

SCHEDULING STATUS: Not scheduled

PROPRIETARY NAME (and dosage form)
EXPECTAMED COUGH SYRUP
(Syrup)

COMPOSITION

Each 10ml liquid contains:
Hedera Helix (English Ivy) (6:1 extract) 10mg
Pelargonium sidoides extract 15mg

Other ingredients:

Glycerine, sorbitol, flavouring, peppermint oil, propylene glycol, aqua, xanthan gum, ammonium chloride.

Preservatives:

Sodium Benzoate 0.12%*m/v*
Potassium Sorbate 0.06%*m/v*

Sugar-free

PHARMACOLOGICAL CLASSIFICATION

D. Complementary Medicine, 10.1 Antitussives and expectorants.

PHARMACOLOGICAL ACTION

English ivy leaves seem to be able to break up chest congestion and relieve muscle spasms. It seems to help breathing in children with chronic bronchitis.

Pelargonium sidoides:

Respiratory effects: *In vitro*, it was determined to significantly and concentration-dependently increase ciliary beat frequency (CBF), which is an important parameter of the defence mechanism of the mucociliary system.

Antibacterial effects: A root extract of *Pelargonium sidoides* seems to have antibacterial activity against several gram-positive and gram-negative bacterial pathogens and some *Leishmania* parasites *in vitro* and this effect may be due to an ability of *Pelargonium sidoides* to prevent bacteria from attaching to cells in the mucous membranes. Anecdotal information suggests that most of the coumarins found in *Pelargonium sidoides* contain a methoxy function at the C7 position and an OH group at either the C6 or C8 positions and that this is primarily responsible for its antibacterial activity.

INDICATION

Indicated to help relieve wet or dry coughs and congestion.

CONTRA-INDICATIONS

Pelargonium sidoides is thought to have immunostimulant effects. This product should not be used if you suffer from auto-immune diseases, immunodeficiencies, immunosuppression, and diseases affecting white blood cells. Avoid in individuals with a known allergy/hypersensitivity to English ivy (*Hedera helix*) or its constituents; or a known allergy/hypersensitivity to *Pelargonium sidoides*, its constituents, or members of the *Geraniaceae* family. Do not use if you are pregnant or lactating.

WARNINGS AND SPECIAL PRECAUTIONS

Use in children under 2 years of age is contraindicated due to the risk of aggravation of respiratory symptoms. Use cautiously in patients with cancer or taking antineoplastic (anticancer) agents. Use cautiously in patients with liver disease or who are using hepatotoxic agents. Use cautiously in patients with blood disorders or who are using anticoagulants or antiplatelets, as *Pelargonium sidoides* contains coumarin, and concurrent use may increase the risk of bleeding. Use cautiously in patients with heart conditions, as high intakes of *Pelargonium sidoides* may cause tachycardia or circulatory failure. Use cautiously in patients with asthma or other chronic respiratory conditions, as *Pelargonium sidoides* has been reported to cause bronchospasm or dyspnea in humans.

PREGNANCY AND LACTATION

Not recommended in pregnant or breastfeeding women.

INTERACTIONS

Always tell your healthcare professional if you are taking any other medicine. Caution is advised when combining English ivy with anticancer agents. English ivy may have antioxidant activity. Although not well studied in humans, combined use of English ivy and antioxidants may have additive effects. **Antibiotics:** Based on *in vitro* study, *Pelargonium sidoides* may exert antibacterial effects against a wide range of gram-negative and gram-positive bacteria. The effects of *Pelargonium sidoides* with antibiotics are not well understood. **Anticoagulants and antiplatelets:** Based on *in vitro* study, *Pelargonium sidoides* contains coumarin, a natural anticoagulant, as one of its main constituents. Theoretically, concurrent use of anticoagulants or antiplatelets and *Pelargonium sidoides* may increase the risk of bleeding. **Cardiovascular agents:** Based on human case reports, high intakes of *Pelargonium sidoides* may cause tachycardia, and theoretically may alter the effects of cardiovascular agents. **Hepatotoxic agents:** Theoretically, concurrent use of hepatotoxic agents and *Pelargonium sidoides* may increase the risk of liver damage. **Immunosuppressants:** Based on *in vitro* studies, *Pelargonium sidoides* may have immunostimulant effects. Theoretically, *Pelargonium sidoides* may interfere with the effects of immunosuppressants. **Laxatives:** Based on human study, high levels of *Pelargonium sidoides* may have a laxative effect. Theoretically, concurrent use of *Pelargonium sidoides* and laxatives may cause additive effects.

DOSAGE AND DIRECTIONS FOR USE

Adults and children 5 years and older: at the onset of a cough, take 2 teaspoons (10 ml) three times a day. Children 2-4 years: take 1 teaspoon (5ml) three times a day. If symptoms do not improve within 5 days of use, consult your healthcare practitioner immediately. For best results, gargle Expectamed in mouth for up to 45 seconds before swallowing, and do not take with food or beverages. Do not exceed the daily recommended dose. In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Do not share medicines prescribed for you with any other person.

SIDE-EFFECTS

The most frequently reported adverse effects related to English ivy are allergy symptoms, such as allergic contact dermatitis, asthmatic bronchitis, or allergic rhinoconjunctivitis (inflammation of the lining of the nose and the mucous membrane that covers the front of the eye and lines the eyelids). Few adverse effects have been reported with *Pelargonium sidoides*, which include skin rash with itching, sometimes with accompanying angioedema or systemic involvement (e.g. bronchospasm or dyspnea, diarrhoea, tachycardia, or circulatory failure), conjunctivitis, and gastrointestinal irritation. Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

None known. Treatment is symptomatic and supportive.

IDENTIFICATION

Light green liquid.

PRESENTATION

Amber glass bottle with white cap.

STORAGE INSTRUCTIONS

Store in a cool (below 25°C), dry place. STORE OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

To be allocated by the Medicines Control Council.

NAME AND BUSINESS ADDRESS OF THE APPLICANT

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DISCIPLINE

Herbal Medicine

This medicine has not been evaluated by the Medicines Control Council. This medicine is not intended to diagnose, treat, cure or prevent any disease.