

PATIENT INFORMATION LEAFLET
Information for the Patient about FLORA FORCE® CAYENNE 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® CAYENNE capsules

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

- Keep this leaflet. You may need to read it again.
- Do not share FLORA FORCE® CAYENNE 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® CAYENNE CAPSULES CONTAIN:
Each FLORA FORCE® CAYENNE capsule contains:

ACTIVE INGREDIENT	QUANTITY
Capsicum minimum fruit powder	500 mg

Inactive ingredients are vegetable capsules.

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

WHAT FLORA FORCE® CAYENNE CAPSULES ARE USED FOR:

FLORA FORCE® CAYENNE capsules are indicated to support circulatory health. Capsicum spp. has been used traditionally to improve peripheral circulation.

BEFORE YOU TAKE FLORA FORCE® CAYENNE CAPSULES:

Do NOT take FLORA FORCE® CAYENNE capsules:

- If you are allergic to any of the ingredients in FLORA FORCE® CAYENNE capsules.
- If you have a bleeding disorder (see "Take special care with FLORA FORCE® CAYENNE capsules").
- If you have diabetes (see "Take special care with FLORA FORCE® CAYENNE capsules").
- If you have gastroesophageal reflux disease.
- If you have hypertension ("Take special care with FLORA FORCE® CAYENNE capsules").
- Surgery (see "Take special care with FLORA FORCE® CAYENNE capsules").
- Pregnancy and lactation (see "Pregnancy and breastfeeding").

Take special care with FLORA FORCE® CAYENNE capsules:

Please discuss the use of FLORA FORCE® CAYENNE 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® CAYENNE capsules (see "Do NOT take FLORA FORCE® CAYENNE capsules").
- Suffer from Diabetes. You may have to arrange increased monitoring of your blood sugar levels (see "Do NOT take FLORA FORCE® CAYENNE capsules").
- Suffer from Hypertension. You may have to arrange increased monitoring of your blood pressure (see "Do NOT take FLORA FORCE® CAYENNE capsules").
- If you are undergoing surgery discontinue use at least 2 weeks prior to the procedure (see "Do NOT take FLORA FORCE® CAYENNE capsules").
- Take iron, as it may decrease the bio-availability of iron. You may have to arrange increased monitoring of your iron levels when starting or stopping treatment with FLORA FORCE® CAYENNE capsules (see "Taking other medicines with FLORA FORCE® CAYENNE capsules").
- Take warfarin or other blood thinning medicines. You may have to arrange increased monitoring of your INR (International Normalised Ratio) levels when starting or stopping treatment with FLORA FORCE® CAYENNE capsules (see "Taking other medicines with FLORA FORCE® CAYENNE capsules").

The use of FLORA FORCE® CAYENNE 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® CAYENNE capsules")

Taking FLORA FORCE® CAYENNE capsules with food and drink:

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

Pregnancy and breastfeeding:

Safety of FLORA FORCE® CAYENNE capsules during pregnancy and breastfeeding has not been established. Avoid taking FLORA FORCE® CAYENNE capsules if you are pregnant or breastfeeding.

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

Take care when handling capsules. Exposure to the contents can cause unpleasant symptoms. It can also cause an allergic reaction characterised by shortness of breath, rash, itching and swelling.

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

FLORA FORCE® CAYENNE capsules are sugar free.

Taking other medicines with FLORA FORCE® CAYENNE 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® CAYENNE capsules with your doctor or pharmacist.

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

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

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

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

- Warfarin or other blood thinning medicines. FLORA FORCE® CAYENNE capsules may potentially increase the effect of blood thinning medicines (see "Take special care with FLORA FORCE® CAYENNE capsules").
- Antidiabetic medicines as FLORA FORCE® CAYENNE capsules may further lower blood sugar levels. Monitor your blood sugar levels regularly if you are using FLORA FORCE® CAYENNE capsules and antidiabetic medicines in combination.
- Cytochrome P450 substrates (CYP2C9, CYP2E1 and CYP3A4) which inhibit certain liver enzymes as these can increase capsaicinoid levels and increase the risk of adverse effects.
- Iron as FLORA FORCE® CAYENNE capsules may decrease the absorption of iron (see "Take special care with FLORA FORCE® CAYENNE capsules").

HOW TO TAKE FLORA FORCE® CAYENNE CAPSULES:

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

Always take FLORA FORCE® CAYENNE 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 professional.

Children (under 18 years of age):

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

FLORA FORCE® CAYENNE 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® CAYENNE capsules than you should:

If you take more FLORA FORCE® CAYENNE capsules than you should, you may experience 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® CAYENNE capsules:

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

POSSIBLE SIDE-EFFECTS:

FLORA FORCE® CAYENNE capsules may have side-effects.

Not all side-effects reported for FLORA FORCE® CAYENNE capsules are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FLORA FORCE® CAYENNE 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 shortness of breath, difficulty breathing, wheezing, hives, or itching, swelling of the face, tongue or whole body.
 - Increased bleeding, heart attack and increased heart rate.
 - 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:
- Less urine than is normal for you.
 - Swollen feet and ankles.

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

- Gastrointestinal disturbances, such as:
 - Stomach discomfort, stomach pain, indigestion, diarrhoea, bloated stomach, heartburn, flatulence, ulcer aggravation, nausea and vomiting.
- An intense feeling of well-being.
- Sensitivity to light and itching.
- Dizziness, light-headedness or increased sensitivity to pain.
- Increased menstrual bleeding.

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

STORING AND DISPOSING OF FLORA FORCE® CAYENNE CAPSULES:

Store all medicines out of reach of children.

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 REACH OF CHILDREN.

PRESENTATION OF FLORA FORCE® CAYENNE CAPSULES:

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

IDENTIFICATION OF FLORA FORCE® CAYENNE CAPSULES:

Clear size 0 all vegetable capsule containing dark red 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.