

PATIENT INFORMATION LEAFLET
Information for the Patient about FLORA FORCE® HERBAL COUGH MIXTURE

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® HERBAL COUGH MIXTURE liquid.

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

- Keep this leaflet. You may need to read it again.
- Do not share FLORA FORCE® HERBAL COUGH MIXTURE 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® HERBAL COUGH MIXTURE CONTAINS:

Each 5 ml of FLORA FORCE® HERBAL COUGH MIXTURE contains:

ACTIVE INGREDIENT	QUANTITY
<i>Inula helenium</i> root EQUIV	52 mg
<i>Lobelia inflata</i> herb EQUIV	52 mg
<i>Marrubium vulgare</i> herb EQUIV	52 mg
<i>Pelargonium sidoides</i> root EQUIV	52 mg
<i>Prunus serotina</i> bark EQUIV	52 mg
<i>Pulmonaria officinalis</i> herb EQUIV	52 mg
<i>Pimpinella anisum</i> seed EQUIV	26 mg
<i>Thymus vulgaris</i> herb EQUIV	15 mg

Inactive ingredients: Alc 30% v/v and *Glycyrrhiza glabra* root as flavouring*.
FLORA FORCE® HERBAL COUGH MIXTURE is free from sugar.

WHAT FLORA FORCE® HERBAL COUGH MIXTURE IS USED FOR:

FLORA FORCE® HERBAL COUGH MIXTURE contains herbs which have been used traditionally as expectorants and to alleviate respiratory conditions.

BEFORE YOU TAKE FLORA FORCE® HERBAL COUGH MIXTURE:

Do NOT take FLORA FORCE® HERBAL COUGH MIXTURE:

- If you are allergic to any of the ingredients in FLORA FORCE® HERBAL COUGH MIXTURE.
- If you have a heart disease (see "Take special care with FLORA FORCE® HERBAL COUGH MIXTURE").
- If you have high blood pressure (see "Take special care with FLORA FORCE® HERBAL COUGH MIXTURE").
- If you have a bleeding disorder (see "Take special care with FLORA FORCE® HERBAL COUGH MIXTURE").
- Surgery (see "Take special care with FLORA FORCE® HERBAL COUGH MIXTURE").
- Pregnancy and lactation (see "Pregnancy and breastfeeding").

Take special care with FLORA FORCE® HERBAL COUGH MIXTURE:

Please discuss the use of FLORA FORCE® HERBAL COUGH MIXTURE with your pharmacist or registered healthcare practitioner if you:

- Suffer from a heart disease or high blood pressure. You may have to arrange increased monitoring of your heart and blood pressure when starting or stopping treatment with FLORA FORCE® HERBAL COUGH MIXTURE (see "Do NOT take FLORA FORCE® HERBAL COUGH MIXTURE").
- Suffer from a bleeding disorder. You may have to arrange increased monitoring of your INR (International Normalised Ratio) levels when starting or stopping treatment with FLORA FORCE® HERBAL COUGH MIXTURE (see "Do NOT take FLORA FORCE® HERBAL COUGH MIXTURE").
- Are undergoing surgery, discontinue use at least 2 weeks prior to the procedure (see "Do NOT take FLORA FORCE® HERBAL COUGH MIXTURE").
- Are pregnant. FLORA FORCE® HERBAL COUGH MIXTURE might act as an abortifacient and is not recommended during pregnancy (see "Pregnancy and breastfeeding").
- Take warfarin, other blood thinning or anti-platelet medicines. You may have to arrange increased monitoring of your INR (International Normalised Ratio) levels when starting or stopping treatment with FLORA FORCE® HERBAL COUGH MIXTURE (see "Taking other medicines with FLORA FORCE® HERBAL COUGH MIXTURE").
- Take anti-hypertensive medication. You may have to arrange increased monitoring of your blood pressure when starting or stopping treatment with FLORA FORCE® HERBAL COUGH MIXTURE (see "Taking other medicines with FLORA FORCE® HERBAL COUGH MIXTURE").

FLORA FORCE® HERBAL COUGH MIXTURE, should not be used continuously. Use under supervision of a registered healthcare practitioner (see "HOW TO TAKE FLORA FORCE® HERBAL COUGH MIXTURE").

