PATIENT INFORMATION LEAFLET
Information for the Patient about 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, STRENGTH AND PHARMACEUTICAL FORM:
FLORA FORCE® SLEEP capsules.

Read all of this leaflet carefully because it contains important information for you. FLORA FORCE® SLEEP capsules are available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use FLORA FORCE® SLEEP capsules carefully to get the best results from it.
- **Keep this leaflet. You may need to read it again.**
- **Do not share FLORA FORCE® SLEEP capsules with any other person.**
- **Ask your pharmacist if you need more information or advice.**
- **You must see a registered healthcare practitioner if your symptoms worsen or do not improve.**

WHAT FLORA FORCE® SLEEP CAPSULES CONTAIN:
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 are vegetable capsules.
FLORA FORCE® SLEEP capsules are free from sugar and lactose.

WHAT FLORA FORCE® SLEEP CAPSULES ARE USED FOR:
FLORA FORCE® SLEEP capsules are traditionally used as a sedative for sleep promotion.

BEFORE YOU TAKE FLORA FORCE® SLEEP CAPSULES:
Do NOT take FLORA FORCE® SLEEP capsules:
- If you are allergic to any of the ingredients in **FLORA FORCE® SLEEP** capsules.
- If you have depression (see "**Take special care with FLORA FORCE® SLEEP capsules**").
- If you have a hormone sensitive condition (see "**Take special care with FLORA FORCE® SLEEP capsules**").
- If you are undergoing surgery (see "**Take special care with FLORA FORCE® SLEEP capsules**").
- If you are pregnant and breastfeeding (see "**Pregnancy and breastfeeding**").

Take special care with FLORA FORCE® SLEEP capsules:
Please discuss the use of **FLORA FORCE® SLEEP** capsules with your pharmacist or registered healthcare practitioner if you:
- Suffer from depression. Some of the ingredients in **FLORA FORCE® SLEEP** capsules may exacerbate the symptoms of depression. Stop using **FLORA FORCE® SLEEP** capsules if your symptoms worsen (see "**Do NOT take FLORA FORCE® SLEEP capsules**").
- Suffer from a hormone sensitive condition. Hops (*Humulus lupulus*) contains active constituents that might act like oestrogen. Until more is known, avoid using hops (see "**Do NOT take FLORA FORCE® SLEEP capsules**").
- Are undergoing surgery, discontinue use at least 2 weeks prior to the procedure (see "**Do NOT take FLORA FORCE® SLEEP capsules**").
- Take warfarin or other blood thinning medicines. You may have to arrange increased monitoring of your INR (International Normalised Ratio) levels when starting or stopping treatment with **FLORA FORCE® SLEEP** capsules (see "**Taking other medicines with FLORA FORCE® SLEEP capsules**").

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 "**HOW TO TAKE FLORA FORCE® SLEEP CAPSULES**").

Taking FLORA FORCE® SLEEP capsules with food and drink:
FLORA FORCE® SLEEP capsules should be taken with water.

Pregnancy and breastfeeding:
Safety of **FLORA FORCE® SLEEP** capsules during pregnancy and breastfeeding has not been established. Avoid taking **FLORA FORCE® SLEEP** capsules if you are pregnant or breastfeeding.

If you are pregnant or breastfeeding your baby, please consult your pharmacist or registered healthcare practitioner for advice before taking FLORA FORCE® SLEEP capsules.

Driving and using 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 driving ability or operation of machinery is impaired, even when taken under strict conditions.

Important information about some of the ingredients of FLORA FORCE® SLEEP capsules:
FLORA FORCE® SLEEP capsules are sugar free.

Taking other medicines with FLORA FORCE® SLEEP capsules:
Always tell your registered healthcare practitioner if you are taking any other medicine (this includes complementary or traditional medicines).

Please discuss the use of the following medicines in combination with **FLORA FORCE® SLEEP** capsules with your pharmacist or registered healthcare practitioner:
- Anti-hypertensive medication for the treatment of high blood pressure.

