Professional information for BENYLIN WET COUGH MENTHOL

SCHEDULING STATUS:

S0

1. NAME OF THE MEDICINE

Benylin Wet Cough Menthol syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 mL contains:

Guaifenesin	200 mg

Excipients with known effect:

Preservative:

Sodium benzoate (E211)	0,2 % *m/v*.
Contains alcohol: Ethyl alcohol 95 %	9,5 % *v/v*

Contains sugar: Each 10 mL contains 2,0 g sucrose and 5,0 mL glucose.

Contains sweetener: Each 10 mL contains 30 mg saccharin sodium.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Syrup.

A reddish brown, syrupy liquid with a strong peppermint-caramel 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: 10 mL – 20 mL (two – four medicine measures) every 4 hours.

If symptoms persist a doctor should be consulted.

For oral use only.

4.3 Contraindications

- Hypersensitivity to guaifenesin or to any of the other ingredients in Benylin Wet Cough Menthol (see section 6.1).
- Pregnancy and lactation (see section 4.6).
- Patients with acute porphyria.

4.4 Special warnings and precautions for use

Benylin Wet Cough Menthol should not be taken for persistent or chronic cough, such as occurs with asthma, or where cough is accompanied by excessive secretions, unless directed by a physician.

A persistent cough may be a sign of a serious condition. If cough persists for more than 7 days, tends to recur, or is accompanied by a fever, rash, or persistent headache, a doctor should be consulted.

Benylin Wet Cough Menthol contains sugar: sucrose and glucose

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take Benylin Wet Cough Menthol.

Benylin Wet Cough Menthol contains sodium benzoate

An increase in bilirubinaemia following its displacement from albumin may increase neonatal jaundice which may develop into kernicterus (non-conjugated bilirubin deposits in the brain tissue).

Benylin Wet Cough Menthol contains sodium

Benylin Wet Cough Menthol contains 114 mg sodium per 10 mL, equivalent to 5,7 % 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 Menthol 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 Menthol can cause side effects, such as drowsiness 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 Menthol are known.

4.8 Undesirable effects

The safety of guaifenesin is based on available data from clinical trials and adverse drug reactions (ADRs) identified during post-marketing experience.

The frequencies are provided according to the following convention:

Very common ≥1/10

Common ≥1/100 and < 1/10

Uncommon ≥1/1,000 and <1/100

Rare ≥1/10,000 and <1/1,000

Very rare <1/10,000

Not known (cannot be estimated from the available data)

System organ class and frequency	**Adverse reactions**
Immune system disorders	
Very rare	Hypersensitivity
Nervous system disorders	
Not known	Drowsiness
Gastrointestinal disorders	
Very rare	Diarrhoea, nausea, vomiting, upper abdominal pain
Not known	Gastrointestinal discomfort
Skin and subcutaneous tissue disorders	
Very rare	Rash

Reporting of suspected adverse reactions:

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

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 3 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.

5.3 Preclinical safety data

No further information of relevance available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Caramel flavour (flavourant)

Citric acid (E330)

D & C Yellow No. 10 (colourant)

Ethyl alcohol (95 %)

FD & C Blue No. 1 (colourant)

FD & C Red No. 40 (colourant)

Glycerine (E422)

L- menthol (flavourant)

Peppermint flavour (flavourant)

Purified water

Saccharin sodium (E954)

Sodium benzoate (E211)

Sodium citrate (E331).

6.2 Incompatibilities

Not applicable.

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.

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

South Africa

8. REGISTRATION NUMBER

28/10.1/0374

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23 March 1994.

10. DATE OF REVISION OF THE TEXT

9 December 2021.

EXPORT REGISTRATION DETAILS

Botswana:	B9326080
Namibia:	05/10.1/0286 NS0
Kenya:	H2018/CTD3874/181ER
Nigeria:	NAFDAC Reg. No.: B4-7112
Zambia:	082/039 P
Zimbabwe:	2019/22.2.2/5828