

## FLORA FORCE® BILBERRY 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® 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 light green 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.

Unit 3 Regent Park,

Bell Crescent

Westlake

Cape Town

South Africa

### DATE OF PUBLICATION:

23/02/2018