Professional information for BENYLIN CHILDREN'S WET COUGH

SCHEDULING STATUS:

S0

1. NAME OF THE MEDICINE

Benylin Children's Wet Cough 100 mg/10 mL liquid

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 m L contains:

Guaifenesin	100 mg

Excipients with known effect:

Preservative: sodium benzoate 0,1 % *m/v*.

Contains sweeteners: Each 10 mL contains 16 mg saccharin sodium and 13 mg sodium cyclamate.

Contains sugar alcohol: Each 10 mL contains 6,71 g sorbitol.

Sugar free and colourant free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Liquid.

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

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Alleviation of cough in children 4 years and older.

4.2 Posology and method of administration

Shake the bottle before use.

Children aged 6 – 12 years: 10 mL – 20 mL (two – four medicine measures) every 4 hours.

For children 6 to less than 12 years of age, the maximum total daily recommended dose of guaifenesin is 1 200 mg over a 24-hour period taken in divided doses not greater than 200 mg (20 mL) every 4 hours.

Children aged 4 to under 6 years: 5 mL – 10 mL (one – two medicine measure) every 4 hours.

For children 4 to less than 6 years of age, the maximum total daily recommended dose of guaifenesin is 600 mg over a 24-hour period taken in divided doses not greater than 100 mg (10 mL) every 4 hours.

If symptoms persist for more than one week a doctor should be consulted.

Not recommended for children under 4 years of age.

4.3 Contraindications

- Hypersensitivity to guaifenesin or to any of the other ingredients in Benylin Children's Wet Cough (see section 6.1).
- Pregnancy and lactation (see section 4.6).
- Patients with acute porphyria.
- Not recommended for children under 4 years of age.

4.4 Special warnings and precautions for use

Benylin Children's Wet Cough should not be taken for persistent or chronic 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.

Benylin [c]Children's [w]Wet [c]Cough contains sorbitol and sodium benzoate

Benylin Children's Wet Cough contains 6,71 g sorbitol per 10 mL.

Sorbitol may cause gastrointestinal discomfort and have a mild laxative effect.

The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account.

The content of sorbitol in medicines for oral use may affect the bioavailability of other medicines for oral use administered concomitantly.

Patients with hereditary fructose intolerance (HFI) should not be given Benylin Children's Wet Cough.

Benylin Children's Wet Cough contains sodium benzoate which may cause an increase in bilirubinaemia following its displacement from albumin and may increase neonatal jaundice (up to 4 weeks old) which may develop into kernicterus (non-conjugated bilirubin deposits in the brain tissue). [See section 4.3]

Benylin CHILDREN'S WET COUGH contains sodium

Benylin Children's Wet Cough contains 57 mg sodium per 10 mL, equivalent to 2,85 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

4.5 Interaction with other medicines and other forms of interaction

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

vanillylmandelic acid.

4.6 Fertility, pregnancy and lactation

Benylin Children's Wet Cough should not be used during pregnancy and lactation (see section 4.3).

4.7 Effects on ability to drive and use machines

Benylin Children's Wet Cough has no or negligible influence on the ability to drive or operate machinery.

4.8 Undesirable effects

Immune system disorders

Frequency unknown: hypersensitivity

Nervous system disorders

Less frequent: headache, drowsiness, dizziness

Gastrointestinal disorders

Less frequent: diarrhoea, nausea, vomiting, gastrointestinal discomfort, upper abdominal pain

Skin and subcutaneous tissue disorders

Less frequent: skin rash, urticaria

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of Benylin Children's Wet Cough is important. It allows continued monitoring of the benefit/risk balance of Benylin Children's Wet

Cough. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

For further information, please contact the Johnson & Johnson call centre on 0860 410032 (landline).

4.9 Overdose

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

It may also cause renal calculi.

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 10.1 Antitussives and expectorants.

Pharmacotherapeutic group: Expectorants.

ATC code: R05CA03.

Guaifenesin has expectorant properties.

5.2 Pharmacokinetic properties

Absorption

Guaifenesin is well absorbed from the gastrointestinal tract following oral administration, although limited information is available on its pharmacokinetics. After the administration of 600 mg guaifenesin to healthy adult volunteers, the maximum blood concentration (C_{max}) and area under the curve (AUC) were approximately 3,18 µg/mL and 4,9 µg.h/mL, with time to maximum blood concentration (T_{max}) occurring approximately 0,7 h after administration of the medicine.

Distribution

No information is available on the distribution of guaifenesin in humans.

Biotransformation

Guaifenesin appears to undergo both oxidation and demethylation. Guaifenesin is rapidly metabolised in the liver via oxidation to β-(2-methoxyphenoxy)-lactic acid.

Elimination

The half-life ($t_{1/2}$) after oral administration is approximately 1 hour, and the medicine is not detectable in the blood after approximately 8 hours. Guaifenesin is excreted predominantly in the urine.

5.3 Preclinical safety data

No further information of relevance available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid (E330)

Glycerine (E422)

Purified water

Saccharin sodium (E954)

Sodium benzoate

Sodium carboxymethyl cellulose

Sodium citrate (E331)

Sodium cyclamate (E952(iv))

Sorbitol (E420)

Strawberry flavour.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store in a cool place at or below 25 °C.

Keep well closed.

Keep container in the outer carton.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

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

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Johnson & Johnson (Pty) Ltd.

241 Main Road

Retreat

7945

Sign: _____

South Africa

8. REGISTRATION NUMBER

35/10.1/0266

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

7 March 2003

10. DATE OF REVISION OF THE TEXT

To be allocated by SAHPRA.

Export Registration Details:

Botswana:	BOT0901568
Kenya:	H2010/20108/833
Uganda:	NDA/MAL/HDP/8953
Nigeria:	NAFDAC Reg. No. B4-8279
Zambia:	082/055 P
Zimbabwe:	2019/22.2.2/5922

Sign: _____