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 Plus cough and cold syrup

Hedera helix (Ivy*) 5 mg/5 ml*

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

Valerianae officinalis L. (Valerian) 12 mg/5 ml

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

Valerianae officinalis L. (Valerian)

[roots, 5:1 extract providing 60 mg of dried herb equivalent]……..12 mg

Excipients with known effect

Contains Sorbitol 4,256 g/ 5 ml

Preservative: Sodium benzoate 0,19 % m/v

Sugar free

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Syrup, Clear green liquid

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

Cepacol Plus cough and cold syrup may assist in providing night time cough relief.

Cepacol Plus cough syrup contains valerian which may cause drowsiness.

Pelargonium is known to have anti-bacterial and anti-viral properties.

4.2 Posology and method of administration

Posology

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

Do not take more than 45 ml in 24 hours.

Shake the bottle before use.

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 Plus cough and cold syrup

Paediatric population

Cepacol Plus cough and cold syrup is contraindicated for children under 12 years of age (see section 4.3).

Method of administration

Oral use.

Cepacol Plus 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); *Geraniaceae (pelargonium)* or Valerian families or to any of the excipients listed in section 6.1.
- Children under 12 years of age due to a lack of data on safety and efficacy.
- 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 case signs of hepatoxocity occur, the administration of Cepacol Plus cough and cold syrup should be stopped immediately and a health care provider should be consulted.
- If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.
- Contains sorbitol which may cause gastrointestinal discomfort and may have a mild laxative effect.

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

Fertility

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

4.7 Effects on ability to drive and use machines

May impair ability to drive and use machines.

Affected patients should not drive or operate machinery.

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.

Valerianae officinalis L. (Valerian):

Gastrointestinal symptoms (e.g. nausea, abdominal cramps) may occur after ingestion of valerian *root preparations. 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.

Valerianae officinalis L. (Valerian)

Valerian root at a dose of approximately 20 g caused symptoms, such as fatigue, abdominal cramp, chest tightness, light-headedness, hand tremor and mydriasis, which disappeared within 24 hours. If symptoms arise, treatment should be supportive.

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.

Valerianae officinalis L. (Valerian)

The sedative effects of preparations of valerian root, which have long been recognised empirically, have been confirmed in controlled clinical studies. Orally administered dry extracts of valerian root prepared with ethanol/water (ethanol maximum 70% (v/v)) in the recommended dosage have been shown to improve sleep latency and sleep quality.

5.2 Pharmacokinetic properties

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

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 genotoxicity, carcinogenity and reproductive toxicity testing are not available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Brilliant Blue FCF 1 % Solution

Eucalyptus Oil 2

Peppermint Essential Oil

Potable Water

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 100 ml clear green liquid.

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

Customer Care: 0860 ADCOCK/232625

8. REGISTRATION NUMBER

To be allocated

9. DATE OF FIRST AUTHORISATION

Not applicable.

10. DATE OF REVISION OF THE TEXT

2 February 2022

adcock ingram