FLORA FORCE® FENNEL 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® FENNEL Capsules

COMPOSITION:
Each FLORA FORCE® FENNEL capsule contains:

ACTIVE INGREDIENT	QUANTITY
Foeniculum vulgare fruit/seed powder	500 mg

Inactive ingredients: vegetable capsules
FLORA FORCE® FENNEL capsules are free from sugar and lactose.

PHARMACOLOGICAL CLASSIFICATION:
D 11.10 Gastro-intestinal tract, Others.

PHARMACOLOGICAL ACTION:
Pharmacodynamic properties:
Fennel and herbal teas containing fennel are traditionally used to improve a variety of gastrointestinal disorders. In an experimental study, enzymes like pancreatic trypsin, lipase, and amylase have been stimulated by fennel.
Fennel seed increased gastrointestinal motility and acted as an antispasmodic at high doses. Fennel extracts produced a reduction in acetylcholine-induced contraction and decreased maximum possible contractility.

INDICATIONS:
FLORA FORCE® FENNEL capsules assists with the relief of digestive disturbances including bloating and flatulence.

CONTRA-INDICATIONS:
FLORA FORCE® FENNEL capsules are contra-indicated in patients with:
- A hypersensitivity to anethole or plants from the Apiaceae family. These plants include carrots, parsley and celery (see "**WARNINGS AND SPECIAL PRECAUTIONS**").
- Bleeding disorders (see "**WARNINGS AND SPECIAL PRECAUTIONS**").
- Hormone sensitive conditions or cancers (see "**WARNINGS AND SPECIAL PRECAUTIONS**").
- Surgery (see "**WARNINGS AND SPECIAL PRECAUTIONS**").
- Pregnancy (see "**PREGNANCY AND LACTATION**").

WARNINGS AND SPECIAL PRECAUTIONS:
Foeniculum vulgare may cause an allergic reaction in individuals sensitive to anethole or plants from the Asteraceae family. Members of this family include carrots, parsley and celery (see "**CONTRA-INDICATIONS**").

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

Certain constituents in fennel may have estrogenic activity**. FLORA FORCE® FENNEL** capsules should be avoided in patients with hormone sensitive conditions and cancers. These conditions include breast, uterine, and ovarian cancer, endometriosis, and uterine fibroids (see "**CONTRA-INDICATIONS**").

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

FLORA FORCE® FENNEL capsules should be used with care in patients taking sedative medications, including midazolam, as it may increase its sedative effects (see "**INTERACTIONS**").

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

INTERACTIONS:
The herbs in **FLORA FORCE® FENNEL** capsules may interact with the following medicines:
- Ciprofloxacin: *Foeniculum vulgare* might reduce its effectiveness.

Foeniculum vulgare, as in **FLORA FORCE® FENNEL** capsules, may potentially increase the effect of oral anti-coagulants and anti-platelet drugs (e.g. warfarin, aspirin, clopidogrel, 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® FENNEL** capsules (see "**WARNINGS AND SPECIAL PRECAUTIONS**").

Foeniculum vulgare, as in **FLORA FORCE® FENNEL** capsules, may increase the sedative effects of midazolam. Patients taking midazolam should use **FLORA FORCE® FENNEL** capsule with caution (see "**WARNINGS AND SPECIAL PRECAUTIONS**").

There is some evidence that *Foeniculum vulgare* may interact with CYP3A4 enzymes and increase bioavailability of medicines metabolised by cytochrome P450 isoenzymes CYP3A4. Patients taking medicines metabolised by these enzymes should use **FLORA FORCE® FENNEL** capsules cautiously. These medicines include calcium channel blockers, chemotherapeutic agents, anti-fungals, glucocorticoids, alfentanil, cisapride, fentanyl, lidocaine, losartan, fluoxetine, omeprazole, ondansetron and fexofenadine.

Foeniculum vulgare, as in **FLORA FORCE® FENNEL** capsules, may have estrogenic activity. Theoretically, concomitant use of large amounts of fennel may interfere with contraceptive medication, hormone replacement therapy and tamoxifen.

PREGNANCY AND LACTATION:
The safety and efficacy of **FLORA FORCE® FENNEL** capsules during pregnancy have not been established. Capsules should therefore not be taken during pregnancy. Consult with a pharmacist or registered healthcare practitioner if you want to use **FLORA FORCE® FENNEL** capsules during breastfeeding.

DOSAGE AND DIRECTIONS FOR USE:
The recommended daily dose should not be exceeded.
Do not tamper with capsule.

Adults (18 years and older):
Take 1-2 capsules twice daily with meals or as prescribed.

Children (under 18 years of age):
Not recommended for use (see "**WARNINGS AND SPECIAL PRECAUTIONS**").

SIDE-EFFECS:
The following side-effects may occur with the use of **FLORA FORCE® FENNEL** capsules:

Infections and Infestations:
Frequency unknown: Botulism.

Blood and the lymphatic system disorders:
Frequency unknown: Iron deficiency, methemoglobinemia.

Eye disorders:
Frequency unknown**:** Rhino conjunctivitis.

Respiratory, thoracic and mediastinal disorders:
Frequency unknown: Cyanosis, bronchial asthma, hay fever, occupational asthma.

Gastrointestinal disorders:
Frequency unknown: Gastro-intestinal complaints and irritation, iron deficiency.

Skin and subcutaneous disorders:
Frequency unknown: Photosensitivity and atopic dermatitis.

Reproductive system and breast disorders:
Frequency unknown: Premature thelarche, increased menstrual flow.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS:
The following symptoms may be experienced in the event of an overdose:
Cyanosis, gastro-intestinal irritation, fatigue, dizziness, light-headedness and seizures.
Contact a poison control centre in area.

IDENTIFICATION:
Clear size 0 all vegetable capsule containing green herbal powder.

PRESENTATION:
60 Capsules packed in a 125ml amber glass bottle with dark green screw cap and safety seal insert, in a box.

STORAGE INSTRUCTIONS:
Store at or below 25 ºC 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 Heath Products (Pty) Ltd.
Unit 3 Regent Park, Bell Crescent,
Westlake, Cape Town.

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