1. NAME OF THE MEDICINAL PRODUCT

DELASED DRY COUGHS (NON-DROWSY) SYRUP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains:
Dextrometorphan HBr BP 7.5mg

3. PHARMACEUTICAL FORM

Light brown, viscous free flowing liquid and free from any visible impurities.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Delased Dry Coughs (Non-Drowsy) is indicated as an antitussive, for the relief of persistent, dry, irritating cough

4.2 Posology and method of administration

Posology

Adults and children aged 12 years and over:

Oral. 10 ml syrup 4 times a day.

Children under 12 years:

Delased dry Coughs is contraindicated in children under the age of 12 years (see section 4.3).

The Elderly:

Normal adult dosage is appropriate, [See Pharmacokinetics in the Elderly].

Do not exceed the stated dose.

Keep out of the reach and sight of children.

Method of Administration

Oral

4.3 Contraindications

Children below 12 years of age

Patients on monoamine oxidase inhibitor therapy within previous 14 days

Dextromethorphan, in common with other centrally acting antitussive agents, should not be given to subjects in, or at risk of developing respiratory failure

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Do not combine with other treatments for coughs and colds.

Delased Dry Coughs (Non- Drowsy) should be used with caution in patients with the following conditions: prostatic hypertrophy, urinary retention, susceptibility to 'closed angle' glaucoma and hepatic disease.

Seek medical advice when suffering from chronic or persistent cough and when also suffering from asthma, and acute asthmatic attack or where cough is accompanied by excessive secretions

Keep out of the reach and sight of children.

Excipient Warnings:

Parahydroxybenzoates may cause allergic reactions (possible delayed).

Sucrose: Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Additive CNS depressant effects with alcohol and other CNS depressants including barbiturates, hypnotics, opiod analgesics, anxiolytic sedatives and anti-psychotics.

Additive anti-muscarinic effects with other drugs of similar properties such as atropine and some anti-depressants.

Not to be taken in patients taking monoamine oxidase inhibitors (MAOIs) or within 14 of stopping treatment as there is a risk of serotonin syndrome.

The concomitant use of a dextromethorphan-containing product and monoamine oxidase inhibitors can occasionally result in symptoms such as hyperpyrexia, hallucinations, gross excitation or coma

Diphenhydramine can inhibit the oxidative metabolism of some drugs.

Diphenhydramine may enhance the effects of ephedrine.

Diphenhydramine may mask the response of the skin to allergenic skin tests and also the ototoxic symptoms associated with certain antibiotics.

4.6 Pregnancy and lactation

Pregnancy

In view of the potential risks versus small benefits, it is recommended that Delased Dry Coughs should not be used during pregnancy particularly as the safety of Delased Dry Coughs in human pregnancy is not established

Lactation

In view of the potential risks versus small benefits, it is recommended that Delased Dry Coughs should not be used during lactation particularly as the safety of Delased Dry Coughs during lactation is not established

Fertility
No fertility data is available.

4.7 Effects on ability to drive and use machines

Delased Dry Coughs (Non-Drowsy) may cause drowsiness. Do not drive or operate machinery. Avoid alcoholic drink.

4.8 Undesirable effects

The overall percentage of treated patients expected to experience adverse reactions is unknown.

Common side effects include:

CNS effects such as nervous drowsiness (usually diminishes within a few days), paradoxical stimulation, nervous headache, nervous psychomotor impairment.

Anti-muscarinic effects such as urinary retention, dry mouth, blurred vision, gastrointestinal disturbances and thickened respiratory tract secretions.

Dextromethorphan: dizziness, nausea, vomiting, or gastro-intestinal disturbance may occur.

Rare side effects include:

Hypotension, extrapyramidal effects, dizziness, confusion, depression, sleep disturbances, tremor, convulsions, palpitation, arrhythmia, hypersensitivity reactions, blood disorders and liver dysfunction.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

4.9 Overdose

Symptoms and signs
The effects of acute toxicity of Deleased dry Cough may include drowsiness, hyperpyrexia, anticholinergic effects, lethargy, nystagmus, ataxia, respiratory depression, nausea, vomiting, and hyperactivity. With higher doses, and particularly in children, symptoms of CNS excitation including hallucinations and convulsions may appear; with massive doses, coma or cardiovascular collapse may follow.

Treatment

Treatment of overdose should be symptomatic and supportive. Measures to promote rapid gastric emptying (with syrup of ipecac-induced emesis or gastric lavage) and, in cases of acute poisoning, the use of activated charcoal, may be useful. The intravenous use of physostigmine may be efficacious in antagonising severe anticholinergic symptoms. Naloxone has been used successfully as a specific antagonist to dextromethorphan toxicity in children. Convulsions may be controlled with diazepam and thiopental sodium.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antihistamines for systemic use

ATC Code: R05DA09

Dextromethorphan is a non-opioid antitussive drug. It exerts its antitussive activity by acting on the cough centre in the medulla oblongata, raising the threshold for the cough reflex

5.2 Pharmacokinetic properties

Dextromethorphan

Dextromethorphan undergoes rapid and extensive first-pass metabolism in the liver after oral administration. Genetically controlled O-demethylation is the main determinant of dextromethorphan pharmacokinetics in human volunteers. It appears that there are distinct phenotypes for this oxidation process resulting in highly variable pharmacokinetics between subjects. Unmetabolised dextromethorphan, together with the three demethylated morphinan metabolites; dextrorphan (also known as 3-hydroxy-N-methylmorphinan), 3-hydroxymorphinan and 3-methoxymorphinan have been identified as conjugated products in the urine. Dextrorphan, which also has antitussive action, is the main metabolite.

5.3 Preclinical safety data

There are no preclinical data of relevance, within are additional to those already included in other sections of the SmPC

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Menthol
Methyl Paraben
Propyl Paraben
Sodium Saccharin (mesh 40 - 80)
Sucrose
Glycerin
Alcohol 90% (Rectified Spirit)
Hydroxyethyl Cellulose (Natrosol HHX250)
Sodium citrate

Citric Acid Anhydrous
Chocolate brown colour
Sunset yellow FD & C yellow 6 colour (E110)
Raspberry Flavour
Purified water

6.2 Incompatibilities
None stated

6.3 Shelf life
36 Months

6.4 Special Precautions for Storage
It should be stored below 25^0C, in a dry and dark place.
Keep out of reach of children.

6.5 Nature and contents of container
100ml glass bottles.

6.6 Special Precautions for disposal and other handling
No special requirements
Any unused product or waste material should be disposed of in accordance with local requirements

7.0 MARKET AUTHORISATION HOLDER
Regal Pharmaceuticals Limited,
P.O Box 44421-00100,
Nairobi,
Kenya.