BENYLIN CHILDREN'S WET COUGH

SCHEDULING STATUS: S0

PROPRIETARY NAME AND DOSAGE FORM:

Benylin Children's Wet Cough (Liquid).

COMPOSITION:

Quantity per 10 ml:

Guaifenesin	100 mg
Sodium Saccharin:	16 mg
Sodium Cyclamate:	13 mg
Sorbitol Solution:	6,71 g
Contains sweetener.	
Preservative:	
Sodium Benzoate	0,1 % m/v

Alcohol free, sugar free and colourant free

PHARMACOLOGICAL CLASSIFICATION:

A: 10.1 Antitussives and Expectorants.

PHARMACOLOGICAL ACTION:

Guaifenesin has expectorant properties.

INDICATIONS:

Alleviation of cough.

CONTRA-INDICATIONS:

Hypersensitivity to any of the ingredients. Pregnancy and lactation.

Guaifenesin is considered unsafe in patients with acute porphyria.

Not recommended for children under 2 years of age.

WARNINGS AND SPECIAL PRECAUTIONS:

Guaifenesin should not be taken for persistent cough such as occurs with smoking, asthma, emphysema or where cough is accompanied by excessive secretions except under the advice and supervision of a doctor. A persistent cough may be a sign of a serious condition. If cough persists for more than one week, tends to recur or is accompanied by high fever, rash or persistent headache, consult a doctor.

INTERACTIONS:

Guaifenesin may interfere with diagnostic measurements of urinary 5-hydroxy-indoleacetic acid or vanillylmandelic acid.

HUMAN REPRODUCTION:

Benylin Children's Wet Cough should not be used during pregnancy and lactation.

DOSAGE AND DIRECTIONS FOR USE:

Children: 6 to 12 years old: 10 ml – 20 ml (two – four medicine measures) every 4 hours.

Children: 2 to 5 years old: 5 ml – 10 ml (one - two medicine measures) every 4 hours.

If symptoms persist, a doctor should be consulted.

SIDE-EFFECTS:

Gastro-intestinal discomfort, diarrhoea, dizziness, headache, nausea, vomiting, skin rash, stomach pains, urticaria and drowsiness may occur.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

In large doses, guaifenesin will cause drowsiness, nausea and vomiting.

Treatment is symptomatic and supportive.

IDENTIFICATION:

A clear, colourless to straw-coloured, syrupy liquid with a strawberry odour and taste.

PRESENTATION:

Amber glass bottles of 50 ml, 100 ml and 200 ml with a plastic measuring cup.

STORAGE INSTRUCTIONS:

Keep well closed and store in a cool place (at or below 25°C).

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

35/10.1/0266

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

Johnson & Johnson (Pty) Ltd.

241 Main Road

RETREAT

7945

South Africa

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