PATIENT INFORMATION LEAFLET
Information for the Patient about 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, STRENGTH AND PHARMACEUTICAL FORM:
FLORA FORCE® DEVIL'S CLAW tablets.

Read all of this leaflet carefully because it contains important information for you. FLORA FORCE® DEVIL'S CLAW tablets are available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use FLORA FORCE® DEVIL'S CLAW tablets carefully to get the best results from it.
- **Keep this leaflet. You may need to read it again.**
- **Do not share FLORA FORCE® DEVIL'S CLAW tablets 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® DEVIL'S CLAW TABLETS CONTAIN:
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.

WHAT FLORA FORCE® DEVIL'S CLAW TABLETS ARE USED FOR:
FLORA FORCE® DEVIL'S CLAW tablets are traditionally used to support joint mobility and health.

BEFORE YOU TAKE FLORA FORCE® DEVIL'S CLAW TABLETS:
Do NOT take FLORA FORCE® DEVIL'S CLAW tablets:
- If you have a stomach ulcer (see "**Take special care with FLORA FORCE® DEVIL'S CLAW tablets**").
- If you have gallstones (see "**Take special care with FLORA FORCE® DEVIL'S CLAW tablets**").
- If you suffer from heart disease, high blood pressure or low blood pressure (see "**Take special care with FLORA FORCE® DEVIL'S CLAW tablets**")
- If you have diabetes (see **"Take special care with FLORA FORCE® DEVIL'S CLAW tablets**").
- If you are undergoing surgery (see "**Take special care with FLORA FORCE® DEVIL'S CLAW tablets**").
- If you are pregnant or breastfeeding (see "**Pregnancy and breastfeeding**").

Take special care with FLORA FORCE® DEVIL'S CLAW tablets:
Please discuss the use of **FLORA FORCE® DEVIL'S CLAW** tablets with your pharmacist or registered healthcare practitioner if you:
- Suffer from a stomach ulcer or gallstones. **FLORA FORCE® DEVIL'S CLAW** tablets might increase gastric acid secretions and bile production and should be avoided if you suffer from a stomach ulcer or gallstones (see "**Do NOT take FLORA FORCE® DEVIL'S CLAW tablets**").
- Suffer from heart disease, high blood pressure or low blood pressure. You may have to arrange increased monitoring of your blood pressure (see "**Do NOT take FLORA FORCE® DEVIL'S CLAW tablets**").
- Suffer from diabetes. *H. procumbens* root, as in **FLORA FORCE® DEVIL'S CLAW** tablets, could decrease your blood sugar levels. You may have to arrange increased monitoring of your blood sugar levels (see "**Do NOT take FLORA FORCE® DEVIL'S CLAW tablets**").
- Are undergoing surgery, discontinue use at least 2 weeks prior to the procedure (see "**Do NOT take FLORA FORCE® DEVIL'S CLAW tablets**").
- Take warfarin or other blood thinning medicines. You may have to arrange increased monitoring of your INR (International Normalised Ratio) levels when starting or stopping treatment with **FLORA FORCE® DEVIL'S CLAW** tablets (see "**Taking other medicines with FLORA FORCE® DEVIL'S CLAW tablets**").

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 "**HOW TO TAKE FLORA FORCE® DEVIL'S CLAW TABLETS**").

FLORA FORCE® DEVIL'S CLAW tablets should be used with caution when taken long-term. Use **FLORA FORCE® DEVIL'S CLAW** tablets under supervision of a registered healthcare practitioner (see "**HOW TO TAKE FLORA FORCE® DEVIL'S CLAW TABLETS**").

Taking FLORA FORCE® DEVIL'S CLAW tablets with food and drink:
FLORA FORCE® DEVIL'S CLAW tablets should be taken after meals with water.

Pregnancy and breastfeeding:
Safety of **FLORA FORCE® DEVIL'S CLAW** tablets during pregnancy and breastfeeding has not been established. Avoid taking **FLORA FORCE® DEVIL'S CLAW** tablets 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® DEVIL'S CLAW tablets.

