

PATIENT INFORMATION LEAFLET

Information for the Patient about 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, STRENGTH AND PHARMACEUTICAL FORM:

FLORA FORCE® FENUGREEK capsules.

Read all of this leaflet carefully because it contains important information for you. FLORA FORCE® FENUGREEK capsules are available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use FLORA FORCE® FENUGREEK capsules carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share FLORA FORCE® FENUGREEK capsules with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

WHAT FLORA FORCE® FENUGREEK CAPSULES CONTAIN:

Each FLORA FORCE® FENUGREEK capsules contains:

ACTIVE INGREDIENT	QUANTITY
Trigonella foenum-graecum seed powder	500 mg

Inactive ingredients are vegetable capsules.

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

WHAT FLORA FORCE® FENUGREEK CAPSULES ARE USED FOR:

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

BEFORE YOU TAKE FLORA FORCE® FENUGREEK CAPSULES:

Do NOT take FLORA FORCE® FENUGREEK capsules:

- If you are allergic to any of the active or inactive ingredients in FLORA FORCE® FENUGREEK capsules.
- If you have a bleeding disorder (see "Take special care with FLORA FORCE® FENUGREEK capsules").
- If you have diabetes (see "Take special care with FLORA FORCE® FENUGREEK capsules").
- Surgery (see "Take special care with FLORA FORCE® FENUGREEK capsules").
- Pregnancy (see "Pregnancy and breastfeeding").

Take special care with FLORA FORCE® FENUGREEK capsules:

Please discuss the use of FLORA FORCE® FENUGREEK capsules with your doctor if you:

- Suffer from a bleeding disorder. You may have to arrange increased monitoring of your blood levels when starting or stopping treatment with FLORA FORCE® FENUGREEK capsules (see "Do NOT take FLORA FORCE® FENUGREEK capsules").
- Suffer from Diabetes. You may have to arrange increased monitoring of your blood sugar levels (see "Do NOT take FLORA FORCE® FENUGREEK capsules").
- If you are undergoing surgery discontinue use at least 2 weeks prior to the procedure (see "Do NOT take FLORA FORCE® FENUGREEK 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® FENUGREEK capsules (see "Taking other medicines with FLORA FORCE® FENUGREEK capsules").
- Take anti-diabetic medicines. You may have to arrange increased monitoring or your blood glucose / sugar levels when starting or stopping treatment with FLORA FORCE® FENUGREEK capsules (see "Taking other medicines with FLORA FORCE® FENUGREEK capsules").

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 "HOW TO TAKE FLORA FORCE® FENUGREEK CAPSULES").

Taking FLORA FORCE® FENUGREEK capsules with food and drink:

FLORA FORCE® FENUGREEK capsules should be taken after meals with water.

Pregnancy and breastfeeding:

Safety of FLORA FORCE® FENUGREEK capsules during pregnancy has not been established. Avoid taking FLORA FORCE® FENUGREEK capsules if you are pregnant.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacists or other healthcare professional for advice before taking FLORA FORCE® FENUGREEK capsules.

Driving and using machinery:

No studies on the effect on the ability to drive and use machinery have been performed. It is unlikely that FLORA FORCE® FENUGREEK 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® FENUGREEK capsules affects you.

Important information about some of the ingredients of FLORA FORCE® FENUGREEK capsules:

FLORA FORCE® FENUGREEK capsules are sugar free.

Taking other medicines with FLORA FORCE® FENUGREEK capsules:

Always tell your healthcare professional 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® FENUGREEK capsules with your doctor or pharmacist:

- Theophylline for the treatment of respiratory diseases such as COPD (chronic obstructive pulmonary disease) and asthma.

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

Taking the above-mentioned medicines at the same time as FLORA FORCE® FENUGREEK capsules can lower or increase their effectiveness. These medicines must be taken at least 2 hours before or after FLORA FORCE® FENUGREEK capsules.

Also, discuss the use of the following medicines in combination with FLORA FORCE® FENUGREEK capsules with your doctor or pharmacist:

- Warfarin or other blood thinning medicines. FLORA FORCE® FENUGREEK capsules may potentially increase the effect of blood thinning medicines. You may have to arrange increased monitoring of your INR levels when taking FLORA FORCE® FENUGREEK capsules (see "Take special care with FLORA FORCE® FENUGREEK capsules").
- Antidiabetic medicines as FLORA FORCE® FENUGREEK may further lower blood sugar levels. Monitor your blood glucose / sugar levels regularly if you are using FLORA

FORCE® FENUGREEK capsules and antidiabetic medicines in combination (see "Take special care with FLORA FORCE® FENUGREEK capsules").

HOW TO TAKE FLORA FORCE® FENUGREEK CAPSULES:

Do not share medicines prescribed to you with any other person.

Always take FLORA FORCE® FENUGREEK capsules exactly as directed. You should check with your pharmacist if you are unsure.

DO NOT EXCEED THE RECOMMENDED DAILY DOSAGE.

Adults (18 years and older):

Take 2 capsules twice daily with meals or as directed by your doctor, pharmacist or healthcare practitioner.

Children (under 18 years of age):

Not recommended for use (see "Take special care with FLORA FORCE® FENUGREEK capsules").

FLORA FORCE® FENUGREEK 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 healthcare practitioner.

If you take more FLORA FORCE® FENUGREEK capsules than you should:

If you take more FLORA FORCE® FENUGREEK capsules than you should, you may experience an increased heart rate, high blood pressure and chest pain

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take FLORA FORCE® FENUGREEK capsules:

Always take FLORA FORCE® FENUGREEK 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 two capsules twice daily. Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE-EFFECTS:

FLORA FORCE® FENUGREEK capsules can have side-effects.

Not all side-effects reported for FLORA FORCE® FENUGREEK capsules are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FLORA FORCE® FENUGREEK capsules, please consult your doctor, pharmacist or other health care professional for advice.

Serious side-effects that you (or a family member if you are unable to) should report to your doctor immediately include:

- An allergic reaction which may present with nasal congestion, hoarseness, persistent coughing, wheezing, swelling of the face, tongue or whole body.
- Signs of shock such as low blood pressure, rapid shallow breathing, cold and clammy skin, rapid weak pulse, dizziness, fainting or weakness.
- Signs of decreased blood sugar such as light headedness, blurred vision and confusion.

Side-effects that you should report to your doctor as soon as possible:

- More urine than is normal for you.

Side-effects that you should report to your doctor or pharmacist if they continue or become bothersome include:

- Gastrointestinal disturbances, such as:
 - Heartburn, stomach discomfort and pain, diarrhoea, bloated stomach, flatulence.
 - Sweet urine odour.
- If you notice any side-effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF FLORA FORCE® FENUGREEK capsules:

Store at or below 25°C 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® FENUGREEK capsules:

60 Capsules packed into 125ml amber glass bottle with light green screw cap and safety seal insert [in a box](#).

IDENTIFICATION OF FLORA FORCE® FENUGREEK capsules:

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

REGISTRATION NUMBER/REFERENCE NUMBER:

To be allocated

NAME AND BUSINESS ADDRESS OF REGISTRATION HOLDER:

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

DATE OF PUBLICATION:

To be allocated