1.3.1.1 PACKAGE INSERT

SCHEDULING STATUS: **S2**

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.

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.

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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.

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 overdosage.

IDENTIFICATION:

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

PRESENTATION:

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

STORAGE INSTRUCTIONS:

Store at or below 25 ºC in a well-closed container. Protect from light. Do not refrigerate.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

38/10.1/0239

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

Private Bag X69,

Bryanston, 2021

www.adcock.com

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