BENYLIN WET COUGH

SCHEDULING STATUS:

S0

PROPRIETARY NAME ~~(~~AND DOSAGE FORM~~)~~:

Benylin Wet Cough ~~(~~Liquid~~)~~

COMPOSITION:

Each 10 ml contains:

Guaifenesin	200 mg
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.

CONTRAINDICATIONS:

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:

Benylin Wet Cough should not be taken for persistent cough, which 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.

PREGNANCY AND LACTATION:

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

DOSAGE AND DIRECTIONS FOR USE:

Adults and children over 12 years:	10 ml - 20 ml (two - four medicine measures) every 4 hours.
Children 6 – 12 years old:	5 ml – 10 ml (one – two medicine measures) every 4 hours.
Children 2 – 5 years old:	2,5 ml – 5 ml (half - one medicine measure) every 4 hours.

If symptoms persist a doctor should be consulted.

SIDE EFFECTS ~~AND SPECIAL PRECAUTIONS~~:

Rare (>1/10 000, ≤ 1/1 000):

Gastro-intestinal: Diarrhoea, nausea, vomiting, stomach pains.

Central Nervous System: Headache, drowsiness, dizziness.

Skin: Skin rash, urticaria.

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:

37/10.1/0061

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

Johnson & Johnson (Pty) Ltd.

241 Main Road

RETREAT

7945

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION:

17 September 2004

EXPORT REGISTRATION DETAILS:

Botswana:	BOT0801444
Ghana:	FDB/SD.123-8383
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Zambia:	082/056 P

BENYLIN WET COUGH

SKEDULERINGSTATUS:

S0

EIENDOMSNAAM ~~(~~EN DOSEERVORM~~)~~:

Benylin Wet Cough ~~(~~Vloeistof~~)~~.

SAMESTELLING:

Hoeveelheid per 10 ml:

Guaifenesien	200 ml

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:

Hypersensitiwiteit teenoor enige van die bestanddele. Swangerskap en borsvoeding.

Guaifenesien word as onveilig beskou by pasiënte met akuut porfirie.

Nie vir kinders jonger as 2 jaar aanbeveel nie.

WAARSKUWINGS:

Benylin Wet Cough 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.

SWANGERSKAP EN LAKTASIE:

Benylin Wet Cough moet nie gedurende swangerskap en laktasie gebruik word nie.

DOSIS EN GEBRUIKSAANWYSINGS:

Volwassenes en kinders ouer as 12 jaar:		10 ml - 20 ml (twee - vier medisynemate) elke 4 uur.
Kinders:	6 – 12 jaar:	5 ml – 10 ml (een – twee medisynemate) elke 4 uur.
Kinders	2 – 5 jaar:	2,5 ml – 5 ml (‘n halwe – een medisynemate) elke 4 uur.

As simptome voortduur raadpleeg ‘n geneesheer.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:

Selde (>1/10 000, ≤ 1/1 000):

Gastro-intestinaal: Diarree, naarheid, vomering, maagpyn.

Sentrale Senuweestelsel: Hoofpyn, lomerigheid, duiseligheid.

Vel: Veluitslag, urtikarie.

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 (op of benede 25°C).

HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:

37/10.1/0061

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

Johnson & Johnson (Edms) Bpk.

Hoofweg 241

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7945

Suid-Afrika

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