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

Read all of this leaflet carefully because it contains important information for you. FLORA FORCE® MILK THISTLE capsules are available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use FLORA FORCE® MILK THISTLE capsules carefully to get the best results from it.
- **Keep this leaflet. You may need to read it again.**
- **Do not share FLORA FORCE® MILK THISTLE 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® MILK THISTLE CAPSULES CONTAIN:
Each **FLORA FORCE® MILK THISTLE** capsule contains:

ACTIVE INGREDIENT	QUANTITY
Silybum marianum seed powder	400 mg

Inactive ingredients are vegetable capsules.
FLORA FORCE® MILK THISTLE capsules are free from sugar and lactose.

WHAT FLORA FORCE® MILK THISTLE CAPSULES ARE USED FOR:
FLORA FORCE® MILK THISTLE capsules are used traditionally to support liver health.

BEFORE YOU TAKE FLORA FORCE® MILK THISTLE CAPSULES:
Do NOT take FLORA FORCE® MILK THISTLE capsules:
- If you have a hypersensitivity to plants from the Asteraceae family (see "**Take special care with FLORA FORCE® MILK THISTLE capsules**").
- If you have a hormone-sensitive condition or cancer (see "**Take special care with FLORA FORCE® MILK THISTLE capsules**").
- If you have diabetes (see **"Take special care with FLORA FORCE® MILK THISTLE capsules**").
- Surgery (see "**Take special care with FLORA FORCE® MILK THISTLE capsules**").
- Pregnancy and lactation (see "**Pregnancy and breastfeeding**").

Take special care with FLORA FORCE® MILK THISTLE capsules:
Please discuss the use of **FLORA FORCE® MILK THISTLE** capsules with your pharmacist or registered healthcare practitioner if you:
- Have a hypersensitivity to plants from the Asteraceae family. Members of this family include sunflowers, chrysanthemums, marigolds and daisies (see "**Do NOT take FLORA FORCE® MILK THISTLE capsules**").
- Suffer from Diabetes. You may have to arrange increased monitoring of your blood sugar levels (see "**Do NOT take FLORA FORCE® MILK THISTLE capsules**").
- Suffer from a hormone sensitive condition or cancer. Milk thistle might act like oestrogen. Until more is known, avoid using milk thistle. (see "**Do NOT take FLORA FORCE® MILK THISTLE capsules**").
- Are undergoing surgery, discontinue use at least 2 weeks prior to the procedure (see "**Do NOT take FLORA FORCE® MILK THISTLE 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® MILK THISTLE** capsules (see "**Taking other medicines with FLORA FORCE® MILK THISTLE capsules**").

The use of **FLORA FORCE® MILK THISTLE** 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® MILK THISTLE CAPSULES**").

Taking FLORA FORCE® MILK THISTLE capsules with food and drink:
FLORA FORCE® MILK THISTLE capsules should be taken after meals with water.

Pregnancy and breastfeeding:
Safety of **FLORA FORCE® MILK THISTLE** capsules during pregnancy and breastfeeding has not been established. Avoid taking **FLORA FORCE® MILK THISTLE** 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® MILK THISTLE capsules.

Driving and using machinery:
No studies on the effect on the ability to drive and use machinery have been performed. It is unlikely that **FLORA FORCE® MILK THISTLE** capsules will impair your ability to drive or use machines. However, please exercise care when driving or operating machinery until you know how **FLORA FORCE® MILK THISTLE** capsules affects you.

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

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

Discuss the use of the following medicines in combination with **FLORA FORCE® MILK THISTLE** capsules with your pharmacist or registered healthcare practitioner:
- Anti-diabetic medicines as **FLORA FORCE® MILK THISTLE** may further lower blood sugar levels. Monitor you blood sugar levels regularly if you are using **FLORA FORCE® MILK THISTLE** capsules and anti-diabetic medicines in combination
- Medicines changed and broken down by the liver (Cytochrome P450 2C9 (CYP2C9) substrates) (such as amitriptyline, diazepam, verapamil, warfarin and zileuton), as **FLORA FORCE® MILK THISTLE** capsules could increase effects and side effects of these medicines.
- Medicines changed and broken down by the liver (Cytochrome P450 2D6 (CYP2D6) substrates) (such as tricyclic antidepressants imipramine, amitriptyline; antipsychotics haloperidol, risperidone, chlorpromazine; beta-blockers propranolol, metoprolol and carvedilol; tamoxifen and others) as **FLORA FORCE® MILK THISTLE** capsules could increase effects and side effects of these medicines.
- Medicines changed and broken down by the liver (Cytochrome P450 (CYP3A4) substrates) (such as tamoxifen, alprazolam, amlodipine, clarithromycin, cyclosporine, erythromycin, lovastatin, ketoconazole, itraconazole, fexofenadine, triazolam, verapamil and others) as **FLORA FORCE® MILK THISTLE** capsules could increase or decrease effects of these medicines.
- Medications changed and broken down by the liver (glucuronidated medication) (such as acetaminophen, oxazepam, haloperidol, lamotrigine, morphine, zidovudine, raloxifene and estrogen) as **FLORA FORCE® MILK THISTLE** capsules could increase or decrease effectiveness of these medicines.
- Medications activated by cell plasma membrane systems (P-Glycoprotein Substrates) (such as chemotherapeutic agents, anti-fungals, protease inhibitors, H2 agonists, calcium channel blockers, digoxin, corticosteroids, erythromycin, cisapride, fexofenadine, cyclosporine, loperamide and quinidine) as **FLORA FORCE® MILK THISTLE** capsules may affect the activity of these systems and increase how much of some medications get absorbed.
- Warfarin or other blood thinning medicines. **FLORA FORCE® MILK THISTLE** capsules may potentially increase the effect of blood thinning medicines (see "**Take special care with FLORA FORCE® MILK THISTLE capsules**").

HOW TO TAKE FLORA FORCE® MILK THISTLE CAPSULES:
Do not share medicines prescribed to you with any other person.
Always take FLORA FORCE® MILK THISTLE 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 1-2 capsules twice daily with meals or as directed by your pharmacist or registered healthcare practitioner.

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

FLORA FORCE® MILK THISTLE 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® MILK THISTLE 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® MILK THISTLE capsules:
Always take **FLORA FORCE® MILK THISTLE** 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 1-2 capsules twice daily. Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE-EFFECTS:
FLORA FORCE® MILK THISTLE capsules may have side-effects.
Not all side-effects reported for FLORA FORCE® MILK THISTLE capsules are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FLORA FORCE® MILK THISTLE 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 shortness of breath, difficulty breathing, wheezing, hives, or itching, swelling of the face, tongue or whole body.

Side-effects that you should report to your pharmacist or registered healthcare practitioner as soon as possible:
- Joint pain and swelling, involuntary muscle contractions.

Side-effects that you should report to your pharmacist or registered healthcare practitioner if they continue or become bothersome include:
- Gastrointestinal disturbances, such as:
  - Nausea, vomiting, bloating, heartburn, stomach discomfort, diarrhoea, pain, wind, constipation and appetite loss.
- Nasal congestion, runny nose, post-nasal drip, sneezing, red eyes, itching of nose and eyes.

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

IDENTIFICATION OF FLORA FORCE® MILK THISTLE capsules:
Clear size 0 all vegetable capsule containing pale green 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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