

FLORA FORCE® BUCHU 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® BUCHU Capsules

COMPOSITION:

Each FLORA FORCE® BUCHU capsule contains:

ACTIVE INGREDIENT	QUANTITY
<i>Agathosma betulina</i> leaf powder	370 mg

Inactive ingredients: vegetable capsules

FLORA FORCE® BUCHU capsules are free from sugar and lactose.

PHARMACOLOGICAL CLASSIFICATION:

D 18.5 Urinary tract antiseptics.

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties:

Agathosma betulina contains diosmin and has known anti-inflammatory activity. Anti-bacterial activity may be due to diosphenol, while flavonoids may contribute to the diuretic activity.

INDICATIONS:

FLORA FORCE® BUCHU capsules are used traditionally to assist with symptoms related to urinary tract infections.

CONTRA-INDICATIONS:

FLORA FORCE® BUCHU capsules are contra-indicated in patients with:

- A hypersensitivity to any of the ingredients in FLORA FORCE® BUCHU capsules.
- Bleeding disorder (see "WARNINGS AND SPECIAL PRECAUTIONS").
- Kidney infection.
- Surgery (see "WARNINGS AND SPECIAL PRECAUTIONS").
- Pregnancy and lactation (see "PREGNANCY AND LACTATION").

WARNINGS AND SPECIAL PRECAUTIONS:

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

FLORA FORCE® BUCHU 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 *Agathosma betulina* containing products, including FLORA FORCE® BUCHU capsules, patients taking warfarin (or other coumarin anti-coagulants) should have increased monitoring of their INR (International Normalised Ratio) levels (see "INTERACTIONS").

The use of FLORA FORCE® BUCHU 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").

Agathosma betulina, as in FLORA FORCE® BUCHU capsules, might act as an abortifacient. FLORA FORCE® BUCHU capsules are not recommended during pregnancy (see "PREGNANCY AND LACTATION").

Effects on the ability to drive or use machinery:

No studies on the effect of FLORA FORCE® BUCHU capsules on the ability to drive or operate machines have been performed. It is unlikely that FLORA FORCE® BUCHU capsules will affect the ability to drive or operate machines.

INTERACTIONS:

Agathosma betulina, as in FLORA FORCE® BUCHU capsules, might reduce excretion of lithium and increase levels in the blood. The dose of lithium may need to be adjusted.

Agathosma betulina, as in FLORA FORCE® BUCHU capsules, may potentially increase the effect of oral anti-coagulants and anti-platelet drugs (e.g. warfarin, aspirin, clopidogrel, NSAIDs, ibuprofen, dalteparin, enoxaparin, heparin) when taken concomitantly. Patients taking anti-coagulants or anti-platelet medicines should have their INR levels monitored more frequently when taking FLORA FORCE® BUCHU capsules (see "WARNINGS AND SPECIAL PRECAUTIONS").

PREGNANCY AND LACTATION:

The safety and efficacy of FLORA FORCE® BUCHU capsules during pregnancy and lactation have not been established. *Agathosma betulina*, as in FLORA FORCE® BUCHU capsules, might act as an abortifacient. Capsules should therefore not be taken during pregnancy and lactation (see "WARNINGS AND SPECIAL PRECAUTIONS").

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-EFFECTS:

The following side-effects may occur with the use of FLORA FORCE® BUCHU capsules.

Vascular disorders:

Frequency unknown: Cardiac arrest.

Gastrointestinal disorders:

Frequency unknown: Gastro-intestinal irritation, diarrhoea

Hepatobiliary disorders:

Frequency unknown: Hepatotoxicity

Renal and urinary disorders:

Frequency unknown: Kidney irritation.

Musculoskeletal, connective tissue and bone disorders:

Frequency unknown: Smooth muscle spasms or relaxation.

Reproductive system and breast disorders:

Frequency unknown: Increased menstrual flow.

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

STORAGE INSTRUCTIONS:

Store at or below 25 °C 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 Health Products (Pty) Ltd.

Unit 3 Regent Park,

Bell Crescent

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