

PATIENT INFORMATION LEAFLET

Information for the Patient about 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, STRENGTH AND PHARMACEUTICAL FORM:

FLORA FORCE® GOTU KOLA capsules.

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

- Keep this leaflet. You may need to read it again.
- Do not share FLORA FORCE® GOTU KOLA capsules with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a registered healthcare practitioner if your symptoms worsen or do not improve.

WHAT FLORA FORCE® GOTU KOLA CAPSULES CONTAIN:

Each FLORA FORCE® GOTU KOLA capsule contains:

ACTIVE INGREDIENT	QUANTITY
<i>Centella asiatica</i> herb powder	400 mg

Inactive ingredients are vegetable capsules.

FLORA FORCE® GOTU KOLA capsules are free from sugar and lactose.

WHAT FLORA FORCE® GOTU KOLA CAPSULES ARE USED FOR:

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

BEFORE YOU TAKE FLORA FORCE® GOTU KOLA CAPSULES:

Do NOT take FLORA FORCE® GOTU KOLA capsules:

- If you are allergic to any of the ingredients in FLORA FORCE® GOTU KOLA capsules.
- If you have a liver disease (see "Take special care with FLORA FORCE® GOTU KOLA capsules").
- If you are undergoing surgery (see "Take special care with FLORA FORCE® GOTU KOLA capsules").
- If you are pregnant and breastfeeding (see "Pregnancy and breastfeeding").

Take special care with FLORA FORCE® GOTU KOLA capsules:

Please discuss the use of FLORA FORCE® GOTU KOLA capsules with your pharmacist or registered healthcare practitioner if you:

- Suffer from liver disease. Gotu Kola, as in FLORA FORCE® GOTU KOLA capsules, may worsen liver disease such as hepatitis or cholestasis. You should avoid taking FLORA FORCE® GOTU KOLA capsules if you have liver disease (see "Do NOT take FLORA FORCE® GOTU KOLA capsules").
- Are undergoing surgery, discontinue use at least 2 weeks prior to the procedure (see "Do NOT take FLORA FORCE® GOTU KOLA capsules").
- Take sedatives or other CNS depressant medicines as FLORA FORCE® GOTU KOLA capsules may increase its effects. You should avoid taking FLORA FORCE® GOTU KOLA capsules in conjunction with CNS depressants (see "Taking other medicines with FLORA FORCE® GOTU KOLA capsules").
- Take hepatotoxic medication. FLORA FORCE® GOTU KOLA capsules may increase the risk of liver damage if taken with other potentially hepatotoxic medication (see "Taking other medicines with FLORA FORCE® GOTU KOLA capsules").

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 "HOW TO TAKE FLORA FORCE® GOTU KOLA CAPSULES").

Taking FLORA FORCE® GOTU KOLA capsules with food and drink:

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

Pregnancy and breastfeeding:

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

If you are pregnant or breastfeeding your baby, please consult your pharmacist or registered healthcare practitioner for advice before taking FLORA FORCE® GOTU KOLA 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® GOTU KOLA 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® GOTU KOLA capsules affects you.

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

FLORA FORCE® GOTU KOLA capsules are sugar free.

Taking other medicines with FLORA FORCE® GOTU KOLA capsules:

Always tell your pharmacist or registered healthcare practitioner if you are taking any other medicine (this includes complementary or traditional medicines).

Discuss the use of the following medicines in combination with FLORA FORCE® GOTU KOLA capsules with your pharmacist or registered healthcare practitioner:

- CNS depressants as FLORA FORCE® GOTU KOLA capsules may increase its effects and side effects (see "Take special care with FLORA FORCE® GOTU KOLA capsules").
- Hepatotoxic medication as FLORA FORCE® GOTU KOLA capsules may increase their potential to cause liver damage (see "Take special care with FLORA FORCE® GOTU KOLA capsules").

HOW TO TAKE FLORA FORCE® GOTU KOLA CAPSULES:

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

Always take FLORA FORCE® GOTU KOLA capsules exactly as directed. You should check with your pharmacist or registered healthcare practitioner if you are unsure. DO NOT EXCEED THE RECOMMENDED DAILY DOSAGE.

Adults (18 years and older):

Take 1-2 capsules twice daily with meals or as directed by your pharmacist or registered healthcare practitioner.

Children (under 18 years of age):

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

FLORA FORCE® GOTU KOLA 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 cycle can commence. However, should you experience any adverse effects or any of the side effects indicated below please consult your pharmacist or registered healthcare practitioner.

If you take more FLORA FORCE® GOTU KOLA capsules than you should:

In the event of over dosage, consult your pharmacist or registered healthcare practitioner. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take FLORA FORCE® GOTU KOLA capsules:

Always take FLORA FORCE® GOTU KOLA 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 1-2 capsules twice daily. Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE-EFFECTS:

FLORA FORCE® GOTU KOLA capsules may have side-effects.

Not all side-effects reported for FLORA FORCE® GOTU KOLA capsules are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FLORA FORCE® GOTU KOLA capsules, please consult your pharmacist or registered healthcare practitioner for advice.

Serious side-effects that you (or a family member if you are unable to) should report to your pharmacist or registered healthcare practitioner 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.
- Stomach pain, stomach irritation and nausea.
- Signs of decreased blood sugar such as light headedness, blurred vision and confusion.
- Sedation.

Side-effects that you should report to your pharmacist or registered healthcare practitioner as soon as possible:

- Increased light sensitivity.

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

STORING AND DISPOSING OF FLORA FORCE® GOTU KOLA capsules:

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® GOTU KOLA capsules:

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

IDENTIFICATION OF FLORA FORCE® GOTU KOLA capsules:

Clear size 0 all vegetable capsule containing a brown 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

South Africa

DATE OF PUBLICATION:

To be allocated.