

**DILINCT DRY COUGH SYRUP
PI – PROPOSED RA TEXT**

PROPRIETARY NAME AND DOSAGE FORM:

DILINCT DRY COUGH SYRUP

COMPOSITION:

Each 5 ml contains:

Dextromethorphan hydrobromide 15,00 mg

Preservative:

Sodium benzoate 0,20 % *m/v*

Alcohol and sugar free

Tartrazine free

Excipients: polyvinylpyrrolidone, acid citric monohydrate, saccharin sodium, xanthan gum, colour raspberry red, levomenthol, propylene glycol, glycerol, sorbitol 70 %, essence raspberry.

PHARMACOLOGICAL CLASSIFICATION:

A 10.1 Antitussives and expectorants.

PHARMACOLOGICAL ACTION:

Dextromethorphan hydrobromide is a cough suppressant. It acts centrally on the cough centre in the medulla by elevating the threshold for coughing.

INDICATIONS:

For the symptomatic relief of a dry, non-productive cough.

CONTRAINDICATIONS:

Not to be given to children under 2 years of age (See '**DOSAGE AND DIRECTIONS FOR USE**').

Hypersensitivity to any of the ingredients.

DILINCT DRY COUGH SYRUP is contraindicated in asthma and hepatic dysfunction.

It should not be given to patients at risk of developing respiratory failure.

Not to be taken for a productive cough.

**DILINCT DRY COUGH SYRUP
PI – PROPOSED RA TEXT**

WARNINGS AND SPECIAL PRECAUTIONS:

Concurrent use of **DILINCT DRY COUGH SYRUP** with monoamine oxidase inhibitors, or use of monoamine oxidase inhibitors within two to three weeks of **DILINCT DRY COUGH SYRUP** may cause hypertension, hyperpyrexia and excitation (See '**INTERACTIONS**').

Concurrent administration with other central nervous system (CNS) depressants may enhance the CNS depressant effects of these medications (See '**INTERACTIONS**').

If the cough persists, a doctor should be consulted.

Patients with the rare hereditary condition of sorbitol intolerance should not take **DILINCT DRY COUGH SYRUP**.

INTERACTIONS:

Concurrent use of **DILINCT DRY COUGH SYRUP** with monoamine oxidase inhibitors, or use of monoamine oxidase inhibitors within two to three weeks of **DILINCT DRY COUGH SYRUP** may cause hypertension, hyperpyrexia and excitation (See '**WARNINGS and SPECIAL PRECAUTIONS**').

Concurrent administration with other central nervous system (CNS) depressants may enhance the CNS depressant effects of these medications (See '**WARNINGS and SPECIAL PRECAUTIONS**').

Cytochrome P450 (CYP2D6) enzyme inhibitors such as amiodarone, fluoxetine or quinidine may inhibit the hepatic metabolism of dextromethorphan, which could result in increased dextromethorphan serum concentrations. This could cause an increased incidence of side effects.

PREGNANCY AND LACTATION:

The safety of this medicine in pregnant and lactating woman has not been established.

DOSAGE AND DIRECTIONS FOR USE:

Not to be given to children under 2 years of age (See '**CONTRAINDICATIONS**').

Shake the bottle before use. 1 medicine measure = 5 ml.

Adults: One medicine measure every four hours, or two medicine measures every six to eight hours.

Children 6 to 12 years: Half to one medicine measure every six to eight hours.

Children 2 to 5 years: Half a medicine measure every six to eight hours.

**DILINCT DRY COUGH SYRUP
PI – PROPOSED RA TEXT**

SIDE EFFECTS:

Nervous system disorders:

Less frequent: dizziness, mild drowsiness and headache.

Psychiatric disorders:

Less frequent: confusion.

Gastrointestinal disorders:

Less frequent: constipation, abdominal pain, nausea and vomiting.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Overdosage with dextromethorphan may cause confusion, excitation, respiratory depression, ataxia, blurred vision, coma, drowsiness or dizziness, severe nausea or vomiting, nervousness, restlessness, irritability or urinary retention.

Treatment is symptomatic and supportive. Gastric lavage, assisted respiration, vital sign monitoring and intravenous naloxone may be used to treat an overdose.

IDENTIFICATION:

A clear, red syrup with a raspberry taste and odour.

PRESENTATION:

Amber glass bottles of 50 ml, 100 ml and 200 ml.

Not all of the above pack sizes may be marketed at the same time.

STORAGE INSTRUCTIONS:

Store at or below 30 °C in a well-closed container. Protect from light. Do not refrigerate.

KEEP OUT OF REACH OF CHILDREN.

MARKETING AUTHORISATION NUMBER:

South Arica: 38/10.1/0239 S2

Ghana: FDB/SD.133-11705

Kenya: H2013/CTD296/027, OTC

**DILINCT DRY COUGH SYRUP
PI – PROPOSED RA TEXT**

Malawi: PMPB/PL1/85, PIM
Mozambique: 3483, PM
Zimbabwe: 2006/22.2.1/4441 P
Rwanda: TBA

NAME AND BUSINESS ADDRESS OF THE MARKETING AUTHORISATION HOLDER:

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

Private Bag X69,

Bryanston, 2021

South Africa

www.adcock.com

MANUFACTURER:

Adcock Ingram Healthcare (Pty) Limited (Clayville)

Corner Axle Drive and Baksteen Road,

Clayville, Olifantsfontein, Johannesburg, 1665, RSA

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

26 January 2006