

## 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 (AND DOSAGE FORM):

FLORA FORCE CAYENNE® Capsules

### COMPOSITION:

Each FLORA FORCE CAYENNE® Capsules contains:

ACTIVE INGREDIENT	QUANTITY
<i>Capsicum minimum</i> fruit powder	500 mg

Inactive ingredients: vegetable capsules

FLORA FORCE CAYENNE® 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:

The major active constituent in *Capsicum minimum* are capsaicinoids including capsaicin. In human, animal and in vitro studies, consumption of *Capsicum minimum* and capsaicin decreased the rate of oxidation, increased lag time to lipoprotein oxidation and enhanced blood flow. Capsaicin is also thought to reduce platelet aggregation and related to increased fibrinolytic activity.

### INDICATIONS:

FLORA FORCE CAYENNE® capsules are indicated to support circulatory health.

*Capsicum minimum* has been used traditionally to improve peripheral circulation.

### CONTRA-INDICATIONS:

FLORA FORCE CAYENNE® capsules are contraindicated in patients with:

- A hypersensitivity to any of the ingredients in FLORA FORCE CAYENNE® capsules.
- Bleeding disorders (see "WARNING AND SPECIAL PRECAUTIONS")
- Diabetes (see "WARNINGS AND SPECIAL PRECAUTIONS")
- Hypertension (see "WARNINGS AND SPECIAL PRECAUTIONS")
- Surgery (see "WARNINGS AND SPECIAL PRECAUTIONS")
- Pregnancy and lactation (see "PREGNACY AND LACTATION")

### WARNINGS AND SPECIAL PRECAUTIONS:

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

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

FLORA FORCE CAYENNE® capsules should be used with care in patients with hypertension. Theoretically *Capsicum* spp. may increase blood pressure.

FLORA FORCE CAYENNE® capsules should be used with care in patients undergoing surgery. Patients should discontinue use at least 2 weeks before elective surgical procedures (see "CONTRAINDICATIONS").

When starting, or stopping treatment with *Capsicum* spp. containing products, including FLORA FORCE CAYENNE®, patients taking warfarin (or other coumarin anticoagulants) should have increased monitoring of their INR (International Normalised Ratio) levels (see "INTERACTIONS").

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 "DOSAGE AND DIRECTIONS FOR USE").

Effects on the ability to drive or use machinery:

No studies on the effect of FLORA FORCE CAYENNE® capsules on the ability to drive or operate machines have been performed. It is unlikely that FLORA FORCE CAYENNE® capsules will affect the ability to drive or operate machines.

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.

### INTERACTIONS:

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

- Theophylline: *Capsicum* spp. may enhance theophylline absorption.
- Cefazolin: Theoretically capsaicin. may enhance absorption.
- Ciprofloxacin: Theoretically capsaicin may increase bioavailability

Advise patients to take any of the above-mentioned medicines at least 2 hours before or after FLORA FORCE CAYENNE® capsules

*Capsicum* spp., as in FLORA FORCE CAYENNE® 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 antiplatelet medicines should have their INR levels monitored more frequently when taking FLORA FORCE CAYENNE® capsules (see "WARNINGS AND SPECIAL PRECAUTIONS").

Theoretically, *Capsicum* spp., as in FLORA FORCE CAYENNE® capsules, may enhance the blood glucose lowering effects of antidiabetic medicines. Patients on antidiabetic medicines should monitor their glucose levels closely when taking FLORA FORCE CAYENNE® capsules.

There is some evidence that capsaicinoids, which are components of *Capsicum* spp., are metabolised by CYP2C9 enzymes. Theoretically CYP2C9 inhibitors might increase capsaicinoid levels and increase the risk of adverse effects. Patients taking these medicines should use FLORA FORCE CAYENNE® capsules cautiously. Some CYP2C9 inhibitors include Cordarone, fluconazole, lovastatin, Paxil, Accolate, and many others.

There is some evidence that capsaicinoids, which are components of *Capsicum* spp., are metabolised by CYP2E1 enzymes. Theoretically CYP2E1 inhibitors might increase capsaicinoid levels and increase the risk of adverse effects. Patients taking these medicines

should use FLORA FORCE CAYENNE® capsules cautiously. Some of these drugs include diethyldithiocarbamate and disulfiram.

There is some evidence that capsaicinoids, which are components of *Capsicum* spp., are metabolised by CYP3A4 enzymes. Theoretically CYP3A4 inhibitors might increase capsaicinoid levels and increase the risk of adverse effects. Patients taking these medicines should use FLORA FORCE CAYENNE® capsules cautiously. Some of these drugs include amiodarone, clarithromycin, diltiazem, erythromycin, indinavir, ritonavir, saquinavir, and many others.

Theoretically, *Capsicum* spp may decrease the bioavailability of iron. Patients taking iron should monitor their iron levels when taking FLORA FORCE CAYENNE® capsules.

### PREGNANCY AND LACTATION:

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

### 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")

### SIDE-EFFECTS:

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

### Endocrine disorders:

*Frequency unknown:* Reduced blood glucose, increase plasma insulin

### Psychiatric disorders:

*Frequency unknown:* Addiction

### Nervous system disorders:

*Frequency unknown:* Dizziness, hyperalgesia,

### Vascular disorders:

*Frequency unknown:* Increased bleeding, myocardial infarct, hypertension and tachycardia

### Gastrointestinal disorders:

*Frequency unknown:* Gastro-intestinal irritation, mouth, throat and oesophageal irritation and pain, stomach discomfort and pain, dyspepsia, diarrhoea, heart burn, rectal hypersensitivity, abdominal distention, gastroesophageal reflux, nausea, flatulence, ulcer aggravation, vomiting and liver damage

### Skin and subcutaneous disorders:

*Frequency unknown:* Photosensitivity, pruritus, oedema

### Renal and urinary disorders:

*Frequency unknown:* Kidney damage

### Reproductive system and breast disorders:

*Frequency unknown:* Increased menstrual bleeding

### 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 dark orange herbal powder.

### PRESENTATION:

90 Capsules packed in a 125ml amber glass bottle with light gold/mustard screw cap and safety seal insert.

### 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 Heath Products (Pty) Ltd.  
Unit 3 Regent Park,  
Bell Crescent,  
Westlake,  
Cape Town  
South Africa

### DATE OF PUBLICATION:

To be allocated