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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BENYLIN CHILDREN'S WET COUGH

SKEDULERINGSTATUS:

S0

EIENDOMSNAAM EN DOSEERVORM:

Benylin Children's Wet Cough Vloeistof

SAMESTELLING:

Hoeveelheid per 10 ml:

Guaifenesien	100 mg
Natriumsakkarien: 16 mg	
Natriumsiklamaat: 13 mg	
Sorbitoloplossing: 6,71 g	
Bevat versoeter.	
Preserveermiddel:	
Natriumbensoaat	0,1% m/v

Alkohol-vry, suiker-vry en kleurstof-vry

FARMAKOLOGIESE KLASSIFIKASIE:

A: 10.1 Hoesonderdrukkers en slymmiddels.

FARMAKOLOGIESE WERKING:

Guaifenesien het ekspektorant eienskappe.

INDIKASIES:

Verligting van hoes.

KONTRA-INDIKASIES:

Allergie vir enige van die bestanddele. Swangerskap en borsvoeding.

Guaifenesien word as onveilig beskou by pasiënte met akuut porfirie.

Word nie vir kinders jonger as 2 jaar aanbeveel nie.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS:

Guaifenesien moet nie vir aanhoudende hoes, soos dié wat met rook, asma, of emfiseem voorkom, of waar hoes met buitensporige afskeidings gepaard gaan, gebruik word nie tensy dit deur ‘n geneesheer aanbeveel en gemoniteer word. ‘n Aanhoudende hoes mag ‘n teken van ‘n ernstige toestand wees. Indien hoes vir langer as een week aanhou, neig om terug te keer, of deur hoë koors, veluitslag of aanhoudende hoofpyn begelei word, moet ‘n geneesheer geraadpleeg word.

INTERAKSIES:

Guaifenesien kan inwerk teen die diagnostiese metings van urinêre 5-hidroksie-indoolaseetsuur of vanillielmandeliese suur.

MENSLIKE VOORTPLANTING:

Benylin Children's Wet Cough moet nie tydens swangerskap en laktasie gebruik word nie.

DOSIS EN GEBRUIKSAANWYSINGS:

Kinders:	6 – 12 jaar:	10 ml – 20 ml (twee – vier medisynemate) elke 4 uur.
Kinders:	2 – 5 jaar:	5 ml – 10 ml (een – twee medisynemate) elke 4 uur.

As simptome voortduur, raadpleeg 'n geneesheer.

NEWE-EFFEKTE:

Gastro-intestinale ongemak, diarree, duiseligheid, hoofpyn, naarheid, braking, veluitslag, maagpyn, urtikarie en slaperigheid mag voorkom.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:

In groot dosisse sal guaifenesien lomerigheid, naarheid en vomering veroorsaak.

Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:

'n Helder, kleurlose tot strooi-kleurige, stroperige vloeistof met 'n aarbeigeur en -smaak.

AANBIEDING:

Amber glasbottels met 50 ml, 100 ml en 200 ml met ‘n plastiek maatkoppie.

BERGINGSINSTRUKSIES:

Hou dig toe en bewaar op 'n koel plek (teen of benede 25ºC).

HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:

35/10.1/0266

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE:

Johnson & Johnson (Edms) Bpk.

Hoofweg 241

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Suid-Afrika

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Update History

Date	Reason for Change	Version
September 2018	Inclusion of 50 ml and 200 ml strengths	3
April 2018	Inclusion of NAFDAC and Mozambique details Cosmetic changes	2
June 2013	Addition of measuring cup and update of storage condition, removal of sachet presentation.	1