FLORA FORCE® DANDELION Capsules

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® DANDELION Capsules

COMPOSITION:
Each **FLORA FORCE® DANDELION** capsule contains:

ACTIVE INGREDIENT	QUANTITY
Taraxacum officinale leaf & root powder	300 mg

Inactive ingredients: vegetable capsules.
FLORA FORCE® DANDELION 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:
Taraxacum offinale contains sesquiterpene lactones which appears to be responsible for its diuretic activity. The high potassium content of the herb ensures replacement of potassium eliminated in the urine.
The principal bitter constituents of the leaf are the sesquiterpene lactones, taraxinic acid glucoside and its 11, 13-dihydro derivative which may produce the choleretic actions.
The root contains bitter substances which are beneficial to the digestive process, increases bile secretions and has an aperient effect[1]
The root contains high concentrations of inulin. Oligo-fructans, such as inulin, are used as food sources by beneficial intestinal bacteria. *Taraxacum officinale* root enhances the growth of bifidobacterial and may be useful as a "prebiotic".

INDICATIONS:
FLORA FORCE® DANDELION capsules are used traditionally to support the body's elimination functions.

CONTRA-INDICATIONS:
FLORA FORCE® DANDELION capsules are contra-indicated in patients with:
- A hypersensitivity to plants from the Asteraceae family (see "**WARNINGS AND SPECIAL PRECAUTIONS**").
- Biliary obstruction (bile duct obstruction and gallstones) (see "**WARNINGS AND SPECIAL PRECAUTIONS**").
- Bleeding disorders (see "**WARNING AND SPECIAL PRECAUTIONS**").
- Diabetes (see "**WARNING AND SPECIAL PRECAUTIONS**").
- Renal impairment & chronic liver disease (CLD) (see "**WARNINGS AND SPECIAL PRECAUTIONS**").
- Surgery (see "**WARNINGS AND SPECIAL PRECAUTIONS**").
- Pregnancy and lactation (see "**PREGNANCY AND LACTATION**").

WARNINGS AND SPECIAL PRECAUTIONS:
Taraxacum officinale may cause an allergic reaction in individuals sensitive to plants from the Asteraceae family. Members of this family include sunflowers, chrysanthemums, marigolds, daisies and other herbs (see "**CONTRA-INDICATIONS**").

FLORA FORCE® DANDELION capsules should be used with care in patients with biliary obstruction (bile duct obstruction and gallstones) and should only be used after consultation with a physician (see "**CONTRA-INDICATIONS**").

When starting, or stopping treatment with *Taraxacum officinale* containing products, including **FLORA FORCE® DANDELION** capsules, patients with bleeding disorders should have increased monitoring of their INR (International Normalised Ratio) levels (see **"CONTRA-INDICATIONS"**).

FLORA FORCE® DANDELION capsules should be used with care in patients with diabetes as *Taraxacum officinale* may decrease blood sugar levels. Diabetic patients should monitor their blood sugar levels when taking **FLORA FORCE® DANDELION** capsules (see "**CONTRA-INDICATIONS**").

FLORA FORCE® DANDELION capsules should be used with care in patients with renal impairment and CLD. You may have to arrange increased monitoring of your oxalate and potassium levels. Theoretically, *Taraxacum officinale* may reduce oxalate clearance and increase the risk of hyperoxalaemia in patients with renal impairment. *Taraxacum officinale* contains potassium and could theoretically increase the risk of hyperkalemia in CLD (see "**CONTRA-INDICATIONS**").

FLORA FORCE® DANDELION 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**").

When starting, or stopping treatment with *Taraxacum officinale* containing products, including **FLORA FORCE® DANDELION** capsules, patients taking oral anti-coagulants or anti-platelet drugs should have increased monitoring of their INR (International Normalised Ratio) levels (see "**INTERACTIONS**").

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

INTERACTIONS:
The herbs in **FLORA FORCE® DANDELION** capsules may interact with the following medicines:
- Lithium: *Taraxacum officinale* may increase levels of lithium.

The dose of the above medications may need to be adjusted when taken in conjunction with **FLORA FORCE® DANDELION** capsules**.**

Taraxacum officinale, as in **FLORA FORCE® DANDELION** capsules, may potentially increase the effect of oral anti-coagulants and anti-platelet drugs (e.g. warfarin, heparin, aspirin, clopidogrel, NSAID's, diclofenac, dalteparin, ibuprofen, naproxen, enoxaparin, heparin) when taken concomitantly (see "**WARNINGS AND SPECIAL PRECAUTIONS**").

Theoretically, *Taraxacum officinale*, as in **FLORA FORCE® DANDELION** 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 **FLORA FORCE® DANDELION** capsules.

There is preliminary evidence that *Taraxacum officinale* might inhibit CYP1A2 enzymes and increase bio-availability of medicines metabolised by cytochrome P450 1A2 (CYP1A2). Patients taking medicines metabolised by these enzymes should use **FLORA FORCE® DANDELION** capsules cautiously or avoid. These medicines include amitriptyline, haloperidol, ondansetron, propranolol, theophylline, verapamil and others.

There is preliminary evidence that *Taraxacum officinale* might induce UDP-glucuronosyltransferase, a phase II enzyme. Theoretically, *Taraxacum officinale* might increase the clearance of drugs that are UDP-glucuronosyltransferase substrates. Patients taking medicines that are UDP-glucuronosyltransferase substrates should use **FLORA FORCE® DANDELION** capsules cautiously. These medicines include acetaminophen, estrogens and oral contraceptives, entacapone, irinotecan and others.

Taraxacum officinale contains significant amounts of potassium. Theoretically, concomitant use of potassium-sparing diuretics with *Taraxacum officinale*, as in **FLORA FORCE® DANDELION** capsules, might increase the risk of hyperkalemia. These medicines include amiloride, spironolactone and triamterene.

Theoretically, *Taraxacum officinale*, might lower fluoroquinolone levels. Preliminary research suggests that a related species, *Taraxacum mongolicum*, reduces absorption of ciprofloxacin and can lower levels by 73%. Patients taking Quinolones should use **FLORA FORCE® DANDELION** capsules with care. Quinolones include ciprofloxacin, enoxacin, gatifloxacin, levofloxacin, lomefloxacin, moxifloxacin, norfloxacin, ofloxacin, sparfloxacin and trovafloxacin.

PREGNANCY AND LACTATION:
The safety and efficacy of **FLORA FORCE® DANDELION ®** 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 two to three times 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® DANDELION** capsules.

Endocrine disorders:
Frequency unknown: Hyper-oxalaemia and hypo-glycaemia.

Vascular disorders:
Frequency unknown: Increased bleeding, palpitations, tachycardia, syncope and peripheral gangrene.

Gastrointestinal disorders:
Frequency unknown: Stomach discomfort, diarrhoea, heartburn, and intestinal blockage.

Skin and subcutaneous disorders:
Frequency unknown: Contact dermatitis, erythema multiforme and skin allergy.

Respiratory, thoracic and mediastinal disorders
Frequency unknown: Allergy, anaphylaxis, rhino-conjunctivitis and asthma.

Renal and urinary disorders:
Frequency unknown: Haemorrhagic cystitis.

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

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

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

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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