REGAL PHARMACEUTICALS LIMITED
NAIROBI, KENYA

1.5.1 SUMMARY OF PRODUCT CHARACTERISTICS

APPLICATION FOR REGISTRATION OF DELASED PAEDIATRIC COUGH SYRUP -RWANDA FOOD AND DRUGS AUTHORITY.

SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

DELASED PAEDIATRIC SYRUP

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1. NAME OF THE MEDICINAL PRODUCT

Delased Paediatric syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains;

Diphenhydramine HCl BP 7 mg, Sodium citrate 28.5mg, Menthol 0.55 mg

3. PHARMACEUTICAL FORM

Syrup

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

It is indicated for eradication of the following:

Delased Paediatric syrup relieves cough and reduces bronchial and nasal congestion in children.it relieves the symptoms of hay fever and other allergic conditions affecting the upper respiratory tract

4.2. Posology and method of administration

Route of administration: Oral

Dosage: Dosages are dependent on the weight of the Patient and the severity of the infection

4.3. Contraindications

Hypersensitivity to the active substance or any of the excipients.

Antihistamines should be used with considerable caution in patients with narrow-angle glaucoma, stenosing peptic ulcer, pyloroduodenal obstruction, symptomatic prostatic hypertrophy, or bladder-neck obstruction.

Do NOT use sodium citrate if:

You have aluminum toxicity, untreated Addison disease, low or no urine production, high blood potassium, congestive heart failure, heart damage, or severe kidney problems, or if you are dehydrated.

4.5 Interaction with other medicinal products and other forms of interaction

Taking Delased Paediatric syrup together with drugs and substances that have anticholinergic effects increases your risk of experiencing side effects such as constipations; difficulty passing urine or scanty urine output; and dryness of mouth, nose and eyes.

4.6 Pregnancy and lactation

No evidence of impaired fertility or harm to the fetus due to Diphenhydramine hydrochloride.

Because of the higher risk of antihistamines for infants generally, and for neonates and premature in particular, antihistamine therapy is contraindicated in nursing mothers.

4.7 Effects on ability to drive and use machines

N/A

4.8 Undesirable effects

- *General:* Urticaria, drug rash, anaphylactic shock, photosensitivity, excessive perspiration, chills, dryness of the mouth, nose and throat.
- *Cardiovascular System:* Hypotension, headache, palpitations, tachycardia, extrasystoles.
- *Hematologic System:* Hemolytic anemia, thrombocytopenia, agranulocytosis.
- *Nervous System:* Sedation,sleepiness,dizziness,disturbedcoordination, fatigue, confusion, restlessness, excitation, nervousness, tremor, irritability, insomnia, euphoria, paraesthesia, blurred vision, diplopia, vertigo, tinnitus, acute labyrinthitis, neuritis, convulsions.
- *GI System:* Epigastric distress, anorexia, nausea, vomiting, diarrhea, constipation.
- *GU System:* Urinary frequency, difficult urination, urinary retention, early menses.
- *Respiratory System:* Thickening of bronchial secretions, tightness of chest or throat and wheezing, nasal stuffiness.

5. PHARMACOLOGICAL PROPERTIES

Diphenhydramine is an antihistamine of the ethanolamine class. Ethanolamine antihistamines have significant antimuscarinic activity and produce marked sedation in most patients. In addition to the usual allergic symptoms, the drug also treats irritant cough and nausea, vomiting, and vertigo associated with motion sickness. It also is used commonly to treat drug-induced extrapyramidal symptoms as well as to treat mild cases of Parkinson's disease. Rather than preventing the release of histamine, as do cromolyn and nedocromil, diphenhydramine competes with free histamine for binding at HA-receptor sites. Diphenhydramine competitively antagonizes the effects of histamine on HA-receptors in the GI tract, uterus, large blood vessels, and bronchial muscle. Ethanolamine derivatives have greater anticholinergic activity than do other antihistamines, which probably accounts for the antidyskinetic action of diphenhydramine.

5.2 Pharmacokinetic properties

Diphenhydramine hydrochloride is well absorbed following oral administration, but apparently undergoes first-pass metabolism in the liver and only about 40-60% of an oral dose reaches systemic circulation as unchanged diphenhydramine. Diphenhydramine can be absorbed percutaneously following topical administration and rarely may result in systemic effects and toxicity, especially following concomitant oral and topical administration of the drug or when extensive disruption of the epidermal barrier

and exhibits anticonvulsant and neuroprotective properties in a variety of experimental Distribution of diphenhydramine into human body tissues and fluids

has not been fully characterized. Following IV administration in rats, highest concentrations of the drug are attained in the lungs, spleen, and brain, with lower concentrations in the heart, muscle, and liver.

Little, if any, is excreted unchanged in the urine; most appears as the degradation products of metabolic transformation in the liver, which are almost completely excreted within 24 hours.

5.3 Preclinical safety data

NA

6. PHARMACEUTICAL PARTICULARS

6.1. List of ingredients

Diphenhydramine HCl
Sodium Citrate
Menthol
Methyl Paraben
Propyl Paraben
Sodium Saccharin (mesh 40 - 80)
Sucrose
Alcohol 90%
(Rectified Spirit)
Hydroxyethyl Cellulose
(Natrosol HHX250)
Carmosine Colour
(E122)
Sunset Yellow FD & C Yellow 6 Colour (E110)
Strawberry Flavour
Raspberry Flavour
Purified water

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

36 month

6.4. Special precautions for storage

Store below 25^0 C, in a dry place. Protect from light keep out of reach of children.

Legal category:

Pharmacy Sale (P)

6.6Special precautions for disposal and other handling

No special requirements.

7. **REGISTRANT**

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