

FLORA FORCE® FENUGREEK 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® FENUGREEK Capsules

COMPOSITION:

Each FLORA FORCE® FENUGREEK capsule contains:

ACTIVE INGREDIENT	QUANTITY
<i>Trigonella foenum-graecum</i> seed powder	500 mg

Inactive ingredients: vegetable capsules

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

PHARMACOLOGICAL CLASSIFICATION:

D 40.1 Complementary medicine not otherwise specified – Discipline specific traditional claim

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties:

Trigonella foenum-graecum seed is thought to act via stimulation of sweat production, thereby enhancing milk secretion (the breast is a modified sweat gland).

INDICATIONS:

FLORA FORCE® FENUGREEK capsules are traditionally used to promote lactation.

CONTRA-INDICATIONS:

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

- A hypersensitivity to the Fabaceae family including soybeans, peanuts, chick peas and green peas. Theoretically, patients who are allergic to other Fabaceae plants, might also be allergic to fenugreek, as in, FLORA FORCE® FENUGREEK capsules.
- Bleeding disorders (see "WARNINGS AND SPECIAL PRECAUTIONS").
- Diabetes (see "WARNINGS AND SPECIAL PRECAUTIONS").
- Surgery (see "WARNINGS AND SPECIAL PRECAUTIONS").
- Pregnancy (see "PREGNANCY AND LACTATION").

WARNINGS AND SPECIAL PRECAUTIONS:

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

FLORA FORCE® FENUGREEK capsules should be used with care in patients with diabetes as *Trigonella foenum-graecum* may decrease blood sugar levels. Diabetic patients should monitor their blood sugar levels when taking FLORA FORCE® FENUGREEK capsules (see "CONTRA-INDICATIONS").

FLORA FORCE® FENUGREEK 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 *Trigonella foenum-graecum* containing products, including FLORA FORCE® FENUGREEK capsules, patients taking warfarin (or other coumarin anti-coagulants) should have increased monitoring of their INR (International Normalised Ratio) levels (see "INTERACTIONS").

The use of FLORA FORCE® FENUGREEK 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® FENUGREEK capsules on the ability to drive or operate machines have been performed. It is unlikely that FLORA FORCE® FENUGREEK capsules will affect the ability to drive or operate machines.

INTERACTIONS:

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

- Theophylline: *Trigonella foenum-graecum* may decrease theophylline absorption.

Advise patients to take any of the above-mentioned medicines at least 2 hours before or after FLORA FORCE® FENUGREEK capsules (see "DOSAGE AND DIRECTIONS FOR USE").

Trigonella foenum-graecum, as in FLORA FORCE® FENUGREEK capsules, may potentially increase the effect of oral anti-coagulants and anti-platelet drugs (e.g. warfarin, aspirin, clopidogrel, NSAIDs, ibuprofen, dalteparin, 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® FENUGREEK capsules (see "WARNINGS AND SPECIAL PRECAUTIONS").

Theoretically, *Trigonella foenum-graecum*, as in FLORA FORCE® FENUGREEK 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® FENUGREEK capsules.

PREGNANCY AND LACTATION:

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

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").

Theophylline must be taken at least 2 hours before or after FLORA FORCE® FENUGREEK capsules (see "INTERACTIONS").

SIDE-EFFECTS:

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

Endocrine disorders:

Frequency unknown: Reduced blood glucose.

Nervous system disorders:

Frequency unknown: Dizziness, loss of consciousness.

Gastrointestinal disorders:

Frequency unknown: Diarrhoea, dyspepsia, abdominal distention and flatulence.

Vascular disorders

Frequency unknown: Shock.

Respiratory, thoracic and mediastinal disorders

Frequency unknown: Allergy, nasal congestion, hoarseness, persistent coughing, wheezing, facial angioedema.

Renal and urinary disorders:

Frequency unknown: Increased micturition, sweet urine odour.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS:

The following symptoms may be experienced in the event of an overdose: Tachycardia, hypertension, hypertensive crisis and myocardial infarct. Contact a poison control centre in area.

IDENTIFICATION:

Clear size 0 all vegetable capsule containing yellow green herbal powder.

PRESENTATION:

60 Capsules packed in a 125ml amber glass bottle with light green screw cap and safety seal insert in a 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 THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

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

DATE OF PUBLICATION:

To be allocated.