PROFESSIONAL INFORMATION FOR HUMAN MEDICINES

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

Vicks Acta Plus Honey & Ginger Cough Syrup

Guaifenesin 200,0 mg.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 15 ml contains:

Guaifenesin 200 mg

Guaifenesin is also known as Glyceryl guaiacolate

Excipients with known effect:

Preservatives:

Ethanol (96 %) 5,00 % *v/v*,

Sodium Benzoate 0,1 % *m/v*

Propylene glycol: 1 500,00 mg

Contains sugar: 5,555 g sucrose

Contains sweetener: 11,25 mg Sodium saccharin

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

A yellow/yellow brown viscous liquid with honey-ginger menthol aromas and flavour, free from visible contamination.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the alleviation of cough associated with viscid/tenacious phlegm.

4.2 Posology and method of administration

Posology

Adults and children over 12 years: 15 ml or 3 medicine measures-full every four hours as needed.

Paediatric population

Children 6 - 12 years: 10 ml or 2 medicine measures-full every four hours as needed.

Do not use more than six doses per day.

Method of administration

Shake well before use.

Drink a glass of water with each dose.

4.3 Contraindications

Vicks Acta Plus Honey & Ginger Cough Syrup is contraindicated in:

- Patients with known hypersensitivity to guaifenesin or any of the excipients in Vicks Acta Plus Honey & Ginger Cough Syrup
- Porphyria
- Safety in pregnancy and lactation has not been established (see section 4.6)

4.4 Special warnings and precautions for use

Care is advised in the administration of guaifenesin to patients with persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, emphysema or cough with excessive mucus to avoid prolonged self-medication and masking the symptoms requiring more complex treatment.

Guaifenesin should not be taken for persistent cough except under the advice and supervision of a medical practitioner.

A persistent cough may be a sign of a serious condition.

If cough persists after the medication has been taken for 7 days, or tends to recur or is accompanied by high fever, rash or persistent headache, a doctor should be consulted.

Do not exceed the recommended dose.

Vicks Acta Plus Honey & Ginger Cough Syrup contains 5,555 g of sucrose per dose. This should be taken into

account in patients with diabetes mellitus.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Vicks Acta Plus Honey & Ginger Cough Syrup contains 631,6 mg of alcohol (ethanol) in each 15 ml dose which is equivalent to 5,00 % *v/v*.

Vicks Acta Plus Honey & Ginger Cough Syrup contains less than 1 mmol sodium (23 mg) per 15 ml dose, that is to say essentially 'sodium-free'.

Vicks Acta Plus Honey & Ginger Cough Syrup contains 15 mg sodium benzoate in each 15 ml dose.

4.5 Interaction with other medicines and other forms of interaction

Guaifenesin interferes with urine tests for 5-hydroxyindoleacetic acid (5-HIAA) and vanillylmandelic acid (VMA).

4.6 Fertility, pregnancy and lactation

Pregnancy

The safety of Guaifenesin in pregnancy has not been fully established.

Physical dependence in the neonate is possible with regular use.

Breastfeeding

The safety of Guaifenesin in lactation has not been fully established.

Fertility

There is insufficient information available to determine whether guaifenesin has the potential to impair fertility.

4.7 Effects on ability to drive and use machines

Do not drive or use machinery because VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP contains alcohol. Therefore, this medicine may lead to drowsiness and impaired concentration, which may be aggravated by simultaneous intake of alcohol or other central nervous system depressant agents.

4.8 Undesirable effects

System Organ Class	Frequency	Side Effects
Immune system disorders	Unknown	Hypersensitivity reactions, anaphylactic reactions, angioedema.
Nervous system disorders	Unknown	Dizziness, headache.
Respiratory, thoracic and mediastinal disorders	Unknown	Difficulty breathing, throat oedema, dyspnoea
Gastrointestinal disorders	Unknown	Gastrointestinal discomfort, diarrhoea, nausea, vomiting, stomach pains, lip oedema, tongue oedema.
Skin and subcutaneous tissue disorders	Unknown	Skin rash, urticaria (hives).
General disorders and administration site conditions	Unknown	Face oedema

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 requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4.9 Overdose

Symptoms: Mild to moderate overdose may cause dizziness or vertigo, drowsiness and gastrointestinal disturbances (nausea and vomiting). Urinary calculi have been reported in patients consuming large quantities of guaifenesin.

Treatment: Treatment is symptomatic, involving general supportive measures. Vomiting would be treated by fluid replacement and monitoring of electrolytes if indicated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A.10.1 Antitussives and Expectorants

ATC code: RO5CAO3

Glyceryl guaiacolate is thought to act as an expectorant by increasing the volume and reducing the viscosity of secretions in the trachea and bronchi. Thus, it may increase the efficiency of the cough reflex and facilitate removal of the secretions.

Glyceryl guaiacolate is reported to increase the volume and reduce the viscosity of tenacious sputum and is used as an expectorant for productive cough.

5.2 Pharmacokinetic properties

Orally administered Glyceryl guaiacolate is well absorbed/readily absorbed from the gastrointestinal tract.

Excretion is in the urine as inactive metabolites.

Glyceryl guaiacolate has an elimination half-life of approximately 1 hour with no detectable amounts in the blood after 8 hours indicating rapid metabolism and excretion.

Elderly

There are no specific data available on the pharmacokinetics of Glyceryl guaiacolate in the elderly.

5.3 Preclinical safety data

Not Applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carmellose sodium (Cellulose Gm 7HoF)

Citric acid, anhydrous

Ethanol 96 % (absolute ethanol)

Flavour Honey-Ginger (198628)

Flavour Verveine (PHL-145439)

Levomenthol

Macrogol stearate (MYRJ52FL)

Propylene glycol

Polyethylene oxide

Purified water

Sodium saccharin

Sodium citrate

Sodium benzoate

Sucrose

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at or below 25 °C.

Do not refrigerate

6.5 Nature and contents of container

Amber glass bottle of 100 ml or 150 ml syrup.

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

7 HOLDER OF CERTIFICATE OF REGISTRATION

P&G South African Trading (Pty) Ltd.

Alice Lane Towers

15 Alice Lane

Sandton, South Africa, 2196.

8 REGISTRATION NUMBER(S)

34/10.1/0017

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

February 2015

10 DATE OF REVISION OF THE TEXT

29 August 2025