FLORA FORCE® GOTU KOLA 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® GOTU KOLA capsules

COMPOSITION:
Each **FLORA FORCE® GOTU KOLA** Capsules contains:

ACTIVE INGREDIENT	QUANTITY
Centella asiatica herb powder	400 mg

Inactive ingredients: vegetable capsules
FLORA FORCE® GOTU KOLA capsules are free from sugar and lactose.

PHARMACOLOGICAL CLASSIFICATION:
D 7.6 Vascular medicine – Other.

PHARMACOLOGICAL ACTION:
Pharmacodynamic properties:
The major principles in Cen*tella asiatica* are the triterpenes, asiatic acid and madecassic acid, and their derived triterpene ester glycosides, asiaticoside and madecassoside. The total triterpenic fraction of *Centella asiatica* (TTFCA) has been noted to reduce ankle edema, foot swelling, and capillary filtration rate, as well as to improve micro-circulatory parameters in subjects with reported venous insufficiency of the lower extremities.

INDICATIONS:
FLORA FORCE® GOTU KOLA capsules is a traditional herbal medicine indicated to support peripheral circulation.

CONTRA-INDICATIONS:
FLORA FORCE® GOTU KOLA capsules are contraindicated in patients with:
- A hypersensitivity to any of the ingredients in **FLORA FORCE® GOTU KOLA** capsules.
- Liver disease (see "**WARNING AND SPECIAL PRECAUTIONS**").
- Surgery (see "**WARNINGS AND SPECIAL PRECAUTIONS**").
- Pregnancy and lactation (see "**PREGNANCY AND LACTATION**").

WARNINGS AND SPECIAL PRECAUTIONS:
FLORA FORCE® GOTU KOLA capsules should be used with care in patients with liver disease. Theoretically, *Centella asiatica* as in **FLORA FORCE® GOTU KOLA** capsules, might exacerbate liver problems in patients with existing liver disease such as hepatitis and cholestasis. Advise these patients to avoid taking **FLORA FORCE® GOTU KOLA** capsules (see "**CONTRAINDICATIONS**").

FLORA FORCE® GOTU KOLA capsules should be used with care in patients undergoing surgery. Theoretically, *Centella asiatica* as in **FLORA FORCE® GOTU KOLA** capsules, might cause additive CNS depression when combined with anaesthesia and other medications during and after surgical procedures. Patients should discontinue use at least 2 weeks before elective surgical procedures (see "**CONTRAINDICATIONS**").

Centella asiatica, as in **FLORA FORCE® GOTU KOLA** capsules, may increase the effect and side effects of CNS depressant and sedative medications when taken in simultaneously Patients taking these medications should use **FLORA FORCE® GOTU KOLA** capsules with caution and be monitored closely (see "**INTERACTIONS**").

The use of **FLORA FORCE® GOTU KOLA** 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® GOTU KOLA** capsules on the ability to drive or operate machines have been performed. It is unlikely that **FLORA FORCE® GOTU KOLA** capsules will affect the ability to drive or operate machines.

INTERACTIONS:
Theoretically, *Centella asiatica*, as in **FLORA FORCE® GOTU KOLA** capsules, if taken with CNS depressants and sedative medication might cause additive effects and side effects Some of these medications include clonazepam, lorazepam, phenobarbital, zolpidem, and others (see "**WARNINGS AND SPECIAL PRECAUTIONS**").

There is some concern that *Centella asiatica*, as in **FLORA FORCE® GOTU KOLA** capsules, might cause hepatotoxicity in some patients. Theoretically, concomitant use with other potentially hepatotoxic medications might increase the risk of liver damage. Some of these medications acarbose, amiodarone, atorvastatin, azathioprine, carbamazepine, cerivastatin, diclofenac, felbamate, fenofibrate, fluvastatin, gemfibrozil, isoniazid, itraconazol, ketoconazole, leflunomide, lovastatin, methotrexate, nevirapine, niacin, nitrofurantoin, pioglitazone, pravastatin, pyrazinamide, rifampin, ritonavir, rosiglitazone, simvastatin, tacrine, tamoxifen, terbinafine, valproic acid, and zileuton (see "**WARNINGS AND SPECIAL PRECAUTIONS**").

PREGNANCY AND LACTATION:
The safety and efficacy of **FLORA FORCE® GOTU KOLA** 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 1-2 capsules twice daily with meals or as prescribed.

Children (under 18 years of age):
Not recommended for use (see "**WARNINGS AND SPECIAL PRECAUTIONS**")

SIDE-EFFECS:
The following side-effects may occur with the use of **FLORA FORCE® GOTU KOLA** capsules.

Endocrine disorders:
Frequency unknown: Hyperglycemia.

Nervous system disorders:
Frequency unknown: Sedation.

Vascular disorders:
Frequency unknown: Cholesterol elevation.

Gastrointestinal disorders:
Frequency unknown: Gastro-intestinal irritation, nausea and reflux.

Skin and subcutaneous disorders:
Frequency unknown: Allergic contact dermatitis and photosensitisation.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS:
The following symptoms may be experienced in the event of an overdose:
Headache, vertigo and drowsiness.
Contact a poison control centre in area.

IDENTIFICATION:
Clear size 0 all vegetable capsule containing a brown herbal powder.

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

STORAGE INSTRUCTIONS:
Store at or below 25 ºC 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.
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