FLORA FORCE® DEVIL'S CLAW Tablets

Complementary medicine.
Western herbal medicine.
This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety and intended use.

SCHEDULING STATUS:
Not Scheduled.

PROPRIETARY NAME (AND DOSAGE FORM):
FLORA FORCE® DEVIL'S CLAW Tablets.

COMPOSITION:
Each **FLORA FORCE® DEVIL'S CLAW** tablet contains:

ACTIVE INGREDIENT	QUANTITY
Harpagophytum procumbens root powder	500 mg

Inactive ingredients: Gum acacia and magnesium stearate.
FLORA FORCE® DEVIL'S CLAW tablets are free from sugar.

PHARMACOLOGICAL CLASSIFICATION:
D 33.6 Complementary Medicines: Discipline-specific Traditional Claims. Western Herbal Medicine.

PHARMACOLOGICAL ACTION:
Pharmacodynamic properties:
Devil's claw root contains iridoid glycoside constituents, primarily harpagoside, but also includes harpagide, harpagide derivatives, and procumbide. The iridoid glycoside constituents seem to have an anti-inflammatory effect. Research suggests that harpagoside inhibits the arachidonic, cyclooxygenase (COX) and lipoxygenase inflammatory pathways, although conflicting research exists. It seems to inhibit COX-2 and nitric oxide synthetase, a modulator of inflammation. Some evidence suggests that the anti-inflammatory effect is due to increased synthesis and release of tumour necrosis factor (TNF)-alpha by compounds other than harpagoside.

INDICATIONS:
FLORA FORCE® DEVIL'S CLAW tablets are traditionally used to support joint mobility and health.

CONTRA-INDICATIONS:
FLORA FORCE® DEVIL'S CLAW tablets are contra-indicated in patients with:
- Peptic ulcer disease (PUD) (see "**WARNINGS AND SPECIAL PRECAUTIONS**").
- Gallstones (see "**WARNINGS AND SPECIAL PRECAUTIONS**").
- Heart disease, hypertension and hypotension (see "**WARNINGS AND SPECIAL PRECAUTIONS**").
- Diabetes (see "**WARNING AND SPECIAL PRECAUTIONS**").
- Surgery (see "**WARNINGS AND SPECIAL PRECAUTIONS**").
- Pregnancy and lactation (see "**PREGNANCY AND LACTATION**").

WARNINGS AND SPECIAL PRECAUTIONS:
FLORA FORCE® DEVIL'S CLAW tablets should be used with caution when administered long-term. Use under supervision of a registered healthcare practitioner (see "**DOSAGE AND DIRECTIONS FOR USE**").

H. procumbens, as in **FLORA FORCE® DEVIL'S CLAW** tablets, might increase gastric acid secretions and bile production and should therefore be avoided by patients with peptic ulcer disease (PUD) or gallstones (see "**CONTRA-INDICATIONS**").

FLORA FORCE® DEVIL'S CLAW should be used with care in patients with heart disease, hypertension and hypotension. Patients with heart disease, hypertension and hypotension should have increased monitoring of their blood pressure when taking **FLORA FORCE® DEVIL'S CLAW** (see "**CONTRA-INDICATIONS**").

FLORA FORCE® DEVIL'S CLAW tablets should be used with care in patients with diabetes as *H. procumbens* may decrease blood sugar levels. Diabetic patients should monitor their blood sugar levels when taking **FLORA FORCE® DEVIL'S CLAW** tablets (see "**CONTRA-INDICATIONS**").

FLORA FORCE® DEVIL'S CLAW tablets should be used with care in patients undergoing surgery. Patients should discontinue use at least 2 weeks before elective surgical procedures (see "**CONTRA-INDICATIONS**").

When starting or stopping treatment with **FLORA FORCE® DEVIL'S CLAW**, patients taking oral anti-coagulants and anti-platelet medications should have increased monitoring of their INR (International Normalised Ratio) levels (see "**INTERACTIONS**").

The use of **FLORA FORCE® DEVIL'S CLAW** tablets 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® DEVIL'S CLAW** tablets on the ability to drive or operate machines have been performed. It is unlikely that **FLORA FORCE® DEVIL'S CLAW** tablets will affect the ability to drive or operate machines.

INTERACTIONS:
The herbs in **FLORA FORCE® DEVIL'S CLAW** tablets may interact with the following medicines:
- Hyperlipidaemic agents: use with *H. procumbens* may reduce cholesterol concentrations.
- Anti-inflammatory medications: *H. procumbens* may result in additive effects.
- Analgesic medications: *H. procumbens* may result in additive effects

The dose of the above medications may need to be adjusted when taken in conjunction with **FLORA FORCE® DEVIL'S CLAW** tablets**.**

FLORA FORCE® DEVIL'S CLAW tablets may have negative chronotropic and inotropic effects when taken with antiarrhythmic agents. Patients on these medicines should use **FLORA FORCE® DEVIL'S CLAW** tablets with caution.

FLORA FORCE® DEVIL'S CLAW may potentially increase the effect of oral anti-coagulants and anti-platelet medications (e.g. warfarin, aspirin, clopidogrel, dalteparin, enoxaparin and heparin) when taken concomitantly. Patients taking anti-coagulants or anti-platelet medicines should have their INR levels monitored more frequently when taking **FLORA FORCE® DEVIL'S CLAW** (see "**WARNINGS AND SPECIAL PRECAUTIONS**").

Theoretically, *H. procumbens*, as in **FLORA FORCE® DEVIL'S CLAW** tablets, might increase stomach acid and decrease effectiveness of proton pump inhibitors (PPIs) and H2 blockers. Patients on these medicines should use **FLORA FORCE® DEVIL'S CLAW** tablets with caution.

PREGNANCY AND LACTATION:
The safety and efficacy of **FLORA FORCE® DEVIL'S CLAW** tablets during pregnancy and lactation have not been established. Tablets 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 tablet.

Adults (18 years and older):
Take 1-2 tablets three times daily with meals or as prescribed.

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

FLORA FORCE® DEVIL'S CLAW, should be used with caution when administered for longer than 2-3 months. Use under supervision of a registered healthcare practitioner (see "**WARNINGS AND SPECIAL PRECAUTIONS**").

SIDE-EFFECS:
The following side-effects may occur with the use of **FLORA FORCE® DEVIL'S CLAW** tablets.
Vascular disorders:
Frequency unknown: Hypertension.

Gastro-intestinal disorders:
Frequency unknown: Diarrhoea.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS:
None known. Contact a poison control centre in area.

IDENTIFICATION:
Dark brown, 12 mm bi-convex tablet.

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