

FLORA FORCE® BILBERRY 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® BILBERRY Capsules

COMPOSITION:

Each FLORA FORCE® BILBERRY capsule contains:

ACTIVE INGREDIENT	QUANTITY
<i>Vaccinium myrtillus</i> berry powder	500 mg

Inactive ingredients: vegetable capsules

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

PHARMACOLOGICAL CLASSIFICATION:

D40.1 Complementary medicine not otherwise specified – Discipline specific traditional claim.

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties:

Vaccinium myrtillus contains several compounds that have demonstrated biological activity. The main chemicals have been shown to be anthocyanins, anthocyanidins, anthocyanins and anthocyanosides; as well as flavonoids, tannins, quercetin, epicatechin, hydroquinone and many more. Flavonoids possess a number of biological properties, including reduction of capillary permeability and fragility. Anthocyanosides have been shown to exert a direct effect on the retina. *Vaccinium myrtillus* improves microcirculation which may also play a role in improvement of visual function.

INDICATIONS:

FLORA FORCE® BILBERRY capsules supports vision and eye health, and helps to relieve symptoms related to non-complicated chronic venous insufficiency.

CONTRA-INDICATIONS:

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

- A hypersensitivity to any of the ingredients in FLORA FORCE® BILBERRY capsules.
- Bleeding disorder (see "WARNING AND SPECIAL PRECAUTIONS").
- Diabetes (see "WARNING AND SPECIAL PRECAUTIONS").
- Surgery (see "WARNINGS AND SPECIAL PRECAUTIONS").
- Pregnancy and lactation (see "PREGNACY AND LACTATION").

WARNINGS AND SPECIAL PRECAUTIONS:

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

FLORA FORCE® BILBERRY 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 *Vaccinium myrtillus* containing products, including FLORA FORCE® BILBERRY 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® BILBERRY 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® BILBERRY capsules on the ability to drive or operate machines have been performed. It is unlikely that FLORA FORCE® BILBERRY capsules will affect the ability to drive or operate machines.

INTERACTIONS:

Vaccinium myrtillus, as in FLORA FORCE® BILBERRY 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® BILBERRY capsules (see "WARNINGS AND SPECIAL PRECAUTIONS").

Theoretically, *Vaccinium myrtillus*, as in FLORA FORCE® BILBERRY 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® BILBERRY capsules.

PREGNANCY AND LACTATION:

The safety and efficacy of FLORA FORCE® BILBERRY capsules during pregnancy and lactation have not been established. 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® BILBERRY capsules.

Endocrine disorders:

Frequency unknown: Hypoglycaemia.

Vascular disorders:

Frequency unknown: Hypotension,

Gastrointestinal disorders:

Frequency unknown: Increased frequency of bowel movements, constipation, gastrointestinal discomfort, nausea and heartburn.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENTS:

The following symptoms may be experienced in the event of an overdose.

Hydroquinone poisoning, anti-coagulation or gastro-intestinal distress.
Contact a poison control centre in area.

IDENTIFICATION:

Clear size 0 all vegetable capsule containing dark red-brown herbal powder.

PRESENTATION:

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

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.
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