PATIENT INFORMATION LEAFLET
Information for the Patient about 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, STRENGTH AND PHARMACEUTICAL FORM:
FLORA FORCE® FENNEL capsules.

Read all of this leaflet carefully because it contains important information for you. FLORA FORCE® FENNEL capsules are available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use FLORA FORCE® FENNEL capsules carefully to get the best results from it.
- **Keep this leaflet. You may need to read it again.**
- **Do not share FLORA FORCE® FENNEL capsules with any other person.**
- **Ask your pharmacist if you need more information or advice.**
- **You must see a registered healthcare practitioner if your symptoms worsen or do not improve.**

WHAT FLORA FORCE® FENNEL CAPSULES CONTAIN:
Each **FLORA FORCE® FENNEL** capsule contains:

ACTIVE INGREDIENT	QUANTITY
Foeniculum vulgare fruit/seed powder	500 mg

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

WHAT FLORA FORCE® FENNEL CAPSULES ARE USED FOR:
FLORA FORCE® FENNEL capsules assists with the relief of digestive disturbances including bloating and flatulence.

BEFORE YOU TAKE FLORA FORCE® FENNEL CAPSULES:
Do NOT take FLORA FORCE® FENNEL capsules:
- If you have a hypersensitivity to anethole or plants from the Apiaceae family (see "**Take special care with FLORA FORCE® FENNEL capsules**").
- If you have a bleeding disorder (see "**Take special care with FLORA FORCE® FENNEL capsules**").
- If you have hormone sensitive conditions or cancers (see "**Take special care with FLORA FORCE® FENNEL capsules**").
- Surgery (see "**Take special care with FLORA FORCE® FENNEL capsules**").
- Pregnancy (see "**Pregnancy and breastfeeding**").

Take special care with FLORA FORCE® FENNEL capsules:
Please discuss the use of **FLORA FORCE® FENNEL** capsules with your pharmacist or registered healthcare practitioner if you:
- Have a hypersensitivity to anethole or plants from the Apiaceae family. Members of this family include carrots, parsley and celery (see "**Do NOT take FLORA FORCE® FENNEL capsules**").
- Suffer from a bleeding disorder. You may have to arrange increased monitoring of your blood levels when starting or stopping treatment with **FLORA FORCE® FENNEL** capsules (see "**Do NOT take FLORA FORCE® FENNEL capsules**").
- Suffer from a hormone-sensitive condition or cancer. These conditions include breast, uterine, and ovarian cancer, endometriosis, and uterine fibroids. Fennel might have oestrogenic effects. Until more is known, women with hormone-sensitive conditions and cancers should avoid use of **FLORA FORCE® FENNEL** capsules (see "**Do NOT take FLORA FORCE® FENNEL capsules**").
- If you are undergoing surgery discontinue use at least 2 weeks prior to the procedure (see "**Do NOT take FLORA FORCE® FENNEL capsules**").
- Take warfarin or other blood thinning medicines. You may have to arrange increased monitoring or your INR (International Normalised Ratio) levels when starting or stopping treatment with **FLORA FORCE® FENNEL** capsules (see "**Taking other medicines with FLORA FORCE® FENNEL capsules**").

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 "**HOW TO TAKE FLORA FORCE® FENNEL CAPSULES**").
Taking FLORA FORCE® FENNEL capsules with food and drink:
FLORA FORCE® FENNEL capsules should be taken after meals with water.

Pregnancy and breastfeeding:
Safety of **FLORA FORCE® FENNEL** capsules during pregnancy has not been established.
Avoid taking **FLORA FORCE® FENNEL** capsules if you are pregnant.

If you are pregnant or breastfeeding, please consult your doctor, pharmacists or registered healthcare practitioner for advice before taking FLORA FORCE® FENNEL capsules.

Driving and using machinery:
No studies on the effect on the ability to drive and use of machinery have been performed. It is unlikely that **FLORA FORCE® FENNEL** capsules will impair your ability to drive or use machines. However, please exercise care when driving or operating machinery until you know how **FLORA FORCE® FENNEL** capsules affects you.

Important information about some of the ingredients of FLORA FORCE® FENNEL capsules:
FLORA FORCE® FENNEL capsules are sugar free.

Taking other medicines with FLORA FORCE® FENNEL capsules:
Always tell your pharmacist or registered healthcare practitioner if you are taking any other medicine (this includes complementary or traditional medicines).

Please discuss the use of the following medicines in combination with **FLORA FORCE® FENNEL** capsules with your pharmacist or registered healthcare practitioner:
- Ciprofloxacin, an antibiotic, for the treatment of bacterial infections.

