

PATIENT INFORMATION LEAFLET

Information for the Patient about FLORA FORCE® DANDELION 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® DANDELION capsules.

Read all of this leaflet carefully because it contains important information for you. FLORA FORCE® DANDELION capsules are available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use FLORA FORCE® DANDELION capsules carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share FLORA FORCE® DANDELION 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® DANDELION CAPSULES CONTAIN:

Each FLORA FORCE® DANDELION capsule contains:

ACTIVE INGREDIENT	QUANTITY
Taraxacum officinale root & leaf powder	300 mg

Inactive ingredients are vegetable capsules.

FLORA FORCE® DANDELION capsules are free from sugar and lactose.

WHAT FLORA FORCE® DANDELION CAPSULES ARE USED FOR:

FLORA FORCE® DANDELION capsules traditionally used to support the body's elimination functions.

BEFORE YOU TAKE FLORA FORCE® DANDELION CAPSULES:

Do NOT take FLORA FORCE® DANDELION capsules:

- If you have a hypersensitivity plants from the Asteraceae family (see "Take special care with FLORA FORCE® DANDELION capsules").
- If you have a bile duct obstruction or gallstones (see "Take special care with FLORA FORCE® DANDELION capsules").
- If you have a bleeding disorder (see "Take special care with FLORA FORCE® DANDELION capsules").
- If you have diabetes (see "Take special care with FLORA FORCE® DANDELION capsules").
- If you have a renal impairment or chronic liver disease (CLD) (see "Take special care with FLORA FORCE® DANDELION capsules").
- Surgery (see "Take special care with FLORA FORCE® DANDELION capsules").
- Pregnancy and lactation (see "Pregnancy and breastfeeding").

Take special care with FLORA FORCE® DANDELION capsules:

Please discuss the use of FLORA FORCE® DANDELION 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, chrysanthemum, marigolds, daisies and other herbs (see "Do NOT take FLORA FORCE® DANDELION capsules").
- Suffer from a bile duct obstruction or gallstones (see "Do NOT take FLORA FORCE® DANDELION capsules").
- Suffer from a bleeding disorder. You may have to arrange increased monitoring of your blood levels when starting or stopping treatment with FLORA FORCE® DANDELION capsules (see "Do NOT take FLORA FORCE® DANDELION capsules").
- Suffer from Diabetes. You may have to arrange increased monitoring of your blood sugar levels (see "Do NOT take FLORA FORCE® DANDELION capsules").
- Suffer from renal impairment CLD. You may have to arrange increased monitoring of your oxalate and potassium levels (see "Do NOT take FLORA FORCE® DANDELION capsules").
- Are undergoing surgery, discontinue use at least 2 weeks prior to the procedure (see "Do NOT take FLORA FORCE® DANDELION capsules").
- Take warfarin, other blood thinning or anti-platelet medicines. You may have to arrange increased monitoring or your INR (International Normalised Ratio) levels when starting or stopping treatment with FLORA FORCE® DANDELION capsules (see "Taking other medicines with FLORA FORCE® DANDELION capsules").

The use of FLORA FORCE® DANDELION 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® DANDELION CAPSULES").

Taking FLORA FORCE® DANDELION capsules with food and drink:

FLORA FORCE® DANDELION capsules should be taken after meals with water.

Pregnancy and breastfeeding:

Safety of FLORA FORCE® DANDELION capsules during pregnancy and breastfeeding has not been established. Avoid taking FLORA FORCE® DANDELION 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® DANDELION 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® DANDELION 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® DANDELION capsules affects you.

Important information about some of the ingredients of FLORA FORCE® DANDELION capsules:

FLORA FORCE® DANDELION capsules are sugar free.

Taking other medicines with FLORA FORCE® DANDELION 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® DANDELION capsules with your pharmacist or registered healthcare practitioner.

- Lithium for the treatment of bipolar disorder.

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

Also, discuss the use of the following medicines in combination with FLORA FORCE® DANDELION capsules with your pharmacist or registered healthcare practitioner:

- Warfarin, other blood thinning or anti-platelet medicines. FLORA FORCE® DANDELION capsules may potentially increase the effect of blood thinning medicines (see "Take special care with FLORA FORCE® DANDELION capsules").
- Anti-diabetic medicines as FLORA FORCE® DANDELION may further lower blood sugar levels. Monitor your blood sugar levels regularly if you are using FLORA FORCE® DANDELION capsules and anti-diabetic medicines in combination.
- Medications which are changed and broken down by the liver (glucuronidated drugs) as FLORA FORCE® DANDELION capsules can influence the absorption and effectiveness of these medicines.
- Medicines which are changed and broken down by the liver (Cytochrome P450 1A2 (CYP1A2) substrates) as FLORA FORCE® DANDELION capsules could decrease effectiveness of these medicines.
- Quinolone Antibiotics as FLORA FORCE® DANDELION may decrease the absorption of these antibiotics.
- Water pills (potassium-sparing diuretics) as FLORA FORCE® DANDELION contains significant amounts of potassium and some of these medications can also increase potassium levels in the body. This might cause too much potassium in the body.

HOW TO TAKE FLORA FORCE® DANDELION CAPSULES:

Do not share medicines prescribed to you with any other person.

Always take FLORA FORCE® DANDELION 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 two to three times 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® DANDELION capsules").

FLORA FORCE® DANDELION 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® DANDELION 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® DANDELION capsules:

Always take FLORA FORCE® DANDELION 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 2-3 times daily. Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE-EFFECTS:

FLORA FORCE® DANDELION capsules may have side-effects.

Not all side-effects reported for FLORA FORCE® DANDELION capsules are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FLORA FORCE® DANDELION 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.
 - Signs of shock such as low blood pressure, rapid shallow breathing, cold and clammy skin, rapid weak pulse, dizziness, fainting or weakness.
 - Increased bleeding.
 - Rapid or irregular heartbeat, loss of consciousness.
 - Signs of decreased blood sugar such as light headedness, blurred vision and confusion.
 - Signs of kidney stones such as severe or sudden abdominal or flank pain, blood in the urine, frequent urge to urinate, pain when urinating and fever and chills.
 - Blood in urine, painful urination and more urine than is normal for you.
- Side-effects that you should report to your pharmacist or registered healthcare practitioner as soon as possible:
- Skin becoming cold, pale, red or swelling. A loss of sensation or severe pain.

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

- Gastrointestinal disturbances, such as:
 - Stomach discomfort, diarrhoea, constipation and heartburn.
- 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® DANDELION capsules:

Store at or below 25°C 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® DANDELION capsules:

60 Capsules packed into 125ml amber glass bottle with screw cap and safety seal insert.

IDENTIFICATION OF FLORA FORCE® DANDELION capsules:

Clear size 0 all vegetable capsule containing green herbal powder.

REGISTRATION NUMBER / REFERENCE NUMBER:

To be allocated.

NAME AND BUSINESS ADDRESS OF REGISTRATION HOLDER:

Flora Force Health Products (Pty) Ltd.

Unit 3 Regent Park

Bell Crescent

Westlake

Cape Town

South Africa

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