

FLORA FORCE® HERBAL COUGH MIXTURE

Complementary medicine.
Western herbal medicine.
This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety and intended use.

SCHEDULING STATUS:

Not scheduled.

PROPRIETARY NAME (AND DOSAGE FORM):

FLORA FORCE® HERBAL COUGH MIXTURE liquid.

COMPOSITION:

Each 5 ml of FLORA FORCE® HERBAL COUGH MIXTURE contains:

ACTIVE INGREDIENT	QUANTITY
<i>Inula helenium</i> root EQUIV	52 mg
<i>Lobelia inflata</i> herb EQUIV	52 mg
<i>Marrubium vulgare</i> herb EQUIV	52 mg
<i>Pelargonium sidoides</i> root EQUIV	52 mg
<i>Prunus serotina</i> bark EQUIV	52 mg
<i>Pulmonaria officinalis</i> herb EQUIV	52 mg
<i>Pimpinella anisum</i> seed EQUIV	26 mg
<i>Thymus vulgaris</i> herb EQUIV	15 mg

Inactive ingredients: Alc 30% v/v and *Glycyrrhiza glabra* root as flavouring*.
FLORA FORCE® HERBAL COUGH MIXTURE is free from sugar.

PHARMACOLOGICAL CLASSIFICATION:

D 10.1 Medicine acting on the respiratory system. Antitussives and expectorants.

PHARMACOLOGICAL ACTION:

The individual herbs in this formula have been used traditionally in respiratory conditions and coughs. *Prunus serotina* bark is thought to have antitussive effects and *Pimpinella anisum* seed to loosen bronchial secretions. *Pelargonium sidoides* root ("umckalaobo") was used by Zulu traditional healers for cough-related illnesses. Compounds in *Marrubium vulgare* herb have expectorant activity. Volatile oils in *Inula helenium* root have relaxant effects on tracheal and ileal smooth muscles.

INDICATIONS:

FLORA FORCE® HERBAL COUGH MIXTURE contains herbs which have been used traditionally as expectorants and to alleviate respiratory conditions.

CONTRA-INDICATIONS:

FLORA FORCE® HERBAL COUGH MIXTURE is contraindicated in patients with:

- A hypersensitivity to any of the ingredients in FLORA FORCE® HERBAL COUGH MIXTURE.
- Heart disease (see "WARNINGS AND SPECIAL PRECAUTIONS").
- Hypertension (see "WARNINGS AND SPECIAL PRECAUTIONS").
- Bleeding disorders (see "WARNINGS AND SPECIAL PRECAUTIONS").
- Surgery (see "WARNINGS AND SPECIAL PRECAUTIONS").
- Pregnancy and lactation (see "PREGNANCY AND LACTATION").

WARNINGS AND SPECIAL PRECAUTIONS:

FLORA FORCE® HERBAL COUGH MIXTURE, should not be used continuously. Use under supervision of a registered healthcare practitioner (see "DOSAGE AND DIRECTIONS FOR USE").

FLORA FORCE® HERBAL COUGH MIXTURE should be used with care in patients with heart disease and hypertension. Patients with heart disease and hypertension should have increased monitoring of their blood pressure when taking FLORA FORCE® HERBAL COUGH MIXTURE (see "CONTRA-INDICATIONS").

When starting or stopping treatment with FLORA FORCE® HERBAL COUGH MIXTURE, patients with bleeding disorders should have increased monitoring of their blood levels (see "CONTRA-INDICATIONS").

FLORA FORCE® HERBAL COUGH MIXTURE should be used with care in patients undergoing surgery. Patients should discontinue use at least 2 weeks before elective surgical procedures (see "CONTRA-INDICATIONS").

When starting or stopping treatment with FLORA FORCE® HERBAL COUGH MIXTURE, patients taking oral anti-coagulants and anti-platelet medications should have increased monitoring of their INR (International Normalised Ratio) levels (see "INTERACTIONS").

When starting or stopping treatment with FLORA FORCE® HERBAL COUGH MIXTURE, patients taking anti-hypertensive medications should have increased monitoring of their blood pressure (see "INTERACTIONS").

Effects on the ability to drive or use machinery:

No studies on the effect of FLORA FORCE® HERBAL COUGH MIXTURE on the ability to drive or operate machines have been performed. It is unlikely that FLORA FORCE® HERBAL COUGH MIXTURE will affect the ability to drive or operate machines.

INTERACTIONS:

The herbs in FLORA FORCE® HERBAL COUGH MIXTURE may interact with the following medicines:

- Digoxin: overuse of *Glycyrrhiza glabra* may increase interaction due to potassium loss.
- Diuretics: overuse of *Glycyrrhiza glabra* may increase risk of potassium loss.
- Corticosteroid: overuse can increase activity of corticosteroids and increase potassium loss and depletion.

FLORA FORCE® HERBAL COUGH MIXTURE may potentially increase the effect of oral anti-coagulants and anti-platelet medications (e.g. warfarin, aspirin, clopidogrel, dalteparin, enoxaparin and heparin) when taken concomitantly (see "WARNINGS AND SPECIAL PRECAUTIONS").

FLORA FORCE® HERBAL COUGH MIXTURE may theoretically decrease the effect of anti-hypertensive medications (e.g. amlodipine, captopril, enalapril, losartan, valsartan, diltiazem, hydrochlorothiazide, furosemide) when taken concomitantly (see "WARNINGS AND SPECIAL PRECAUTIONS").

PREGNANCY AND LACTATION:

The safety and efficacy of FLORA FORCE® HERBAL COUGH MIXTURE during pregnancy and lactation has not been established. FLORA FORCE® HERBAL COUGH MIXTURE should therefore not be taken during pregnancy and lactation.

DOSAGE AND DIRECTIONS FOR USE:

The recommended daily dose should not be exceeded.

Adults (18 years and older):

Take one teaspoon three times daily before meals or as directed by your pharmacist or registered healthcare practitioner.

Children (under 18 years of age):

Children 8-17 years: Take one teaspoon three times daily before meals or as directed by your pharmacist or registered healthcare practitioner.

Children under 8 years: ½ teaspoon diluted in a little water 3 times daily before meals or as directed by your pharmacist or registered healthcare practitioner.

If symptoms have not improved after 1-2 weeks, advise patients to consult a registered healthcare practitioner (see "WARNINGS AND SPECIAL PRECAUTIONS").

SIDE-EFFECTS:

The following side-effects may occur with the use of FLORA FORCE® HERBAL COUGH MIXTURE:

Immune system disorders:

Frequency unknown: Allergic or anaphylactic reaction.

Endocrine disorders:

Frequency unknown: Hypokalemia.

Nervous system:

Frequency unknown: Headache.

Gastrointestinal disorders:

Frequency unknown: Nausea, vomiting and stomach pain.

Skin and subcutaneous disorders:

Frequency unknown: Skin rash.

Renal disorders:

Frequency unknown: Kidney problems.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS:

None known. Contact a poison control centre in area.

IDENTIFICATION:

Dark brown liquid with liquorice flavour.

PRESENTATION:

100 ml amber glass bottle with white tamper evident screw cap within a product box.

STORAGE INSTRUCTIONS:

Store at or below 25°C in a dry place.

Protect from light.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

To be allocated.

NAME AND BUSINESS ADDRESS OF APPLICANT:

Flora Force Health Products (Pty) Ltd.
Unit 3 Regent Park
Bell Crescent
Westlake
Cape Town
South Africa

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

21/08/2018

* *Glycyrrhiza glabra* root as flavouring contains less than 2 mg glycyrrhizin per 100 ml.