

FLORA FORCE® TURMERIC 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® TURMERIC Capsules.

COMPOSITION:

Each FLORA FORCE® TURMERIC capsule contains

ACTIVE INGREDIENT	QUANTITY
<i>Curcuma longa</i> rhizome powder	500 mg

Inactive ingredients: vegetable capsules.

FLORA FORCE® TURMERIC 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 constituents in *Curcuma longa* are curcuminoids including curcumin. Preliminary research suggests that turmeric and its constituent curcumin may have antioxidant effects. Both turmeric and its constituents have been found to scavenge free radicals and phenolic oxidants and decrease levels of reactive oxygen species.

INDICATIONS:

FLORA FORCE® TURMERIC capsules provide antioxidants for the maintenance of good health.

CONTRA-INDICATIONS:

FLORA FORCE® TURMERIC capsules are contraindicated in patients with:

- A hypersensitivity to *Curcuma longa*.
- Biliary obstruction (bile duct obstruction and gallstones) (see "WARNINGS AND SPECIAL PRECAUTIONS").
- Bleeding disorders (see "WARNING AND SPECIAL PRECAUTIONS").
- Diabetes (see "WARNINGS AND SPECIAL PRECAUTIONS").
- Gastroesophageal reflux disease.
- Hormone sensitive cancers/conditions.
- Infertility.
- Iron deficiency (see "WARNINGS AND SPECIAL PRECAUTIONS").
- Surgery (see "WARNINGS AND SPECIAL PRECAUTIONS").

WARNINGS AND SPECIAL PRECAUTIONS:

FLORA FORCE® TURMERIC capsules should be used with care in patients with cholelithiasis (gallstones) and should only be used after consultation with a physician (see "CONTRAINDICATIONS").

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

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

FLORA FORCE® TURMERIC capsules should be used with caution in patients with iron deficiency. Patient should monitor their iron levels (see "CONTRAINDICATIONS").

FLORA FORCE® TURMERIC 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 turmeric containing products, including FLORA FORCE® TURMERIC capsules, patients taking warfarin (or other coumarin anticoagulants) should have increased monitoring of their INR (International Normalised Ratio) levels (see "INTERACTIONS").

FLORA FORCE® TURMERIC 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® TURMERIC 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").

Vitamins and minerals obtained from other sources should be taken into consideration when taking FLORA FORCE® TURMERIC capsules.

Effects on the ability to drive or use machinery:

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

INTERACTIONS:

FLORA FORCE® TURMERIC capsules may interact with the following medicines:

- Beta blockers: curcumin may decrease the absorption of talinolol and may increase the absorption of celiprolol.
- Sulfasalazine: *Curcuma longa* might increase absorption of sulfasalazine.
- Oestrogen: *Curcuma longa* might decrease the effects of oestrogen
- Norfloxacin: *Curcuma longa* might increase levels

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

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

Curcuma longa, as in FLORA FORCE® TURMERIC capsules, may potentially increase the effect of oral anti-coagulants and anti-platelet drugs (e.g. warfarin, aspirin, clopidogrel,

dalteparin, enoxaparin, heparin, ticlopidine) when taken in conjunction. Patients taking anti-coagulants or antiplatelet medicines should have their INR levels monitored more frequently when taking FLORA FORCE® TURMERIC capsules (see "WARNINGS AND SPECIAL PRECAUTIONS").

Theoretically, *Curcuma longa*, as in FLORA FORCE® TURMERIC 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® TURMERIC capsules (see "WARNINGS AND SPECIAL PRECAUTIONS")

Theoretically, *Curcuma longa*, as in FLORA FORCE® TURMERIC capsules, might increase levels of p-glycoprotein substrates. Some of these medicines include chemotherapeutic agents, antifungals, protease inhibitors, H2 agonists, calcium channel blockers, digoxin, corticosteroids, erythromycin, cisapride, fexofenadine, cyclosporine, loperamide and quindine.

Curcuma longa, as in FLORA FORCE® TURMERIC capsules, may increase the sedative effects of Midazolam. Patients taking Midazolam should use FLORA FORCE® TURMERIC capsules with caution (see "WARNINGS AND SPECIAL PRECAUTIONS").

There is some evidence that *Curcuma longa* and/or curcumin 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® TURMERIC capsules cautiously. Some of these medicines include calcium channel blockers, chemotherapeutic agents, antifungals, glucocorticoids, alfentanil, cisapride, fentanyl, lidocaine, losartan, fluoxetine, omeprazole, ondansetron and fexofenadine.

There is some evidence that *Curcuma longa* may interact with CYP1A2 enzymes and increase the bioavailability of medicines metabolised by cytochrome P450 1A2 isoenzymes CYP1A2. Patients taking medicines metabolised by these enzymes should use FLORA FORCE® TURMERIC capsules cautiously. Some of these medicines include clozapine, fluvoxamine, haloperidol, imipramine, olanzapine, pentazocine, propranolol and zolmitriptan.

There is some evidence that *Curcuma longa* as in FLORA FORCE® TURMERIC capsules, may increase levels of certain antineoplastic agents. Some of these include docetaxel, paclitaxel, etoposide, vinblastine, vincristine and vindesine.

Theoretically, *Curcuma longa* may decrease the absorption of iron. Patients taking iron should monitor their iron levels when taking FLORA FORCE® TURMERIC capsules.

PREGNANCY AND LACTATION:

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

DOSAGE AND DIRECTIONS FOR USE:

The recommended daily dose should not be exceeded.

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® TURMERIC capsules.

Psychiatric disorders:

Frequency unknown: Giddiness.

Nervous system disorders:

Frequency unknown: Vertigo.

Gastrointestinal disorders:

Frequency unknown: Constipation, flatulence and yellow, hard stools, nausea and vomiting, diarrhoea or loose stool, dyspepsia, gastritis, distension and gastroesophageal reflux disease, abdominal fullness and pain, epigastric burning and tongue staining.

Skin and subcutaneous disorders:

Frequency unknown: Pruritus, pitting oedema, photosensitivity.

Renal and urinary disorders:

Frequency unknown: Diuresis.

Reproductive system and breast disorders:

Frequency unknown: Increased menstrual bleeding.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

None known. Contact a poison control centre in area.

IDENTIFICATION:

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

PRESENTATION:

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

STORAGE INSTRUCTIONS:

Store at or below 25°C.

Protect from light.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

To be allocated

NAME AND BUSINESS ADDRESS OF APPLICANT:

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