BENYLIN COUGH LOZENGES BERRIES

COMPLEMENTARY MEDICINE: COMBINATION PRODUCT (AYURVEDA / WESTERN HERBAL)

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS

S0

1. NAME OF THE MEDICINE

BENYLIN COUGH LOZENGES BERRIES

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains:

Glycyrrhiza glabra (L.) (Liquorice) root [equivalent to 5:1 dry herb extract 3,0 mg]	15 mg
Phyllanthus emblica (L.) (Indian gooseberry) fruit [equivalent to 4:1 dry herb extract 2,5 mg]	10 mg
Zingiber officinale (L.) (Ginger) rhizome [equivalent to 10:1 dry herb extract 1,0 mg]	10 mg
Levomenthol	7 mg

Contains preservatives:

Methylparaben	0,20 % *m/m*
Propylparaben	0,02 % *m/m*

Excipients with known effects:

Contains sugar (1,62 g sucrose and 1,04 g glucose per lozenge).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lozenge.

Pinkish-brown to brown, round, biconvex lozenges with occasional presence of air bubbles entrapped in the lozenges and rough edges.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

BENYLIN COUGH LOZENGES BERRIES is indicated for symptomatic treatment of acute inflammation from infectious or postoperative irritation of the upper respiratory tract accompanied with dry cough.

4.2 Posology and method of administration

Adults and children (12 years and older):

Slowly dissolve 1 lozenge every 2 hours in the mouth. The maximum daily dose is 10 lozenges.

Children:

Do not use in children under 12 years of age.

Do not use for longer than 3 weeks, unless directed by a doctor.

Do not chew or swallow the lozenge whole.

4.3 Contraindications

- Hypersensitivity to any of the active or inactive ingredients of BENYLIN COUGH LOZENGES BERRIES (see sections 2 and 6.1).
- Pregnancy and lactation.
- Patients with epilepsy, asthma, persistent or chronic cough, or other chronic lung conditions.

4.4 Special warnings and precautions for use

Patients suffering from any medical condition/chronic disease and/or are taking chronic medications, should consult their doctor before using BENYLIN COUGH LOZENGES BERRIES.

Lozenges can represent a choking hazard.

Keep out of reach of children.

BENYLIN COUGH LOZENGES BERRIES should be used with caution in individuals with aspiration and swallowing problems.

BENYLIN COUGH LOZENGES BERRIES is not recommended to be used with antitussive and sputum reducing medicines, as this complicates removal of mucous.

The patient should stop taking BENYLIN COUGH LOZENGES BERRIES and consult a health care provider if symptoms persist or worsens, if new symptoms occur, or if symptoms are accompanied by a fever, rash or persistent headache, while taking BENYLIN COUGH LOZENGES BERRIES.

Bleeding disorders:

BENYLIN COUGH LOZENGES BERRIES decreases platelet aggregation and may increase the risk of bleeding (see section 4.5).

Perioperative:

Patients should be advised to discontinue BENYLIN COUGH LOZENGES BERRIES at least 2 weeks prior to any surgical procedures.

BENYLIN COUGH LOZENGES BERRIES contains sugar

BENYLIN COUGH LOZENGES BERRIES contains sucrose and glucose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take BENYLIN COUGH LOZENGES BERRIES.

BENYLIN COUGH LOZENGES BERRIES contains an azo dye

BENYLIN COUGH LOZENGES BERRIES contains an azo dye (Azorubine [E122]), which may cause allergic reactions.

4.5 Interaction with other medicines and other forms of interaction

Warfarin:

Patients on warfarin therapy may experience increased international normalised ratio (INR) due to the interaction with the intestinal or hepatic CYP P450 enzyme system. Ginger can enhance the anticoagulant activity of warfarin by influencing vitamin K epoxide reductase and potentially other critical components in the clotting system.

This suggests that bleeding in people on chronic warfarin therapy can be increased.

Anticoagulant or antiplatelet medicines:

BENYLIN COUGH LOZENGES BERRIES may potentiate the effects of anticoagulant and antiplatelet medicines or herbal supplements with blood thinning effects. (see section 4.4).

Antidiabetic medicines:

Concomitant use of BENYLIN COUGH LOZENGES BERRIES with antidiabetic medicines or herbal supplements may interfere with blood glucose control and caution is advised during concomitant use (see section 4.4).

Camphor, menthol, eucalyptol and/or eucalyptus essential oil:

BENYLIN COUGH LOZENGES BERRIES should not be taken with other products containing camphor, menthol, eucalyptol and/or eucalyptus essential oil.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

BENYLIN COUGH LOZENGES BERRIES should not be taken during pregnancy and lactation (see section 4.3). The patient should be advised to consult a health care provider if they are

pregnant, become pregnant or if they are breastfeeding a baby.

4.7 Effects on ability to drive and use machines

BENYLIN COUGH LOZENGES BERRIES may cause side effects such as dizziness which can affect the ability to drive a vehicle and use machines (see section 4.8).

Caution is advised when driving a vehicle or operating machinery until the effects of BENYLIN COUGH LOZENGES BERRIES are known.

4.8 Undesirable effects

BENYLIN COUGH LOZENGES BERRIES is generally well tolerated.

Immune system disorders:

Less frequent: hypersensitivity reactions

Nervous system disorders:

Less frequent: headache, dizziness

Gastrointestinal disorders:

Frequent: nausea, vomiting, abdominal discomfort, loose stools, burping

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of BENYLIN COUGH LOZENGES BERRIES is important. It allows continued monitoring of the benefit/risk balance of BENYLIN COUGH LOZENGES BERRIES. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 .

For further information, please contact the Consumer Care Contact Centre, e-mail: consumer-za@kenvue.com.

4.9 Overdose

See section 4.8.

In the event of overdose, treatment should be symptomatic and supportive.

Excessive use of menthol may lead to abdominal pain, vomiting, flushed face, dizziness, weakness, tachycardia, stupor and ataxia.

In the event of an overdosage, the patient should be advised to consult their doctor or pharmacist. If neither is available, they should contact the nearest hospital or poison centre.

5. PHARMACOLOGICAL PROPERTIES

Category and class: D 33.7 Combination product

Mechanism of action:

The main active constituent of *Glycyrrhiza glabra* is considered to be glycyrrhizin, otherwise known as glycyrrhizic acid or glycyrrhizinic acid. Glycyrrhizin is metabolised to glycyrrhetinic acid (also called glycyrrhetic acid) in the intestine by intestinal flora.

The applicable part of Indian gooseberry is primarily the fruit. Indian gooseberry has anti-inflammatory properties.

The applicable parts of *Zingiber officinale* are the rhizome and root. Following consumption, glucuronides, thiol-conjugates, and sulfates of 6-gingerol, 8-gingerol, 10-gingerol and 6-shogaol were detected. The plasma half-life of the constiuents has been estimated to be 0,5 – 3 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Berries flavour,

Citric acid,

Colour Azorubine (E 122),

Colour Brilliant Blue (E133),

Glucose,

Glycerin,

Methylparaben,

Propylparaben,

Purified water,

Sucrose.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

Store at or below 25 °C.

6.4 Special precautions for storage

Store in a dry place.

6.5 Nature and contents of container

Carton containing 20 lozenges packed in 5 aluminium/aluminium foil strip packs containing 4 lozenges per strip.

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

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF THE TEXT

December 2023.