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

Also, discuss the use of the following medicines in combination with **FLORA FORCE® SLEEP** capsules with your pharmacist or registered healthcare practitioner:
- Central Nervous System (CNS) depressants (such as alcohol, benzodiazepines, barbiturates, opioids, tricyclic antidepressants, anti-histamines and other sedatives) as **FLORA FORCE® SLEEP** capsules may enhance their effects (see "**Take special care with FLORA FORCE® SLEEP capsules**").
- Warfarin or other blood thinning or anti-platelet medicines. **FLORA FORCE® SLEEP** capsules may potentially increase the effect of these medicines (see "**Take special care with FLORA FORCE® SLEEP capsules**").

HOW TO TAKE FLORA FORCE® SLEEP CAPSULES:
Do not share medicines prescribed to you with any other person.
Always take FLORA FORCE® SLEEP capsules exactly as directed. You should check with your pharmacist or registered healthcare practitioner if you are unsure.

DO NOT EXCEED THE RECOMMENDED DAILY DOSAGE.

Adults (18 years and older):
Take 2 capsules before bedtime or as directed by your pharmacist or registered healthcare practitioner. Dosage can be repeated.

Children (under 18 years of age):
Not recommended for use (see "**Take special care with FLORA FORCE® SLEEP capsules**").

FLORA FORCE® SLEEP capsules may be taken for a period of up to 12 weeks followed by an interval of 1 week after which the next 12-week cycle can commence. However, should you experience any adverse effects or any of the side effects indicated below please consult your pharmacist or registered healthcare practitioner.

If you take more FLORA FORCE® SLEEP capsules than you should:
In the event of over dosage, consult your pharmacist or registered healthcare practitioner. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take FLORA FORCE® SLEEP capsules:
Always take **FLORA FORCE® SLEEP** capsules as directed. If you miss a dose, take it as soon as you remember. If you do not remember the missed dose till the next dose is due, skip the missed dose and go back to your regular dosing schedule of 2 capsules before bedtime. Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE-EFFECTS:
FLORA FORCE® SLEEP capsules may have side-effects.
Not all side-effects reported for FLORA FORCE® SLEEP capsules are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FLORA FORCE® SLEEP capsules, please consult your pharmacist or registered healthcare practitioner for advice.

Serious side-effects that you (or a family member if you are unable to) should report to your pharmacist or registered healthcare practitioner immediately include:
- An allergic reaction which may present with nasal congestion, hoarseness, persistent coughing, wheezing, swelling of the face, tongue or whole body.
- Drowsiness, lethargy and dizziness.
- Increased heart rate, nausea, vomiting and drowsiness.

Side-effects that you should report to your pharmacist or registered healthcare practitioner as soon as possible:
- Nosebleeds.
- Menstrual disturbances, pain and cramps.

Side-effects that you should report to your pharmacist or registered healthcare practitioner if they continue or become bothersome include:
- Muscle relaxation.

If you notice any side-effects not mentioned in this leaflet, please inform your pharmacist or registered healthcare practitioner.

STORING AND DISPOSING OF FLORA FORCE® SLEEP capsules:
Store at or below 25ºC in a dry place.
Protect from light / moisture.
Do not take the capsules after the expiry date stated on the packaging material.
Return all unused capsules to your pharmacist.
Do not dispose of unused capsules in drains or sewerage systems (e.g. toilets).
STORE ALL MEDICINE OUT OF REACH OF CHILDREN.

PRESENTATION OF FLORA FORCE® SLEEP capsules:
60 Capsules packed into 125ml amber glass bottle with a dark green screw cap and safety seal insert, in a box.

IDENTIFICATION OF FLORA FORCE® SLEEP capsules:
Clear size 0 all vegetable capsule containing greenish brown herbal powder.

REGISTRATION NUMBER / REFERENCE NUMBER:
To be allocated.

NAME AND BUSINESS ADDRESS OF REGISTRATION HOLDER:
Flora Force Heath Products (Pty) Ltd.
Unit 3 Regent Park
Bell Crescent
Westlake
Cape Town
South Africa

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