PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S0

VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP

Guaifenesin 200 mg

Contains sugar: 5,555 g sucrose

Contains sweetener: 11,25 mg Sodium saccharin

Read all of this leaflet carefully because it contains important information for you

VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

What is in this leaflet

1. What VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP is and what it is used for
2. What you need to know before you take VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP
3. How to take VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP
4. Possible side effects
5. How to store VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP
6. Contents of the pack and other information

1. What VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP is and what it is used for

VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP helps to loosen mucus (phlegm) from the lungs and make it easier to cough up.

For the alleviation of cough associated with thick/sticky phlegm.

2. What you need to know before you take VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP

Do not take VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP:

- if you are hypersensitive (allergic) to guaifenesin or any of the other ingredients of VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP (listed in section 6).
- If you are aware that you suffer from porphyria.

Safety in pregnancy and lactation has not been established.

Warnings and precautions

Take special care with VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP

- If you know or suspect that you are Diabetic Type I, Diabetic Type II, Pre-diabetic and/or Insulin resistant.
- if you are suffering from asthma, emphysema or chronic bronchitis.
- have had a cough for more than one week or you have a recurrent cough
- have a persistent cough that may be caused by asthma or other respiratory conditions
- have a cough which brings up a lot of mucus (phlegm).
- If you develop a fever, or if there is exacerbation or no improvement after 7 days, do not increase the doses beyond the recommended level, but consult your doctor.

Children and adolescents

VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP should not be used in children under 6 years of age.

Other medicines and VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Some urine tests may be affected if taken within 24 hours of taking VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP.

Tell the doctor or nurse taking the urine sample that you are taking VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP

VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP with food and drink

No interactions or warnings are known.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before taking this medicine.

Driving and using machines

It is not always possible to predict to what extent VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP affects them.

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.

VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP contains:

- Sucrose: If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. 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. Do not use in patients who are known/ suspected to be Diabetic Type I, Diabetic Type 11, Pre-diabetic and/or Insulin resistant.
- 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.

3. HOW TO TAKE VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP

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

Always take **VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP** exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Shake well before use.

Take **VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP** every four hours as needed. Drink a glass of water with each dose. Do not use more than six doses per day.

The usual dose is:

Adults and children over 12 years: 3 medicine measuresful (15 ml)

Children 6 - 12 years: 2 medicine measuresful (10 ml)

A persistent cough may be a sign of a serious condition. If the cough persists for more than 1 week, tends to recur, or is accompanied by high fever, rash or persistent headache, consult a medical practitioner.

If you take more VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. You may feel exceptionally dizzy or drowsy, have a headache or may experience some gastrointestinal disturbances.

If you forget to take VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP

Do not take a double dose to make up for forgotten individual doses.

If you stop taking VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP

None known.

4. POSSIBLE SIDE EFFECTS

VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP can have side effects.

Not all side effects reported for **VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your healthcare provider for advice.

If any of the following happens, stop taking VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Allergic reactions e.g. skin rashes, itching, swelling of lips, tongue, throat, face or difficulty breathing
- Severe nausea, vomiting and stomach pains
- Confusion

These are all serious adverse effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Uncommon side effects: nausea, vomiting, stomach discomfort or diarrhoea, dizziness and headache

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP

5. How to store VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP

Store at or below 25 °C

Keep all medicines out of the reach and sight of children.

Keep the container in the outer carton.

Do not refrigerate.

Do not store in a bathroom

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP contains

The active ingredient/substance per 15 ml is: Guaifenesin 200 mg

The other ingredients are carmellose sodium (cellulose Gm 7HoF), citric acid (anhydrous), flavour honey-ginger 198628, flavour verveine PHL-145439, levomenthol, macrogol stearate MYRJ52FL, polyethylene oxide, propylene glycol, purified water, sodium saccharin, sodium citrate and sucrose.

Preservatives: Ethanol (96 %) as 5 % *v/v*, Sodium benzoate 0,1 % *m/v*

What VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP looks like and contents of the pack

VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP is a yellow/ yellow brown viscous liquid with honey and ginger aroma and flavour.

VICKS ACTA PLUS HONEY & GINGER COUGH SYRUP is packed in amber, flint glass bottles in sizes of 100 ml and 150 ml with white child resistant closures.

Holder of Certificate of Registration

P&G South African Trading (Pty) Ltd.

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Access to the corresponding Professional Information

www.vicks.co.za/en-za/product-information