

HEDERA HELIX™

ORIGINAL FLAVOUR



COUGH SYRUP

HEDERA HELIX COUGH SYRUP is unregistered and has not been evaluated by SAHPRA for its quality, safety or intended use. This medicine is not intended to diagnose, treat, cure or prevent any disease.

SCHEDULING STATUS

Not scheduled

NAME OF THE MEDICINE

HEDERA HELIX COUGH SYRUP ORIGINAL

QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient:

Each 5 ml contains Hedera Helix L. folium (Ivy Leaf extract 6:1) 35mg

EXCIPIENTS:

Potassium Sorbate (1,00% v/m) as preservative
Sorbitol 70% (3g/5ml)

PHARMACEUTICAL FORM

HEDERA HELIX COUGH SYRUP ORIGINAL: Naturally coloured light brown syrup with a sweet taste. Hedera Helix L extract is a natural extract therefore the colour may vary occasionally but this does not affect efficacy.

CLINICAL PARTICULARS

Therapeutic indications

HEDERA HELIX COUGH SYRUP is a Western Herbal Complementary Medicine product used as an expectorant in case of productive cough and helps with the release and elimination of mucus.

POSODOGY AND METHOD OF ADMINISTRATION

SHAKE WELL BEFORE USE

Special populations

DOSAGE AND DIRECTIONS FOR USE

Adults and elderly:
5ml three times daily.

Children over 6 years and adolescents:
5ml three times daily.

Children between 2 and 5 years:
2,5ml three times daily.

CONTRAINDICATIONS

Hypersensitivity to the active substance, to plants of the Araliaceae family or to any of the excipients of HEDERA HELIX COUGH SYRUP.

Children under 2 years of age because of the general risk of aggravation of respiratory symptoms through secretolytic drugs.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

HEDERA HELIX COUGH SYRUP contains Sorbitol 70% and may have a laxative effect.

Patients with the rare hereditary condition of sorbitol intolerance should not take HEDERA HELIX COUGH SYRUP.

When shortness of breath, dyspnoea, fever or purulent sputum occurs, a doctor or pharmacist should be consulted.

Caution is recommended in patients with gastritis or gastric ulcers.

PAEDIATRIC POPULATION

Persistent or recurrent cough in children between 2 and 4 years of age requires medical diagnosis before treatment.

The use of HEDERA HELIX COUGH SYRUP in children below 2 years is not recommended due to the risk of abnormal swallowing of sputum that may lead to dyspnoea as well as vomiting and diarrhoea may occur more frequently in this age group.

In children below 4 years, it should only be used with medical supervision and in children below 12 years, it should be used under supervision of an adult.

Interaction with other medicines and other forms of interaction

No interaction studies were performed.

Concomitant use with other expectorants such as a codeine or dextromethorphan without medical supervision is not recommended.

Fertility, pregnancy and lactation

The safety of HEDERA HELIX COUGH SYRUP during pregnancy and lactation has not been established.

NOT RECOMMENDED FOR USE DURING PREGNANCY OR LACTATION

Effects on ability to drive and use machines

HEDERA HELIX COUGH SYRUP has no effect on your ability to drive vehicles or operate machinery.

However, do take care if you take HEDERA HELIX COUGH SYRUP until you know how it will affect you.

UNDESIRABLE EFFECTS

Frequency not known:

Gastrointestinal reactions - Nausea, vomiting, diarrhea.

Allergic reactions - Urticaria, skin rash, dyspnea, anaphylactic reaction.

REPORTING OF SUSPECTED ADVERSE REACTIONS.

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

CONTEGO PHARMACEUTICALS (PTY) LTD

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Gauteng, South Africa

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OVERDOSE

Overdose can provoke nausea, vomiting, diarrhea and agitation.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Pharmacological classification: D 32.16 Other - Western Herbal Complementary Medicine

Pharmacotherapeutic group: Respiratory system

The mechanism of action is not known

This medicine has not yet been evaluated by SAHPRA and is not intended to diagnose, treat, cure or prevent any disease.

PHARMACEUTICAL PARTICULARS

List of excipients

Potassium sorbate

Sorbitol 70% (3g/5ml)

INCOMPATIBILITIES

Not applicable

SHELF LIFE

In-use shelf life: 3 months

SPECIAL PRECAUTIONS FOR STORAGE

Store at or below 25 °C.

Shake bottle before use.

KEEP OUT OF REACH OF CHILDREN.

NATURE AND CONTENTS OF CONTAINER

HEDERA HELIX COUGH SYRUP is packed into generic amber glass bottles with a white tamper evident screw cap.

Pack sizes available are 100ml and 200ml and each bottle are packed into an outer carton box.

SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING

No special requirements.

HOLDER OF CERTIFICATE OF REGISTRATION

CONTEGO PHARMACEUTICALS (PTY) LTD

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Robertville, Roodepoort,

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REGISTRATION NUMBER

To be allocated

NAPPI CODE

100ml - 3001523002

200ml - 3001523001

