Category D: Complementary Medicine

Discipline Specific: 33.7 Combination Product

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

CEPACOL EFFERVESCENT

Multicomponent formulation, effervescent tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Ascorbic acid (Vitamin C)	500 mg
Zinc citrate 3-hydrate providing Zinc (elemental)	39,2 mg 12,4 mg
Hedera helix L. (Ivy leaf) [leaf, standardised to provide min 10 % saponins]	35 mg
Pelargonium sidoides DC (African geranium) [root]	12,5 mg
Vitamin A acetate (Vitamin A)	379 µg RAE
Cholecalciferol (Vitamin D_3)	250 IU

Contains sweetener: Sucralose 20 mg/tablet.

Sugar free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Effervescent tablets.

White to off-white round tablets.

After effervescence: red solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Cepacol Effervescent is a combination product which helps to relief symptoms of cold and flu such as sore throat, nasal congestion, sneezing and cough. It assists with chesty cough relief, opening of the airways, thinning of mucus and providing relief of coughs associated with

inflammation of the airways. Supports the immune function within the upper respiratory tract and provides antioxidant support for the maintenance of good health.

4.2 Posology and method of administration

Posology

Adults and children 14 years and older: Take 1 effervescent tablet twice daily.
Children 6-13 years: Take 1 effervescent tablet once daily.
Dissolve the effervescent tablet in a glass of cold water.

Paediatric population

The use in children under 6 years of age is not recommended.

Method of administration

For oral administration
Drop the tablet in a glass of cold water. The tablet dissolves quickly producing an effervescent drink. Drink the contents of the whole glass as soon as the effervescing has stopped.

4.3 Contraindications

- Known hypersensitivity to any the active substances, to plants of the Araliaceae family or to any of the excipients listed under section 6.1.

4.4 Special warnings and precautions for use

- Hepatotoxicity and hepatitis cases have been reported in association with the administration *Pelargonium sidoides* (as in **Cepacol Effervescent)**. Advise patients to stop taking **Cepacol Effervescent** and immediately contact a doctor if they notice signs of hepatotoxicity (yellowing of the skin and whites of the eyes (jaundice), itching, passing dark urine, pain in the upper right portion of the abdomen, fatigue, loss of appetite) occur.
- Caution is recommended in patients with gastritis or gastric ulcer.
- Advise patients to consult a doctor or a healthcare practitioner if the symptoms persist for longer than 1 week, or if the symptoms worsen or dyspnoea, fever, or purulent sputum occurs while taking **Cepacol Effervescent**.
- **Cepacol Effervescent** contains azo colouring agent (E129) which may cause allergic reactions.

4.5 Interaction with other medicines and other forms of interaction

- Due to its immunostimulatory effects, theoretically*, Perlagonium sidoides* (as in **Cepacol Effervescent**) might decrease the effectiveness of immunosuppressant therapy. It might

also exacerbate autoimmune diseases by stimulating disease activity. Avoid use or use with caution in patients with autoimmune diseases such as multiple sclerosis, systemic lupus erythematosus (SLE), rheumatoid arthritis (RA), etc.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

There is no fertility data available.

4.7 Effects on ability to drive and use machines

Cepacol Effervescent has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable Effects

a) Summary of the safety profile

Cepacol Effervescent is generally well-tolerated.

b) Tabulated list of adverse reactions

SYSTEM ORGAN CLASS	FREQUENCY	ADVERSE REACTIONS
Immune system disorders	*Less frequent*	allergic reactions
Gastrointestinal disorders	*Less frequent*	mild gastrointestinal complaints (diarrhoea, epigastric discomfort, nausea or vomiting, dysphagia),
Ear and labyrinth disorders	*Less frequent*	mild nasal bleeding
Hepato-biliary disorders	*Frequency not known*	hepatotoxicity
General disorders and administration site conditions	*Less frequent*	mild gingival bleeding

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**.** Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4.9 Overdose

In overdose side effects can be precipitated and/or be of increased severity. See section 4.8. Treatment should be symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

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Discipline Specific: 33.7 Combination Product
ATC code: R05X - Other cold preparations

Cepacol Cold and Flu Effervescent Tablets a combination product containing Vitamins A and D and Zinc which contribute to normal function and maintenance of the immune system.
It contains traditional herbal ingredients *Pelargonium sidoides* and *Hedera helix* which assist with symptomatic relief of common cold.

Pelargonium sidoides has been used in traditional herbal products for symptomatic treatment of common cold. It is thought to have immunostimulatory effects and mucolytic effects which can improve the symptoms of respiratory disorders such as bronchitis. *Pelargonium sidoides* seems to have antibacterial effects against various bacterial pathogens, including *Streptococcus pneumoniae*, *Hemophilus influenzae*, *Klebsiella pneumoniae* and *Pseudomonas aeruginosa*.

Hedera helix has been used in herbal preparations as an expectorant in case of productive cough. Its use is well established in the treatment of productive cough and may also be used for the adjuvant therapy of inflammatory bronchial diseases associated with hypersecretion of viscous mucus and as an adjuvant treatment of inflammatory bronchial diseases. This is due to its broncholytic and secretolytic efficacy.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid anhydrous (E330)
Sodium carbonate anhydrous (E500)
Sodium bicarbonate (E500)
Maltodextrin
Malic acid (E296)
Carbowax sentry PEG 8000 macrogol
Sucralose (E955)
Allura Red (E129)

Raspberry flavour (656569).

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

2 years

6.4 Special precautions for storage

Store at or below 25 ºC.

Protect from light and moisture.

Keep in the original container until required for use.

Keep the container tightly closed.

6.5 Nature and contents of container

10 or 20 tablets in a polyethylene tube with a desiccant lid, packed in a cardboard carton.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused 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/ RENEWAL OF THE AUTHORISATION

To be allocated

10. DATE OF REVISION OF THE TEXT

12 August 2024

PI T038074 09/2024

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