

PATIENT INFORMATION LEAFLET
Information for the Patient about FLORA FORCE® BILBERRY 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® BILBERRY capsules.

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

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

Each FLORA FORCE® BILBERRY capsule contains:

ACTIVE INGREDIENT	QUANTITY
Vaccinium myrtillus berry powder	500 mg

Inactive ingredients are vegetable capsules.

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

WHAT FLORA FORCE® BILBERRY CAPSULES ARE USED FOR:

FLORA FORCE® BILBERRY capsules supports vision and eye health, and helps to relieve symptoms related to non-complicated venous insufficiency.

BEFORE YOU TAKE FLORA FORCE® BILBERRY CAPSULES:

Do NOT take FLORA FORCE® BILBERRY capsules:

- If you have are allergic to any of the ingredients in FLORA FORCE® BILBERRY capsules.
- If you have a bleeding disorder (see "Take special care with FLORA FORCE® BILBERRY capsules").
- If you have diabetes (see "Take special care with FLORA FORCE® BILBERRY capsules").
- Surgery (see "Take special care with FLORA FORCE® BILBERRY capsules").
- Pregnancy and lactation (see "Pregnancy and breastfeeding").

Take special care with FLORA FORCE® BILBERRY capsules:

Please discuss the use of FLORA FORCE® BILBERRY capsules with your pharmacist or registered healthcare practitioner if you:

- Suffer from a bleeding disorder. You may have to arrange increased monitoring of your blood levels when starting or stopping treatment with FLORA FORCE® BILBERRY capsules (see "Do NOT take FLORA FORCE® BILBERRY capsules").
- Suffer from diabetes. You may have to arrange increased monitoring of your blood sugar levels (see "Do NOT take FLORA FORCE® BILBERRY capsules").
- Are undergoing surgery, discontinue use at least 2 weeks prior to the procedure (see "Do NOT take FLORA FORCE® BILBERRY 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® BILBERRY capsules (see "Taking other medicines with FLORA FORCE® BILBERRY capsules").

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

Taking FLORA FORCE® BILBERRY capsules with food and drink:

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

Pregnancy and breastfeeding:

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

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

FLORA FORCE® BILBERRY capsules are sugar free.

Taking other medicines with FLORA FORCE® BILBERRY capsules:

Always tell your pharmacist or 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® BILBERRY capsules with your pharmacist or registered healthcare practitioner:

- Warfarin, other blood thinning or anti-platelet medicines. FLORA FORCE® BILBERRY capsules may potentially increase the effect of blood thinning medicines (see "Take special care with FLORA FORCE® BILBERRY capsules").
- Anti-diabetic medicines as FLORA FORCE® BILBERRY capsules may further lower blood sugar levels. Monitor your blood sugar levels regularly if you are using FLORA FORCE® BILBERRY capsules and anti-diabetic medicines in combination.

HOW TO TAKE FLORA FORCE® BILBERRY CAPSULES:

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

Always take FLORA FORCE® BILBERRY 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® BILBERRY capsules").

FLORA FORCE® BILBERRY 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 healthcare practitioner.

If you take more FLORA FORCE® BILBERRY 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® BILBERRY capsules:

Always take FLORA FORCE® BILBERRY 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® BILBERRY capsules may have side-effects.

Not all side-effects reported for FLORA FORCE® BILBERRY capsules are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FLORA FORCE® BILBERRY 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 decreased blood sugar or blood pressure such as light headedness, blurred vision and confusion.

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

- Gastrointestinal disturbances, such as:
 - Increased frequency of bowel movements, constipation, stomach discomfort, nausea and heartburn.

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® BILBERRY 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® BILBERRY capsules:

90 Capsules packed into 125ml amber glass bottle with light green screw cap and safety seal insert, packed in box.

IDENTIFICATION OF FLORA FORCE® BILBERRY capsules:

Clear size 0 all vegetable capsule containing a dark red-brown 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

DATE OF PUBLICATION:

23/02/2018.