

PROFESSIONAL INFORMATION

Category D: Complementary Medicine

Discipline Specific: D33.6 Western Herbal Medicine

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

SCHEDULING STATUS: **S0**

1. NAME OF THE MEDICINE

Cepacol cough and cold syrup

Hedera helix (Ivy) 5 mg/5 ml

Pelargonium sidoides DC (African Geranium) 150 mg/ 5ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per 5 ml:

Pelargonium sidiodes DC (African Geranium)

[roots, 1:10 ethanolic (0,52 % v/v) extract providing 15 mg of dried herb equivalent].....150 mg

Hedera helix (Ivy)

[dry leaf extract, 10:1 extract providing 50 mg of dried herb equivalent].....5 mg

Excipients with known effect

Contains Sorbitol 4,256 g/ 5 ml

Contains sugar: Honey CR 357 9,6 mg/5 ml.

Preservative: Sodium benzoate 0,19 % m/v

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Syrup, light orange with characteristic odour

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Cepacol cough and cold syrup is a herbal medicinal syrup used for the relief of symptoms associated with upper respiratory tract infections such as influenza and the common cold.

Cepacol cough and cold syrup provides relief from the symptoms of the common cold such as nasal congestion or rhinitis; rhinosinusitis, pharyngitis, tight chest, and cough.

Cepacol cough and cold syrup is used as an expectorant in case of productive cough. Pelargonium is known to have anti-bacterial and anti-viral properties.

Cepacol cough and cold syrup is suitable for use in adults, adolescents and children from 6 years of age.

Cepacol cough and cold syrup is non-sedating and suitable for daytime use.

4.2 Posology and method of administration

Posology

Adults and children 12 years and older: Take two to three medicine measures (10 – 15 ml) every eight hours.

Children 6-11 years: Give one to two medicine measures (5 – 10 ml) every eight hours.

Special populations

Renal and Hepatic impairment

Due to lack of data in these patient groups, a dose recommendation is not possible.

Patients are advised to consult their health care provider before taking Cepacol cough and cold syrup.

Paediatric population

Cepacol cough and cold syrup is contraindicated for children under 6 years of age (see section 4.3).

Method of administration

Oral use.

Cepacol cough and cold syrup should be taken undiluted. Shake well before use.

If the symptoms persist longer than one week during the use of this medicinal product, a doctor or a pharmacist should be consulted.

4.3 Contraindications

- Hypersensitivity to the active substances or to plants of the *Araliaceae* (ivy) or *Geraniaceae* (pelargonium) families or to any of the excipients listed in [section 6.1](#).
- Children under 6 years of age because of the general risk of aggravation of respiratory symptoms through secretolytic medicines.
- Safety in pregnancy and lactation has not been established (see section 4.6).

4.4 Special warnings and precautions for use

- When dyspnoea, fever or purulent sputum occurs, a health care provider should be consulted.
- Caution is recommended in patients with gastritis or gastric ulcer
- Caution is recommended in patients with hepatic impairment as hepatotoxicity and hepatitis cases were reported.
- In cases where signs of hepatotoxicity occur, the administration of Cepacol cough and cold syrup should be stopped immediately and a health care provider should be consulted.
- Contains sorbitol which may cause gastrointestinal discomfort and may have a mild laxative effect.
- Contains fructose and glucose which may have an effect on the glycaemic control of patients with diabetes mellitus.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed or reported.

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety in pregnancy has not been established.

Cepacol cough and cold syrup is not recommended during pregnancy.

Lactation

Safety in lactation has not been established.

It is unknown whether constituents or metabolites of ivy leaf and *pelargonium* are excreted in human breast milk. A risk to the newborn/infant cannot be excluded.

Cepacol cough and cold syrup should not be used during breastfeeding.

Fertility

There is no data on the effects of ivy leaf and *pelargonium* on fertility available.

4.7 Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Pelargonium sidiodes DC (African Geranium):

Mild gastrointestinal complaints (diarrhoea, epigastric discomfort, nausea or vomiting, dysphagia), mild nasal and gingival bleeding and allergic reactions have been reported. The frequency was less frequent.

Hepatotoxicity has been reported. The frequency is not known.

Hedera helix (Ivy)

Gastrointestinal reactions (nausea, vomiting, diarrhoea) have been reported. The frequency is not known.

Allergic reactions (urticaria, skin rash, dyspnoea, anaphylactic reaction) have been reported. The frequency is not known.

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>

4.9 Overdose

Pelargonium sidiodes DC (African Geranium):

No case of overdose has been reported.

Hedera helix (Ivy)

Overdose can provoke nausea, vomiting, diarrhoea and agitation.

Treatment is symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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Mechanism of action

Pelargonium sidiodes DC (African Geranium):

Pharmacological activities include antiviral and antibacterial action as well as immunomodulatory capabilities.

Hedera helix (Ivy)

The broncholytic and secretolytic efficacy, are well established in the treatment of productive cough and may also be used for the adjuvant therapy of inflammatory bronchial diseases.

5.2 Pharmacokinetic properties

There are no available data about pharmacokinetic parameters of *Pelargonium* extract and *Hedera helix* (Ivy).

5.3 Preclinical safety data

Based on the long standing clinical use there is a sufficiently established safety of the usage in the given posology in humans. Data on carcinogenicity; genotoxicity and reproductive toxicity testing are not available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Honey CR 357

Potable Water

Quinoline yellow 1 % solution

Sodium Benzoate

Sorbitol 70 % NC

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store at or below 25 °C.

Protect from light and moisture.

6.5 Nature and contents of container

Brown, amber glass bottle with plastic screw-cap in a carton box containing a light orange syrup, with characteristic odour.

Pack size: 100 ml.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Adcock Ingram Limited

1 New Road,

Erand Gardens,

Midrand

1685

www.adcock.com

8. REGISTRATION NUMBER

To be allocated

9. DATE OF FIRST AUTHORISATION

Not applicable.

10. DATE OF REVISION OF THE TEXT

2 February 2022

