

FLORA FORCE® SIBERIAN GINSENG 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® SIBERIAN GINSENG Capsules.

COMPOSITION:

Each FLORA FORCE® SIBERIAN GINSENG capsule contains

ACTIVE INGREDIENT	QUANTITY
<i>Eleutherococcus senticosus</i> root powder	400 mg

Inactive ingredients: vegetable capsules.

FLORA FORCE® SIBERIAN GINSENG capsules are free from sugar and lactose.

PHARMACOLOGICAL CLASSIFICATION:

D 32.1 Other substances or agents. Tonics.

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties:

The use of Siberian ginseng may date back over 2000 years in China. Recent studies have confirmed its adaptogenic effects. The adaptogenic effects of *Eleutherococcus senticosus* roots are thought to be produced through metabolic regulation of energy, nucleic acids and proteins of the body tissues. The use of Siberian ginseng is claimed to result in a more economical utilisation of glycogen and high-energy phosphorus compounds, and in a more intense metabolism of lactic and pyruvic acids during stress.

INDICATIONS:

FLORA FORCE® SIBERIAN GINSENG capsules are used as a tonic to improve mental and physical performance.

CONTRA-INDICATIONS:

FLORA FORCE® SIBERIAN GINSENG capsules are contraindicated in patients with:

- Cardiovascular conditions such as hypertension (see "WARNINGS AND SPECIAL PRECAUTIONS").
- Bleeding disorders (see "WARNING AND SPECIAL PRECAUTIONS").
- Diabetes (see "WARNINGS AND SPECIAL PRECAUTIONS").
- Surgery (see "WARNINGS AND SPECIAL PRECAUTIONS").

WARNINGS AND SPECIAL PRECAUTIONS:

FLORA FORCE® SIBERIAN GINSENG capsules should be used with care in patients with cardiovascular conditions such as hypertension as Siberian ginseng may affect these conditions. Hypertensive patients should monitor their blood pressure regularly when taking FLORA FORCE® SIBERIAN GINSENG capsules (see "CONTRA-INDICATIONS").

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

FLORA FORCE® SIBERIAN GINSENG capsules should be used with care in patients with diabetes as Siberian ginseng may decrease blood sugar levels. Diabetic patients should monitor their blood sugar levels when taking FLORA FORCE® SIBERIAN GINSENG capsules (see "CONTRA-INDICATIONS").

FLORA FORCE® SIBERIAN GINSENG 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 Siberian ginseng containing products, including FLORA FORCE® SIBERIAN GINSENG capsules, patients taking warfarin (or other coumarin anticoagulants) should have increased monitoring of their INR (International Normalised Ratio) levels (see "INTERACTIONS").

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

INTERACTIONS:

FLORA FORCE® SIBERIAN GINSENG capsules may interact with the following medicines:

- Digoxin: *Eleutherococcus senticosus* might increase levels.
- Lithium: theoretically, *Eleutherococcus senticosus*, due to its diuretic action, might decrease levels of lithium.

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

Eleutherococcus senticosus, as in FLORA FORCE® SIBERIAN GINSENG capsules, may potentially increase the effect of oral anti-coagulants and anti-platelet drugs (e.g. warfarin, aspirin, clopidogrel, dalteparin, enoxaparin, heparin, ticlopidine) when taken in conjunction. Patients taking anti-coagulants or antiplatelet medicines should have their INR levels monitored more frequently when taking FLORA FORCE® SIBERIAN GINSENG capsules (see "WARNINGS AND SPECIAL PRECAUTIONS").

Eleutherococcus senticosus, as in FLORA FORCE® SIBERIAN GINSENG capsules, may enhance the blood glucose lowering effects of antidiabetic medicines. Patients on antidiabetic medicines should monitor their glucose levels closely when taking FLORA FORCE® SIBERIAN GINSENG capsules.

Eleutherococcus senticosus, as in FLORA FORCE® SIBERIAN GINSENG capsules, may increase or decrease the effects of hypo- or hypertensive medication. Patients on hypo- or hypertensive medications should monitor their blood pressure closely when taking FLORA FORCE® SIBERIAN GINSENG capsules.

PREGNANCY AND LACTATION:

The safety and efficacy of FLORA FORCE® SIBERIAN GINSENG capsules during pregnancy and lactation has not been established. FLORA FORCE® SIBERIAN GINSENG capsules should therefore not be taken during pregnancy and lactation.

DOSAGE AND DIRECTIONS FOR USE:

The recommended daily dose should not be exceeded.

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").

FLORA FORCE® SIBERIAN GINSENG capsules may be taken by healthy individuals for a period of up to 6 weeks followed by an interval of 2 week after which the next 6-week cycle can commence. However, should any adverse effects or any of the side effects be experienced as indicated below the patient should consult a pharmacist or registered healthcare practitioner.

SIDE-EFFECs:

The following side-effects may occur with the use of FLORA FORCE® SIBERIAN GINSENG capsules:

Cardiac disorders:

Frequency unknown: Tachycardia, palpitations and hypertension.

Psychiatric disorders:

Frequency unknown: Nervousness, anxiety, irritability and melancholy

Nervous system disorders:

Frequency unknown: Headaches.

Skin and subcutaneous disorders:

Frequency unknown: Urticaria and pruritis.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

None known. Contact a poison control centre in area.

IDENTIFICATION:

Clear size 0 all vegetable capsule containing light brown to green herbal powder.

PRESENTATION:

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

STORAGE INSTRUCTIONS:

Store at or below 25°C.

Protect from light.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

To be allocated.

NAME AND BUSINESS ADDRESS OF APPLICANT:

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