

FLORA FORCE® GINGER Capsules

Western 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.

SCHEDULING STATUS:

Not Scheduled.

PROPRIETARY NAME (AND DOSAGE FORM):

FLORA FORCE® GINGER Capsules

COMPOSITION:

Each FLORA FORCE® GINGER capsule contains:

ACTIVE INGREDIENT	QUANTITY
<i>Zingiber officinale</i> rhizome powder	500 mg

Inactive ingredients: vegetable capsules.

FLORA FORCE® GINGER capsules are free from sugar and lactose.

PHARMACOLOGICAL CLASSIFICATION:

D 11.10, Gastro-intestinal tract, Other.

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties:

Preliminary research suggests the gastro-intestinal effects of ginger might be due to increases in levels of protective prostaglandins in the gut wall. Gastro-intestinal motility is enhanced by 6-shogaol.

The anti-nausea activity of *Zingiber officinale* may be due to the active constituents such as gingerols, shogaols and galano-lactone. These seem to act primarily on the 5-HT₃ receptors of the ileum. The predominant anti-emetic action of ginger is localized in the GI tract, but there is some evidence that ginger constituents may also have central nervous system (CNS) activity.

INDICATIONS:

FLORA FORCE® GINGER capsules are traditionally used to relieve digestive disturbances and nausea.

CONTRA-INDICATIONS:

FLORA FORCE® GINGER capsules are contra-indicated in patients with:

- Bleeding disorders (see "WARNINGS AND SPECIAL PRECAUTIONS").
- Diabetes (see "WARNINGS AND SPECIAL PRECAUTIONS").
- Heart conditions (see "WARNINGS AND SPECIAL PRECAUTIONS").
- Surgery (see "WARNINGS AND SPECIAL PRECAUTIONS").
- Pregnancy and lactation (see "PREGNANCY AND LACTATION").

WARNINGS AND SPECIAL PRECAUTIONS:

When starting, or stopping treatment with *Zingiber officinale* containing products, including FLORA FORCE® GINGER capsules, patients with bleeding disorders should have increased monitoring of their INR (International Normalised Ratio) levels (see "CONTRA-INDICATIONS").

FLORA FORCE® GINGER capsules should be used with care in patients with diabetes. Theoretically, *Zingiber officinale* may decrease blood sugar levels. Diabetic patients should monitor their blood sugar levels when taking FLORA FORCE® GINGER capsules (see "CONTRA-INDICATIONS").

FLORA FORCE® GINGER capsules should be used with care in patients with heart conditions. Theoretically, excessive doses of ginger might worsen some heart conditions (see "CONTRA-INDICATIONS").

FLORA FORCE® GINGER capsules 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 *Zingiber officinale* containing products, including FLORA FORCE® GINGER capsules, patients taking oral anti-coagulants or anti-platelet drugs should have increased monitoring of their INR (International Normalised Ratio) levels (see "INTERACTIONS").

The use of FLORA FORCE® GINGER capsules in children and adolescents under 18 years of age is not recommended due to lack of adequate data (see "DOSAGE AND DIRECTIONS FOR USE").

Effects on the ability to drive or use machinery:

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

INTERACTIONS:

The herbs in FLORA FORCE® GINGER capsules may interact with the following medicines:

- Metronidazole: *Zingiber officinale* may increase levels of metronidazole.

The dose of the above medications may need to be adjusted when taken in conjunction with FLORA FORCE® GINGER capsules.

Zingiber officinale, as in FLORA FORCE® GINGER capsules, may potentially increase the effect of oral anti-coagulants and anti-platelet drugs (e.g. warfarin, phenprocoumon, heparin, aspirin, clopidogrel, enoxaparin, dalteparin, ticlopidine, enoxaparin, heparin) when taken concomitantly. Patients taking anti-coagulants or anti-platelet medicines should have their INR levels monitored more frequently when taking FLORA FORCE® GINGER capsules (see "WARNINGS AND SPECIAL PRECAUTIONS").

Theoretically, *Zingiber officinale* as in FLORA FORCE® GINGER capsules, may enhance the blood glucose lowering effects of anti-diabetic medicines. Patients on anti-diabetic medicines should monitor their glucose levels closely when taking FLORA FORCE® GINGER capsules.

In an animal model, *Zingiber officinale* taken 2 hours prior to cyclosporine administration reduced the maximum concentration. This effect was not observed when *Zingiber officinale* and cyclosporine were administered at the same time. Patients taking cyclosporine should use FLORA FORCE® GINGER capsules with care.

Preliminary research suggests *Zingiber officinale* might have hypotensive and calcium channel-blocking effects. Theoretically *Zingiber officinale* might have an additive effect with calcium channel blockers. These include nifedipine, verapamil, diltiazem, isradipine, felodipine and amlodipine. Patients taking calcium channel-blockers should use FLORA FORCE® GINGER capsules with care.

PREGNANCY AND LACTATION:

The safety and efficacy of FLORA FORCE® GINGER® capsules during pregnancy and lactation have not been established. Capsules should therefore not be taken during pregnancy and lactation.

DOSAGE AND DIRECTIONS FOR USE:

The recommended daily dose should not be exceeded. Do not tamper with capsule.

Adults (18 years and older):

Take 2 capsules twice daily with meals or as prescribed.

Children (under 18 years of age):

Not recommended for use (see "WARNINGS AND SPECIAL PRECAUTIONS").

SIDE-EFFECTS:

The following side-effects may occur with the use of FLORA FORCE® GINGER capsules.

Nervous system disorders:

Frequency unknown: Sedation, drowsiness and dizziness.

Vascular disorders:

Frequency unknown: Mild arrhythmia.

Gastrointestinal disorders:

Frequency unknown: Abdominal discomfort, heartburn, burning pepper-like irritation in mouth, nausea, belching, dry retching, vomiting, burning sensation in tongue and throat and oral numbness.

Skin and subcutaneous disorders:

Frequency unknown: Hives, bruising and flushing.

Renal and urinary disorders:

Frequency unknown: Urinary urgency.

Reproductive system and breast disorders

Frequency unknown: Increased menstrual bleeding.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS:

None known. Contact a poison control centre in area.

IDENTIFICATION:

Clear size 0 all vegetable capsule containing cream coloured herbal powder.

PRESENTATION:

60 Capsules packed in a 125ml amber glass bottle with light green screw cap and safety seal insert.

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 THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Flora Force Health Products (Pty) Ltd.
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Bell Crescent
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