Professional information for BENYLIN® ORIGINAL

SCHEDULING STATUS:

S2

1. NAME OF THE MEDICINE:

BENYLIN® ORIGINAL syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each 5 mL contains:

Diphenhydramine hydrochloride	12,5 mg
Ammonium chloride	125,0 mg

Excipients with known effects:

Ethanol 97 % *v/v*	5,0 % *v/v*

Preservative: Sodium benzoate 0,2 % *m/v*

BENYLIN® ORIGINAL contains sugar: Each 5 mL contains 1 g sucrose and 2,3 mL glucose.

BENYLIN® ORIGINAL contains sweetener: Each 5 mL contains 15,5 mg saccharin sodium and 20 mg sodium cyclamate.

For the full list of excipients, see section 6 .1.

3. PHARMACEUTICAL FORM:

Syrup.

A clear, dark brown syrup having a raspberry odour and taste.

4. CLINICAL PARTICULARS:

4.1 Therapeutic indications:

BENYLIN® ORIGINAL is indicated for the relief of cough.

4.2 Posology and method of administration:

A maximum of four doses per day should not be exceeded.

Adults and children over 12 years:

One to two medicine measures (5 mL -10 mL) every 4 hours.

Children 6 to 12 years:

A half to one medicine measure (2,5 mL – 5 mL) every 4 hours.

Children under 6 years of age:

Not recommended for children under 6 years of age.

4.3 Contraindications:

- Known hypersensitivity to diphenhydramine hydrochloride, ammonium chloride or any of the other ingredients of BENYLIN® ORIGINAL (see section 6.1).
- Diphenhydramine should not be used with monoamine oxidase inhibitors or within 14 days of stopping monoamine oxidase inhibitor treatment.
- BENYLIN® ORIGINAL is contraindicated during acute asthmatic attacks.
- Patients with liver or renal impairment.
- Should not be used in children under the age of 6 years.

4.4 Special warnings and precautions for use:

- BENYLIN® ORIGINAL may lead to drowsiness and impaired concentration which may be aggravated by the simultaneous intake of alcohol, sedatives, tranquilisers or other central nervous system depressants. Paradoxical stimulation may occur, especially in high doses, and in children or elderly patients. Patients should be warned not to drive a motor vehicle,

operate dangerous machinery or climb dangerous heights as impaired decision-making could lead to accidents.

- Do not use with any other product containing diphenhydramine, even one used on skin.
- Patients should not use BENYLIN® ORIGINAL for persistent or chronic cough, such as occurs with asthma, or where cough is accompanied by excessive secretions, unless directed by a doctor.
- Use with caution in conditions such as glaucoma, urinary retention or prostatic hyperplasia.
- Use with caution in patients with respiratory conditions such as emphysema, chronic bronchitis or acute or chronic bronchial asthma.
- Use with caution in patients with cardiovascular disease.
- If symptoms persist or worsen, or if new symptoms occur, stop using BENYLIN® ORIGINAL and consult your doctor.
- BENYLIN® ORIGINAL contains sugar, sucrose and glucose.
  Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase isomaltase insufficiency should not take BENYLIN® ORIGINAL.
- BENYLIN® ORIGINAL contains sugar, sucrose and glucose (see section 2), which may have an effect on the glycaemic control of patients with diabetes mellitus.
- BENYLIN® ORIGINAL 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® ORIGINAL contains alcohol. It contains 0,258 mL of alcohol (ethanol) in each 5 mL. The small amount of alcohol in BENYLIN® ORIGINAL will not have any noticeable effects.

4.5 Interaction with other medicines and other forms of interaction:

- Diphenhydramine may enhance the sedative effects of central nervous system depressants, including alcohol, barbiturates, hypnotics, narcotic analgesics, sedatives and tranquilisers.

- Diphenhydramine should not be used with monoamine oxidase inhibitors or within 14 days of stopping monoamine oxidase inhibitor treatment.
- Diphenhydramine may have an additive effect with medicines such as atropine, tricyclic antidepressants and monoamine oxidase inhibitors.
- Diphenhydramine may mask the damage caused by ototoxic medicines such as aminoglycoside antibiotics and may affect the metabolism of other medicines in the liver.
- *Laboratory tests:* Positive results from skin tests may be suppressed by diphenhydramine.

4.6 Fertility, pregnancy and lactation:

Pregnancy

Safety during pregnancy has not been established.

Lactation

Diphenhydramine crosses the placenta and is excreted into breast milk.

Mothers on BENYLIN® ORIGINAL should not breastfeed their infants.

4.7 Effects on ability to drive and use machines:

BENYLIN® ORIGINAL may cause side effects, such as drowsiness, dizziness, incoordination or blurred vision. Patients should be warned not to drive a motor vehicle, operate dangerous machinery or climb dangerous heights as impaired decision making could lead to accidents (see above).

4.8 Undesirable effects:

The following side effects are for diphenhydramine and ammonium chloride and the frequencies are estimated from spontaneous reporting rates.

Blood and lymphatic system disorders

Less frequent: Agranulocytosis, leucopenia, haemolytic anaemia and thrombocytopenia.

Immune system disorders

Less frequent: Angioedema, hypersensitivity, allergic reactions and anaphylaxis.

Metabolism and nutrition disorders

Less frequent: Increased appetite, anorexia.

Psychiatric disorders

Less frequent: Confusional state, irritability, hallucinations, euphoria and nervousness.

Nervous system disorders

Frequent: Sedation varying from slight drowsiness to deep sleep including lassitude, dizziness, and incoordination, headache and antimuscarinic effects, such as dry mouth and thickened respiratory tract secretions.