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® DEVIL'S CLAW** tablets will impair your ability to drive or use machines. However, please exercise care when driving or operating machinery until you know how **FLORA FORCE® DEVIL'S CLAW** tablets affect you.

Important information about some of the ingredients of FLORA FORCE® DEVIL'S CLAW tablets:
FLORA FORCE® DEVIL'S CLAW tablets are sugar free.

Taking other medicines with FLORA FORCE® DEVIL'S CLAW tablets:
Always tell your pharmacist or registered healthcare practitioner if you are taking any other medicine (this includes complementary or traditional medicines).

Please discuss the use of the following medicines in combination with **FLORA FORCE® DEVIL'S CLAW** tablets with your pharmacist or registered healthcare practitioner:
- Hyperlipidaemic medication used in treatment of high levels of fat, such as cholesterol.
- Anti-inflammatory medication used in the treatment of inflammation.
- Analgesic medication used for the relief of pain.

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

Also, discuss the use of the following medicines in combination with **FLORA FORCE® DEVIL'S CLAW** tablets with your pharmacist or registered healthcare practitioner:
- Anti-arrhythmic agent used to treat abnormal heart rhythms. **FLORA FORCE® DEVIL'S CLAW** tablets may affect these medications.
- Warfarin, other blood thinning or anti-platelet medicines. **FLORA FORCE® DEVIL'S CLAW** tablets may potentially increase the effect of blood thinning medicines. You may have to arrange increased monitoring of your INR levels when taking **FLORA FORCE® DEVIL'S CLAW** tablets (see "**Take special care with FLORA FORCE® DEVIL'S CLAW tablets**").
- Proton pump inhibitors (PPIs) and H2 blockers used to decrease stomach acid. **FLORA FORCE® DEVIL'S CLAW** tablets might increase stomach acid and theoretically decrease effectiveness of these medications.

HOW TO TAKE FLORA FORCE® DEVIL'S CLAW TABLETS:
Do not share medicines prescribed to you with any other person.
Always take FLORA FORCE® DEVIL'S CLAW tablets 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 tablets three times 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® DEVIL'S CLAW tablets**").

FLORA FORCE® DEVIL'S CLAW tablets, should not be used for periods exceeding 2-3 months without seeking advice from your pharmacist or registered healthcare practitioner (see "**Take special care with FLORA FORCE® DEVIL'S CLAW tablets**").

If you take more FLORA FORCE® DEVIL'S CLAW tablets 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® DEVIL'S CLAW tablets:
Always take **FLORA FORCE® DEVIL'S CLAW** tablets 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 tablets three times daily. Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE-EFFECTS:
FLORA FORCE® DEVIL'S CLAW tablets may have side-effects.
Not all side-effects reported for FLORA FORCE® DEVIL'S CLAW tablets are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FLORA FORCE® DEVIL'S CLAW tablets, 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:
- Headache, fatigue, chest pain, difficulty breathing, blurred vision and irregular heartbeat.

Side-effects that you should report to your doctor as soon as possible:
- Loose stool.

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® DEVIL'S CLAW tablets:
Store at or below 25ºC in a dry place.
Protect from light / moisture.
Do not take the tablets after the expiry date stated on the packaging material.
Return all unused tablets to your pharmacist.
Do not dispose of unused tablets in drains or sewerage systems (e.g. toilets).
STORE ALL MEDICINE OUT OF REACH OF CHILDREN.

PRESENTATION OF FLORA FORCE® DEVIL'S CLAW tablets:
60 Tablets packed in a 125ml amber glass bottle with light green screw cap and safety seal insert, in a box

IDENTIFICATION OF FLORA FORCE® DEVIL'S CLAW tablets:
Dark brown, 12 mm bi-convex tablet.

REGISTRATION NUMBER / REFERENCE NUMBER:
To be allocated.

NAME AND BUSINESS ADDRESS OF REGISTRATION HOLDER:
Flora Force Heath Products (Pty) Ltd.
Unit 3 Regent Park
Bell Crescent
Westlake
Cape Town
South Africa

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