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

Also, discuss the use of the following medicines in combination with **FLORA FORCE® FENNEL** capsules with your pharmacist or registered healthcare practitioner:
- Warfarin or other blood thinning medicines. **FLORA FORCE® FENNEL** capsules may potentially increase the effect of blood thinning medicines (see "**Take special care with FLORA FORCE® FENNEL capsules**").
- Medicines which are changed and broken down by the liver (Cytochrome P450 substrates) as **FLORA FORCE® FENNEL** capsules can influence the absorption and effectiveness of these medicines.
- Midazolam as **FLORA FORCE® FENNEL** capsules may increase its sedative effects.
- Medicine with oestrogenic activity (such as contraceptive medications, hormone replacement therapy and tamoxifen) as **FLORA FORCE® FENNEL** capsules might interfere with their activity.

HOW TO TAKE FLORA FORCE® FENNEL CAPSULES:
Do not share medicines prescribed to you with any other person.
Always take FLORA FORCE® FENNEL capsules exactly as directed. You should check with your pharmacist or registered healthcare practitioner if you are unsure.
DO NOT EXCEED THE RECOMMENDED DAILY DOSAGE.

Adults (18 years and older):
Take 1-2 capsules twice daily with meals or as directed by your pharmacist or registered healthcare practitioner.

Children (under 18 years of age):
Not recommended for use (see "**Take special care with FLORA FORCE® FENNEL capsules**").

FLORA FORCE® FENNEL capsules may be taken for a period of up to 12 weeks followed by an interval of 1 week after which the next 12-week period can commence. However, should you experience any adverse effects or any of the side effects indicated below please consult your pharmacist or registered healthcare practitioner.

If you take more FLORA FORCE® FENNEL capsules than you should:
If you take more **FLORA FORCE® FENNEL** capsules than you should, you may experience a bluish discoloration of the skin, stomach irritation, fatigue, dizziness, light-headedness and convulsions (seizures).
In the event of over dosage, consult your pharmacist or registered healthcare practitioner. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take FLORA FORCE® FENNEL capsules:
Always take **FLORA FORCE® FENNEL** capsules as directed. If you miss a dose, take it as soon as you remember. If you do not remember the missed dose till the next dose is due, skip the missed dose and go back to your regular dosing schedule of 1-2 capsules twice daily. Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE-EFFECTS:
FLORA FORCE® FENNEL capsules can have side-effects.
Not all side-effects reported for FLORA FORCE® FENNEL capsules are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FLORA FORCE® FENNEL capsules, please consult your doctor, pharmacist or registered healthcare practitioner for advice.

Serious side-effects that you (or a family member if you are unable to) should report to your pharmacist or registered healthcare practitioner immediately include:
- An allergic reaction which may present with shortness of breath, difficulty breathing, wheezing, hives, or itching, swelling of the face, tongue or whole body.
- Slight discoloration (e.g. pale, grey, blue) of the skin, headache, difficulty breathing, light-headedness, weakness, confusion, palpitations and chest pain.
- Facial weakness, facial paralysis, vomiting and nausea.
- Difficulty shallowing, breathing and speaking.

Side-effects that you should report to your pharmacist or registered healthcare practitioner as soon as possible:
- Tearing, eye itching and redness, sneezing and congestion

Side-effects that you should report to your pharmacist or registered healthcare practitioner if they continue or become bothersome include:
- Gastrointestinal disturbances, such as:
  - Stomach discomfort and pain.
- Sensitivity to light and itching.
- Early breast development or increased menstrual bleeding.

If you notice any side-effects not mentioned in this leaflet, please inform your pharmacist or registered healthcare practitioner.

STORING AND DISPOSING OF FLORA FORCE® FENNEL capsules:
Store at or below 25ºC in a dry place.
Protect from light / moisture.
Do not take the capsules after the expiry date stated on the packaging material.
Return all unused capsules to your pharmacist.
Do not dispose of unused capsules in drains or sewerage systems (e.g. toilets).
STORE ALL MEDICINE OUT OF THE REACH OF CHILDREN.

PRESENTATION OF FLORA FORCE® FENNEL capsules:
60 capsules in a 125ml amber glass bottle with dark green screw cap and safety seal insert, packed in a box.

IDENTIFICATION OF FLORA FORCE® FENNEL capsules:
Clear size 0 all vegetable capsule containing green herbal powder.

REGISTRATION NUMBER/REFERENCE NUMBER:
To be allocated

NAME AND BUSINESS ADDRESS OF REGISTRATION HOLDER:
Flora Force Heath Products (Pty) Ltd.
Unit 3 Regent Park
Bell Crescent
Westlake
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