Taking FLORA FORCE® HERBAL COUGH MIXTURE with food and drink:

FLORA FORCE® HERBAL COUGH MIXTURE may be taken between meals with water if needed.

Pregnancy and breastfeeding:

Safety of FLORA FORCE® HERBAL COUGH MIXTURE during pregnancy and breastfeeding has not been established. Avoid taking FLORA FORCE® HERBAL COUGH MIXTURE if you are pregnant or breastfeeding.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacists or registered healthcare practitioner for advice before taking FLORA FORCE® HERBAL COUGH MIXTURE.

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® HERBAL COUGH MIXTURE will impair your ability to drive or use machines. However, please exercise care when driving or operating machinery until you know how FLORA FORCE® HERBAL COUGH MIXTURE affects you.

Important information about some of the ingredients of FLORA FORCE® HERBAL COUGH MIXTURE:

FLORA FORCE® HERBAL COUGH MIXTURE is sugar free.

Taking other medicines with FLORA FORCE® HERBAL COUGH MIXTURE:

Always tell your pharmacist or 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® HERBAL COUGH MIXTURE with your pharmacist or registered healthcare practitioner:

- Digoxin, as overuse of FLORA FORCE® HERBAL COUGH MIXTURE may increase interaction.
- Diuretics, as overuse of FLORA FORCE® HERBAL COUGH MIXTURE may increase interaction.
- Corticosteroids, as overuse of FLORA FORCE® HERBAL COUGH MIXTURE may increase activity.
- Warfarin, other blood thinning or anti-platelet medicines. FLORA FORCE® HERBAL COUGH MIXTURE may potentially increase the effect of blood thinning medicines (see "Take special care with FLORA FORCE® HERBAL COUGH MIXTURE").
- Anti-hypertensive medications, as FLORA FORCE® HERBAL COUGH MIXTURE may theoretically decrease the effect of these medications (see "Take special care with FLORA FORCE® HERBAL COUGH MIXTURE").

HOW TO TAKE FLORA FORCE® HERBAL COUGH MIXTURE:

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

Always take FLORA FORCE® HERBAL COUGH MIXTURE 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 one teaspoon three times daily before meals or as directed by your pharmacist or registered healthcare practitioner.

Children (under 18 years of age):

Children 8-17 years: Take one teaspoon three times daily before meals or as directed by your pharmacist or registered healthcare practitioner.

Children under 8 years: ½ teaspoon dilute in a little water three times daily before meals or as directed by your pharmacist or registered healthcare practitioner.

If symptoms have not improved after 1-2 weeks consult a registered health care practitioner (see "Take special care with FLORA FORCE® HERBAL COUGH MIXTURE").

If you take more FLORA FORCE® HERBAL COUGH MIXTURE 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® HERBAL COUGH MIXTURE:

Always take FLORA FORCE® HERBAL COUGH MIXTURE 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. Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE-EFFECTS:

FLORA FORCE® HERBAL COUGH MIXTURE may have side-effects.

Not all side-effects reported for FLORA FORCE® HERBAL COUGH MIXTURE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FLORA FORCE® HERBAL COUGH MIXTURE, 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.
- Nausea, vomiting and stomach pain.
- Constipation, fatigue, muscle weakness and spasms.
- Less urine, swollen feet/ankles, shortness of breath, drowsiness, fatigue and confusion.

Side-effects that you should report to your pharmacist or registered healthcare practitioner as soon as possible:

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

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® HERBAL COUGH MIXTURE:

Store at or below 25°C in a dry place.

Protect from light / moisture.

Do not take the liquid after the expiry date stated on the packaging material.

Return all unused liquid to your pharmacist.

Do not dispose of unused liquid in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINE OUT OF REACH OF CHILDREN.

PRESENTATION OF FLORA FORCE® HERBAL COUGH MIXTURE:

100 ml amber glass bottle with white tamper evident screw cap within a product box.

IDENTIFICATION OF FLORA FORCE® HERBAL COUGH MIXTURE:

Dark brown liquid with liquorice flavour.

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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* *Glycyrrhiza glabra* root as flavouring contains less than 2 mg glycyrrhizin per 100 ml.