1. NAME OF THE MEDICINE

Benylin Wet Cough Mucus Relief Syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 mL contains:

Guaifenesin	200 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 4,015 g sorbitol.

Alcohol 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.

4.2 Posology and method of administration

Shake the bottle before 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 4 to under 6 years: 2,5 mL – 5 mL (half - one medicine measure) every 4 hours.

If symptoms persist 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 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 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.

Caution should be exercised when using Benylin Wet Cough in the presence of severe renal or severe hepatic impairment.

Benylin Wet Cough contains sorbitol and sodium benzoate

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 medicinal products for oral use administered concomitantly.

Patients with hereditary fructose intolerance (HFI) should not take/be given Benylin Wet Cough.

Benylin Wet Cough contains sodium benzoate which may cause an increase in bilirubinaemia following its displacement from albumin and may increase neonatal jaundice which may develop into kernicterus (non-conjugated bilirubin deposits in the brain tissue).

Benylin Wet Cough contains sodium

Benylin 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 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 Wet Cough can cause side effects, such as drowsiness or dizziness and may affect the ability to drive and use machinery.

Caution is advised before driving a vehicle or operating machinery until the effects of Benylin Wet Cough are known.

4.8 Undesirable effects

Immune system disorders

Less frequent: hypersensitivity

Nervous system disorders

Less frequent: headache, drowsiness, dizziness

Gastrointestinal disorders

Less frequent: diarrhoea, nausea, vomiting, 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 Wet Cough is important. It allows continued monitoring of the benefit/risk balance of Benylin 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, excluding combinations with cough suppressants.

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 tablets to fasted 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.

After the administration of 600 mg oral liquid dose of guaifenesin to healthy adult volunteers, the C_{max} was approximately 1,4 µg/mL, with T_{max} occurring approximately 15 minutes after administration.

The half-life was approximately 1 hour and there was no detectable levels in the blood after approximately 8 hours, indicating rapid metabolism and excretion.

Distribution

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

Biotransformation

Guaifenesin appears to undergo both oxidation and demethylation.

Elimination

Following an oral dose of 600 mg guaifenesin to 27 healthy male volunteers, the $t_{1/2}$ was approximately 1 hour, and the medicine was not detectable in the blood after approximately 8 hours. Guaifenesin is excreted predominantly in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid (E330)

Glycerine (E422)

L- menthol (flavourant)

Polyethylene glycol (E521)

Propylene glycol (E1520)

Purified water

Saccharin sodium (E954)

Sodium benzoate

Sodium carboxymethyl cellulose

Sodium citrate (E331)

Sodium cyclamate (E952(iv))

Sorbitol (E420)

Strawberry flavour.

6.2 Incompatibilities

None known.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store at or below 25 °C.

Keep well closed and store in a cool place.

Keep the 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.<APPLICANT/MANUFACTURER>

Johnson & Johnson West Africa Limited,
Ground Floor Landmark Towers. 5B Water Cooperation Road, Onuru V.I. Annex,
Lagos State.

8. **Manufacturer**

Johnson & Johnson (Pty) Ltd.

241 Main Road

Retreat

7945

South Africa

5893