Less frequent: Agitation, abnormal coordination, convulsions (large doses may precipitate fits in epileptics), headache, insomnia, paraesthesia, sedation, somnolence, deepening coma, extrapyramidal effects and tremor.

BENYLIN® ORIGINAL may act as a cerebral stimulant in infants and children. Symptoms of stimulation include insomnia, nervousness, tachycardia, tremors and convulsions.

Elderly patients are more susceptible to central nervous system effects.

Eye disorders

Less frequent: Blurred vision.

Ear and labyrinth disorders

Less frequent: Tinnitus.

Cardiac disorders

Less frequent: Palpitations and tachycardia.

Vascular disorders

Less frequent: Hypotension.

Elderly patients are more susceptible to hypotensive effects.

Respiratory, thoracic and mediastinal disorders

Less frequent: Chest discomfort, chest tightness, dry throat and nasal dryness.

Gastrointestinal disorders

Less frequent: Abdominal pain, epigastric pain, application site reaction (burning sensation, glossitis, glossodynia, oral hypoaesthesia, lip blister, dry lip, lip pain, mouth ulceration, oral discomfort, oral disorder, erythema of oral mucosa, oropharyngeal blistering, stomatitis, tongue disorder, tongue eruption), dry mouth, diarrhoea, constipation, dyspepsia, nausea and vomiting.

Skin and subcutaneous tissue disorders

Less frequent: Pruritus, rash, photosensitisation and urticaria.

Musculoskeletal and connective tissue disorders

Less frequent: Muscular weakness.

Renal and urinary disorders

Less frequent: Urinary retention, dysuria, difficulty in micturition.

General disorders and administration site conditions

Less frequent: Asthaenia

Investigations

Frequency unknown: Suppression of positive skin test results.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of BENYLIN® ORIGINAL is important. It allows continued monitoring of the benefit/risk balance of BENYLIN® ORIGINAL. 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

Diphenhydramine hydrochloride

Overdosage may be fatal especially in infants and children.

In infants and children central nervous system (CNS) stimulation predominates over CNS depression causing ataxia, excitement, tremors, psychoses, hallucinations and convulsions; hyperpyrexia may also occur. Deepening coma and cardiorespiratory collapse may follow. In adults: CNS depression with drowsiness, coma and convulsions, progressing to respiratory failure or possibly cardiovascular collapse.

Other symptoms of overdose include:

Mild to moderate symptoms:

Anticholinergic syndrome (mydriasis, flushing, fever, dry mouth, urinary retention, decreased

bowel sounds), tachycardia, mild hypertension, nausea and vomiting are common after overdose. Agitation and confusion may develop with moderate poisoning.

Severe symptoms:

Effects may include delirium, hypotension, QRS widening, and ventricular dysrhythmias, including torsades de pointe, but are generally reported in adults after large ingestions. Rhabdomyolysis and renal failure may rarely develop in patients with prolonged agitation, coma or seizures.

Ammonium chloride

Large doses of ammonium chloride may cause nausea, vomiting, drowsiness, thirst, headache, hyperventilation, profound acidosis and hypokalaemia. Excessive doses may give rise to hepatic encephalopathy. Metabolic acidosis occurred with the prolonged intake of ammonium chloride above the recommended dose and/or in cases of renal impairment. Symptoms of metabolic acidosis may include headache, generalised muscle weakness, hyperventilation, hyperreflexia, progressive drowsiness, mental confusion and coma.

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties:

Category and class: A: 10.1 Antitussives and expectorants

Pharmacotherapeutic group: Antihistamines for systemic use

ATC code: R06AA52

Diphenhydramine hydrochloride is an antihistamine with anticholinergic properties. Ammonium chloride is an expectorant.

5.2 Pharmacokinetic properties:

Diphenhydramine

Diphenhydramine is well absorbed from the gastrointestinal tract, although high first-pass metabolism appears to affect systemic availability. Peak plasma concentrations occur about 1 to 4 hours after oral doses. Diphenhydramine is widely distributed throughout the body, including the central nervous system. It crosses the placenta and has been detected in breast milk.

Diphenhydramine is highly bound to plasma proteins.

Metabolism is extensive.

Diphenhydramine is excreted mainly in the urine as metabolites; little is excreted as unchanged molecule. The elimination half-life has been reported to range from 2,4 to 9,3 hours.

Ammonium chloride

Ammonium chloride is absorbed from the gastrointestinal tract.

5.3 Preclinical safety data

There are no preclinical data identified that would suggest any adverse findings that would be relevant to humans.

6. PHARMACEUTICAL PARTICULARS:

6.1 List of excipients:

The other ingredients are:

Caramel (colourant),

citric acid (E330),

glucose,

glycerine,

H & R special flavour (flavourant),

menthol (flavourant),

ponceau red (colourant),

raspberry flavour (flavourant),

saccharin sodium,

sodium benzoate (E221),

sodium citrate (E331),

sodium cyclamate (E952),

sucrose, and

purified water.

6.2 Incompatibilities:

Not applicable.

6.3 Shelf life:

2 years.

6.4 Special precautions for storage:

Store at or below 25 ˚C.

Store in a cool place.

Keep the bottle sealed.

Keep the bottle in the outer carton.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container:

Round, amber glass bottles containing 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. REFERENCE NUMBER:

G829 (Act 101/1965)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION:

2 October 1974

10. DATE OF REVISION OF THE TEXT:

30 May 2023

EXPORT REGISTRATION DETAILS

Botswana:	B9321910
Kenya:	H2002/280
Malawi:	PMPB/PL 353/7
Mozambique:	1056
Namibia:	14/10.1/0364 NS1
Nigeria:	NAFDAC Reg. No. B4-7109
Uganda:	1650/25/97
Zambia:	082/050 POM
Zimbabwe:	76/22.2.5/642 P