FLORA FORCE® SLEEP 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® SLEEP Capsules.

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

ACTIVE INGREDIENT	QUANTITY
Passiflora incarnata herb powder	83 mg
Humulus lupulus strobile powder	83 mg
Lavandula officinalis flower powder	83 mg

Inactive ingredients: vegetable capsules
FLORA FORCE® SLEEP capsules are free from sugar and lactose.

PHARMACOLOGICAL CLASSIFICATION:
D 2.2 Central nervous system depressants. Sedatives, hypnotics.

PHARMACOLOGICAL ACTION:
Pharmacodynamic properties:
A sedative, sleep promoting effectiveness is documented for lavender, hops and passion flower. Some studies suggest that passion flower inhibits uptake of gamma-aminobutyric acid (GABA) into neuronal synapses and has affinity for GABAA and GABAB receptors. The sedative effect of hops is attributed to alpha-bitter acids, beta-bitter acids and hop oil.

INDICATIONS:
FLORA FORCE® SLEEP capsules are traditionally used as a sedative for sleep promotion.

CONTRA-INDICATIONS:
FLORA FORCE® SLEEP capsules are contra-indicated in patients with:
- A hypersensitivity to any of the ingredients in **FLORA FORCE® SLEEP** capsules.
- Depression (see "**WARNINGS AND SPECIAL PRECAUTIONS**").
- Hormone sensitive conditions (see "**WARNINGS AND SPECIAL PRECAUTIONS**").
- Surgery (see "**WARNINGS AND SPECIAL PRECAUTIONS**").
- Pregnancy and lactation (see "**PREGNANCY AND LACTATION**").

WARNINGS AND SPECIAL PRECAUTIONS:
FLORA FORCE® SLEEP capsules should be avoided in patients with depression. *Humulus lupulus* may contribute to depression (see "**CONTRA-INDICATIONS**").

Humulus lupulus, as in **FLORA FORCE® SLEEP** capsules, should be avoided in patients with hormone sensitive conditions. Some active constituents of *Humulus lupulus* have estrogenic activity. These conditions include breast, uterine and ovarian cancer, endometriosis and uterine fibroids (see "**CONTRA-INDICATIONS**").

FLORA FORCE® SLEEP 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 **FLORA FORCE® SLEEP** 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® SLEEP** 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:
Avoid use of **FLORA FORCE® SLEEP** capsules when driving or using machinery. Medications with sleep-promoting actions can change the ability to react, so that participation in traffic or operation of machinery is impaired, even when taken under strict conditions.

INTERACTIONS:
The herbs in **FLORA FORCE® SLEEP** capsules may interact with the following medicines:
- Anti-hypertensive medication: may increase effects.

Advise patients to be cautious of these combinations and to use **FLORA FORCE® SLEEP** capsules under supervision from a registered healthcare practitioner.

FLORA FORCE® SLEEP capsules, may enhance the effects of CNS depressants. These include alcohol, benzodiazepines (lorazepam, alprazolam, diazepam, and midazolam), barbiturates (amobarbital, butobarbital, mephobarbital, pentobarbital, phenobarbital and secobarbital), opioids, tricyclic antidepressants (amitriptyline, amoxapine, doxepin, nortriptyline and others), anti-histamines and other sedative medication.

FLORA FORCE® SLEEP capsules, may potentially increase the effect of oral anti-coagulants and anti-platelet drugs (e.g. warfarin, phenprocoumon, heparin, aspirin, clopidogrel, enoxaparin, dalteparin, ticlopidine, 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® SLEEP** capsules (see "**WARNINGS AND SPECIAL PRECAUTIONS**").

PREGNANCY AND LACTATION:
The safety and efficacy of **FLORA FORCE® SLEEP** 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.

Adults (18 years and older):
Take 2 capsules before bedtime. Dosage can be repeated.

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® SLEEP** capsules.

Blood and the lymphatic system disorders:
Frequency unknown: Epistaxis.

Immune system disorders:
Frequency unknown: Allergic reaction.

Nervous system disorders:
Frequency unknown: Confusion and dizziness.

Cardiac disorders:
Frequency unknown: Tachycardia, nausea, vomiting and drowsiness.

Musculoskeletal, connective tissue and bone disorders:
Frequency unknown: Muscle relaxation.

Reproductive system and breast disorders:
Frequency unknown: Uterine contractions and menstrual disturbances.

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 greenish brown herbal powder.

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

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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