

## PROFESSIONAL INFORMATION

### SCHEDULING STATUS

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### 1 NAME OF THE MEDICINE

CRECHE GUARD COUGH REMEDY

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains *Hedera Helix E. Fol.Spi.Sicc* (Ivy leaf) [100 % Native dry extract] 35mg

For full list of excipients, see section 6.1

### 3 PHARMACEUTICAL FORM

Dark purple viscous liquid with a sweet blackcurrant flavour.

### 4 CLINICAL PARTICULARS

#### 4.1 Therapeutic indication

CRECHE GUARD COUGH REMEDY syrup helps relieve a wet or dry cough.

#### 4.2 Posology and method of administration

Infants 0-1 year and children 2-5 years: 2,5 ml three times daily.

Children 6-12 years and adults: 5 ml three times daily.

Shake well before use.

**Do not use continuously for more than 10 days without consulting a doctor.**

#### 4.3 Contraindications

Not for use in patients who are hypersensitive to any of the ingredients, including the excipients.

#### 4.4 Special warnings and precautions for use

- Contains sorbitol which may have an effect on the glycaemic control of children with *Diabetes Mellitus*. Children with the rare hereditary condition of sorbitol intolerance should not take this product.
- Use in children under 2 years of age is at the discretion of a healthcare provider.

#### 4.5 Interaction with other medicines and other forms of interaction

There are no known interactions with other medicines.

#### 4.6 Undesirable effects

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

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

#### 4.7 Overdose

Symptoms of overdosage include severe stomach upset, nausea, diarrhoea and agitation.

Treatment is symptomatic and supportive.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 PHARMACOLOGICAL CLASSIFICATION

Complementary Medicines: Discipline Specific Traditional Claims

D33.6 Western Herbal Medicine

### 5.2 PHARMACOLOGICAL ACTION

Ivy leaf may possess expectorant, secretolytic and spasmolytic activity.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Blackcurrant flavouring and colourant, citric acid monohydrate, glycerine, maltodextrin, microcrystalline cellulose, polydimethylsiloxane emulsion (aqueous), sodium carboxymethyl cellulose, water.

Contains sugar: sorbitol 2,75 g/5ml

Preservatives: Potassium sorbate 0,035 % (*m/v*) and Sodium benzoate 0,045 % (*m/v*)

Alcohol, Caffeine and Tartrazine free

### 6.2 Incompatibilities

Unknown

### 6.3 Shelf life

2 years

### 6.4 Special precautions for storage

Store at or below 25 °C. Keep bottle tightly closed and protect from sunlight and moisture.

KEEP OUT OF THE REACH OF CHILDREN.

### 6.5 Nature and contents of container

CRECHE GUARD COUGH REMEDY is available in bottles containing 100 ml.

### 6.6 Special precautions for disposal and other handling

No special requirements

## 7 HOLDER OF CERTIFICATE OF REGISTRATION

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## 8 REGISTRATION NUMBER

To be allocated.

This unregistered medicine has not been evaluated by the South African Health Products Regulatory Authority for its quality, safety or intended use.

## 9 DATE OF PUBLICATION OF PROFESSIONAL INFORMATION

September 2020