

TURMERYNNE® 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):

TURMERYNNE® Capsules

COMPOSITION:

Each TURMERYNNE® capsule contains:

ACTIVE INGREDIENT	QUANTITY
<i>Curcuma longa</i> rhizome powder	215 mg
<i>Capsicum minimum</i> fruit powder	215 mg
<i>Piper nigrum</i> fruit powder	20 mg

Inactive ingredients: vegetable capsules

TURMERYNNE® 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 anti-oxidant effects. Both turmeric and its constituents have been found to scavenge free radicals and phenolic oxidants and decrease levels of reactive oxygen species. Curcumin has anti-inflammatory activity, possibly by inhibiting cyclooxygenase-2 (COX-2), prostaglandins, leukotrienes and other cytokines involved in pro-inflammatory signalling pathways.

The major active constituent in *Capsicum minimum* is capsaicin. Various studies suggest that *Capsicum minimum* and capsaicin have anti-oxidant effects and decrease inflammation.

The active constituent, piperine, found in *Piper nigrum* increases the oral absorption and bio-availability of other substances.

INDICATIONS:

TURMERYNNE® capsules provide anti-oxidants for the maintenance of good health, and may reduce inflammation.

CONTRA-INDICATIONS:

TURMERYNNE® capsules are contra-indicated in patients with:

- A hypersensitivity to any of the ingredients in TURMERYNNE® capsules.
- 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").
- Hypertension (see "WARNINGS AND SPECIAL PRECAUTIONS").
- Gastro-oesophageal reflux disease.
- Infertility.
- Iron deficiency (see "WARNINGS AND SPECIAL PRECAUTIONS").
- Surgery (see "WARNINGS AND SPECIAL PRECAUTIONS").
- Pregnancy and lactation (see "PREGNACY AND LACTATION").

WARNINGS AND SPECIAL PRECAUTIONS:

TURMERYNNE® capsules should be used with care in patients with cholelithiasis (gallstones) and should only be used after consultation with a physician (see "CONTRA-INDICATIONS").

When starting, or stopping treatment with *Capsicum* spp. and *Curcuma longa* containing products, including TURMERYNNE® capsules, patients with bleeding disorders should have increased monitoring of their INR (International Normalised Ratio) levels (see "CONTRA-INDICATIONS").

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

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

TURMERYNNE® capsule should be used with caution in patients with iron deficiency. Patient should monitor their iron levels (see "CONTRA-INDICATIONS").

TURMERYNNE® capsules should be used with care in patients undergoing surgery. Patients should discontinue use at least 2 weeks before elective surgical procedures (see "CONTRA-INDICATIONS").

TURMERYNNE® capsules should be used with care in patients with hormone-sensitive cancers. Theoretically, turmeric might have mild estrogenic effects. Until more is known, advise women with hormone-sensitive conditions to use turmeric cautiously.

When starting, or stopping treatment with capsicum and turmeric containing products, including TURMERYNNE® capsules, patients taking warfarin (or other coumarin anti-coagulants) should have increased monitoring of their INR (International Normalised Ratio) levels (see "INTERACTIONS").

TURMERYNNE® 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 TURMERYNNE® 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 TURMERYNNE® capsules on the ability to drive or operate machines have been performed. It is unlikely that TURMERYNNE® capsules will affect the ability to drive or operate machines.

INTERACTIONS:

The herbs in TURMERYNNE® capsules may interact with the following medicines:

- Theophylline: *Capsicum* spp. and piperine may enhance theophylline absorption.
- Beta blockers: curcumin may decrease or increase absorption. Piperine may increase absorption of propranolol.
- Sulfasalazine: *Curcuma longa* might increase absorption of sulfasalazine.
- Oestrogen: *Curcuma longa* might decrease the effects of oestrogen

- Lithium: *Piper nigrum* may increase levels of lithium.
- Rifampin: piperine might increase absorption.
- Norfloxacin: *Curcuma longa* might increase levels

Advise patients to take any of the above-mentioned medicines at least 2 hours before or after TURMERYNNE® capsules (see "DOSAGE AND DIRECTIONS FOR USE").

Capsicum spp. and *Curcuma longa*, as in TURMERYNNE® 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 anti-platelet medicines should have their INR levels monitored more frequently when taking TURMERYNNE® capsules (see "WARNINGS AND SPECIAL PRECAUTIONS").

Piper nigrum, as in TURMERYNNE® capsules, may increase the effect of medications for epilepsy when taken concomitantly. Patients taking these medications should use TURMERYNNE® capsules with caution and be monitored closely. Some of these medications include carbamazepine and phenytoin.

Theoretically, *Capsicum* spp. and *Curcuma longa*, as in TURMERYNNE® capsules, may enhance the blood glucose lowering effects of anti-diabetic medicines. Patients on anti-diabetic medicines should monitor their glucose levels closely when taking TURMERYNNE® capsules.

Theoretically, *Piper nigrum* and *Curcuma longa* might increase levels of p-glycoprotein substrates. Some of these medicines include chemotherapeutic agents, anti-fungals, protease inhibitors, H2 agonists, calcium channel blockers, digoxin, corticosteroids, erythromycin, cisapride, fexofenadine, cyclosporine, loperamide and quinidine.

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

Piperine increases the bio-availability of curcumin in Turmeric. This may increase the potential of curcumin to interacting with other medicines.

There is some evidence that *Curcuma longa* and/or curcumin, *Capsicum* spp. and *Piper nigrum* 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 TURMERYNNE® capsules cautiously. These medicines include calcium channel blockers, chemotherapeutic agents, anti-fungals, 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 bio-availability of medicines metabolised by cytochrome P450 1A2 isoenzymes CYP1A2. Patients taking medicines metabolised by these enzymes should use TURMERYNNE® capsules cautiously. Some of these medicines include clozapine, fluvoxamine, haloperidol, imipramine, olanzapine, pentazocine, propranolol and zolmitriptan.

There is some evidence that *Curcuma longa* and *Piper nigrum*, as in TURMERYNNE® capsules, may increase levels of certain anti-neoplastic agents such as docetaxel, paclitaxel, etoposide, vinblastine and vincristine.

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

PREGNANCY AND LACTATION:

The safety and efficacy of TURMERYNNE® 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").

Theophylline, beta-blockers, sulfasalazine, oestrogen, lithium, rifampicin and norfloxacin must be taken at least 2 hours before or after TURMERYNNE® capsules (see "INTERACTIONS").

SIDE-EFFECTS:

The following side-effects may occur with the use of TURMERYNNE® capsules.

Endocrine disorders:

Frequency unknown: Reduced blood glucose, increase plasma insulin.

Psychiatric disorders:

Frequency unknown: Addiction.

Nervous system disorders:

Frequency unknown: Dizziness, hyperalgesia, vertigo.

Vascular disorders:

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

Gastrointestinal disorders:

Frequency unknown: Gastro-intestinal irritation, mouth and throat irritation, stomach discomfort, dyspepsia, diarrhoea, constipation, yellow hard stools, abdominal distention, gastro-oesophageal 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.

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 Health Products (Pty) Ltd.

Unit 3 Regent Park, Bell Crescent,

Westlake, Cape Town

DATE OF PUBLICATION:

To be allocated.