CORILIEF DRY COUGH ®

REGISTRATION NUMBER: TBA

PROPIETARY NAME:
Dextromethorphan Hydrobromide15mg/5ml Syrup

PHARMACOLOGICAL CLASSIFICATION: R05DA09 - Cough Suppressants, Excl. Combinations with Expectorants - Opium alkaloids and derivatives

CATEGORY OF DISTRIBUTION: Pharmacy Only

COMPOSITION:
Each 5ml contains: Dextromethorphan hydrobromide 15 mg

Preservatives:
Sodium Benzoate……0.5% m/v

IDENTIFICATION: Dark Brown Syrup

PRESENTATION: 100ml HDPE and Amber Glass bottles.

PHARMACOLOGICAL ACTION: Dextromethorphan has antitussive effects.

INDICATIONS: Corilief Dry Cough Syrup is indicated for the relief of persistent, dry, irritating cough.

CONTRA-INDICATIONS: Corilief Dry Cough Syrup is contraindicated in individuals with known hypersensitivity to the product or any of its components. Contra-indicated in asthma and hepatic dysfunction
Corilief Dry Cough Syrup is contraindicated in individuals who are taking, or have taken, monoamine oxidase inhibitors within the preceding two weeks. Dextromethorphan, in common with other centrally acting antitussive agents, should not be given to subjects in, or at risk of developing respiratory failure.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE:
Due to the extensive hepatic metabolism of dextromethorphan, caution should be exercised in the presence of hepatic impairment. Do not use continuously for more than 10 days: if symptoms persist, irrespective of therapy used, consult your doctor.

DOSAGE AND DIRECTIONS FOR USE
Adults: 5ml every 4 hours or 10ml every 6 to 8 hours
Children 6 to 12 years: 2.5ml -5ml every 6 to 8hours
Children 1 to 6 years: 2.5ml every 6 to 8 hours

INTERACTIONS
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.

SIDE EFFECTS
Side effects attributed to dextromethorphan are uncommon; occasionally dizziness, nausea, vomiting, or gastro-intestinal disturbance may occur.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Overdose may include drowsiness, lethargy, nystagmus, ataxia, respiratory depression, nausea, vomiting, and hyperactivity. Treatment should be symptomatic and supportive. Gastric lavage may be of use. Naloxone has been used successfully as a specific antagonist to dextromethorphan toxicity in children

STORAGE CONDITIONS:
Store in a cool place, below 30°C. Protect from light. Keep out of reach of children.

NAME OF APPLICANT

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