

Professional Information for Benylin Four Cough
COMPLEMENTARY MEDICINE: WESTERN HERBAL MEDICINE

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

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

Benylin Four Cough syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 mL syrup contains:

<i>Hedera helix</i> L. (Ivy)	8,25 mg
[leaf, 4 – 8:1 extract]	

Excipients with known effects:

Contains sugar alcohol (708 mg sorbitol per mL).

Contains preservative: potassium sorbate 0,18 % w/v.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Syrup.

Brown, opalescent solution with a characteristic odour.

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4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Benylin Four Cough helps with the symptomatic relief of productive cough and chest congestion and to loosen bronchial mucus for improved expectoration.

Adults only: Benylin Four Cough helps to support/improve respiratory function in patients with bronchitis, helps to relieve coughs and loosens mucus in patients with bronchitis. It can be used as an expectorant to help relieve symptoms associated with bronchitis.

4.2 Posology and method of administration

Posology

Adults and children 12 years and over:

Take 4 mL two to three times daily, or 6 mL one to two times a day.

Children 6 to under 12 years:

Take 4 mL two times daily.

Children 2 to under 6 years:

Take 2 mL two times daily.

Duration of use is recommended not to exceed 7 days.

Do not exceed the recommended dosage.

Method of administration

For oral use only.

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Shake the bottle well before each use.

If the symptoms worsen or persist longer than one week during the use of Benylin Four Cough, a doctor or qualified health care provider should be consulted.

4.3 Contraindications

- Hypersensitivity to ivy leaf or to any of the excipients listed in section 6.1.
- Do not use in children under 2 years of age.

4.4 Special warnings and precautions for use

Use of Benylin Four Cough with antitussives, such as codeine or dextromethorphan, is not recommended without medical advice.

If symptoms persist or get worse, or if new symptoms occur, stop use and consult a doctor.

Benylin Four Cough contains sorbitol

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 take/be given Benylin Four Cough.

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4.5 Interaction with other medicines and other forms of interaction

None known.

See section 4.4.

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety in pregnancy has not been established.

Breastfeeding

It is not known whether ivy leaf or its metabolites are excreted in human milk.

Fertility

No fertility data are available.

4.7 Effects on ability to drive and use machines

Benylin Four Cough is unlikely to affect the ability to drive and use machines.

4.8 Undesirable effects

Immune system disorders:

Frequency unknown: Hypersensitivity (urticaria, rash, dyspnoea).

Gastrointestinal disorders:

Frequency unknown: Nausea, vomiting, diarrhoea.

Reporting of suspected adverse reactions

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

4.9 Overdose

Overdose can cause nausea, vomiting, diarrhoea, aggression and agitation. In the event of overdose, the patient should immediately get medical help or contact a poison control center.

5. PHARMACOLOGICAL PROPERTIES

Category and class: D 33.6 Western Herbal Medicine.

Mechanism of action:

Hedera helix (Ivy) leaf extracts as a herbal medicine is considered to have mucolytic, spasmolytic, bronchodilatory, anti-inflammatory and antibacterial effects. The active principles contained in *Hedera helix* are pentacyclic triterpene saponins, the major one being hederacoside C, a bidesmosidic glycoside that in the body is transformed into the monodesmosidic α -hederin, which is the main component responsible for the pharmacological activity. The ingredients of *Hedera helix* (Ivy) leaf extract elicit bronchospasmolytic and secretolytic effects, which reduces the airway resistance and clears the respiratory system. The saponin extracts from *Hedera helix* (Ivy) leaf exert an anti-inflammatory effect suggested by blocking histamine and/or serotonin release in a better way than

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prostaglandin and/or bradykinin in acute inflammation and exerting their activities by inhibiting the functions of macrophages and fibrosis for chronic inflammation.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid,

Ethanol (extraction solvent),

Potassium sorbate,

Purified water,

Sorbitol liquid (E 420),

Xanthan gum.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 3 years.

Opened: 3 months.

6.4 Special precautions for storage

Store at or below 25 °C.

Keep the bottle tightly closed.

Protect from light and moisture.

Do not store in a bathroom.

Keep in the original container until required for use.

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6.5 Nature and contents of container

Benylin Four Cough is available in 100 mL bottles made of amber glass.

The bottles are closed with white screw caps (HDPE) with a cone sealing.

The bottle is further packed into cartons together with a measuring spoon (with a 2 mL and 4 mL graduation).

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.