pregnant women. The potential risk for humans is unknown. Use during the third trimester may result in reactions in the newborn or premature neonates. Not to be used during pregnancy unless considered essentially by a physician..

Lactation

Chlorpheramine maleate and other antihistamine may inhibit lactation and may be secreted in breast milk. Not to be used during lactation unless considered essential by a physician..

4.7 Effects on the ability to drive and operate machinery

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

4.8 Undesirable effects

Blood and lymphatic system disorders

Unknown: haemolytic anaemia, blood dyscrasias

Immune system disorders:

Unknown: allergic reaction, angioedema, anaphylactic reactions

Metabolism and nutritional disorders:

Unknown: anorexia

Psychiatric disorders:

Unknown: confusion*, excitation*, irritability y*, nightmares*, depression

Nervous system disorders*:

Very common: sedation, somnolence

Common: disturbance in attention, abnormal coordination, dizziness headache

Eye Disorders:

Common: blurred vision

Ear and labyrinth disorders:

Unknown: tinnitus

Cardiac disorders:

Unknown: palpitations, tachycardia, arrythmias

4.9 Overdose

Symptoms and signs

The estimated lethal dose of chlorpheramine is 25 to 50mg/kg body weight. Symptoms and signs include sedation, paradoxical excitation of the CNS, toxic psychosis, convulsions, apnoea, anticholinergic effects, dystonic reactions and cardiovascular collapse including arrhythmias.

Treatment

Symptomatic and supportive measures should be provided with special attention to cardiac, respiratory, renal and hepatic functions and fluid and electrolyte balance. If overdosage is by the oral route, treatment with activated charcoal should be considered provided there are no contraindications for use and the overdose has been taken recently (treatment is most effective if given within an hour of ingestion). Treat hypotension and arrhythmias vigorously. CNS convulsions may be treated with i.v. diazepam. Haemoperfusion may be used in severe cases.

5 Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: **Antihistamines for systemic use**
ATC code: R06AB04

Antihistamines diminish or abolish the actions of histamine in the body by competitive reversible blockade of histamine H_1-receptor sites on tissues. Chlorpheramine also has anticholinergic activity.
Antihistamines act to prevent the release of histamine, prostaglandins and leukotrienes and have been shown to prevent the migration of inflammatory mediators. The actions of chlorpheramine include inhibit ion of histamine on smooth muscle, capillary permeability and hence reduction of oedema and wheal in hypersensitivity react ions such as allergy and anaphylaxis.

5.2 Pharmacokinetic properties

Chlorpheramine 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.
Chlorpheramine is metabolized to the monodesmethyl and didesmethyl derivatives. About 22% of an oral dose is excreted unchanged in the urine. Only trace amounts have been found in the faeces.

5.3 Preclinical safety data

N/A..

6 Pharmaceutical particulars

6.1 List of excipients

Methyl Paraben
Propyl Paraben
Sucrose
Hydroxyethyl Cellulose
(Natrosol HHX250)
Citric Acid Anhydrous
Peppermint oil
Tartrazine yellow FD & C Yellow 5 Colour (E102)
Sunset yellow FD & C Yellow 6 Colour (E110)
Purified water

6.2 Incompatibilities - None known.

6.3Shelf-life -

- **In the original unopened container;** 36 months
- **After reconstitution (where appropriate)** NA
- **Shelf-life after first opening:** Not applicable

6.4 Special precautions for storage:

Intamine should be stored below 25^{O}C, in a dry and dark place.

Keep out of the reach of children

6.5 **Nature and composition of containers**

Pack Size: 60ml; 100ml. 60ml,100ml glass amber bottle , Rinalin Syrup Leaflets, Rinalin Syrup unit cartons,

6.6Instruction for use/handling

For internal use only

Restriction on sale / distribution:

Prescription only medicine (POM)

7 Administrative data

Name and address of holder of a registration.

Regal Pharmaceuticals Limited

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8. Registration number. – H92/075

ii. Date of first registration- **30/08/1992**