

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **[S0]**

PRODUCT NAME
BIOGEN VEIN-VINE

Each vegetable capsule contains:

Vitis vinifera L. (Red Vine Leaf) [Leaf; 10:1 extract standardised to 7,0 % Flavonoids] 360,00 mg

Sugar free.

D 33.6 Western Herbal Medicine. Complementary medicine.
This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

Read all of this leaflet carefully because it contains important information for you.
BIOGEN VEIN-VINE is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to take BIOGEN VEIN-VINE carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share BIOGEN VEIN-VINE with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What BIOGEN VEIN-VINE is and what it is used for.
2. What you need to know before you take BIOGEN VEIN-VINE.
3. How to take BIOGEN VEIN-VINE.
4. Possible side effects.
5. How to store BIOGEN VEIN-VINE.
6. Contents of the pack and other information.

1. What BIOGEN VEIN-VINE is and what it is used for
BIOGEN VEIN-VINE, may assist with the relief of symptoms associated with chronic venous insufficiency (CVI) in association with varicose veins, including swelling of the lower leg, heavy or tired legs, and sensation of tension, tingling and pain.

2. What you need to know before you take BIOGEN VEIN-VINE

Do not take BIOGEN VEIN-VINE:

- If you have a hypersensitivity to Red vine leaf extract or any of the other ingredients listed (see section 6).
- Not recommended during pregnancy and lactation.

Warnings and precautions

Special care should be taken with BIOGEN VEIN-VINE.

If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine.

Please take note of the following:

- Consult a health care provider prior to use if symptoms worsen.
- Consult a healthcare provider prior to use if you are pregnant or breastfeeding.
- BIOGEN VEIN-VINE is not recommended for use in children under the age of 18 years.

Nutritional supplementation should not replace a balanced diet. Do not exceed the recommended dose without consulting a healthcare provider.

Children and adolescents

BIOGEN VEIN-VINE is not recommended for use in children under the age of 18 years.

Other medicines and BIOGEN VEIN-VINE

Always tell your healthcare provider if you are taking any other medicine, including complementary or traditional medicine. It is advised to consult your doctor if you want to take BIOGEN VEIN-VINE combined with other medicines or treatments such as:

- Red vine leaf extract may have antiplatelet effects and may increase the risk of bleeding if used with anticoagulant or antiplatelet drugs.
- Red vine leaf extract inhibits CYP2C9, may increase the levels of CYP2D6 and CYP2E1 substrates.
- Red vine leaf extract taken at high doses of a 1 000 mg daily with 500 mg vitamin C daily significantly increases systolic and diastolic blood pressure, as well as daytime and nighttime blood pressure variability in patients with hypertension and caution is advised.

Other Diseases / Impairments and BIOGEN VEIN-VINE

- Red vine leaf extract might increase the risk of bleeding and bruising in individuals with bleeding conditions.
- Red vine leaf extract might increase the risk of excessive bleeding and bruising if used prior to surgery. Patients are advised to discontinue using red vine leaf extract at least 2 weeks prior to elective surgical procedures.

BIOGEN VEIN-VINE with food and drink

- Vitamins, minerals and nutrients obtained from other sources should be taken into account when prescribing / suggesting BIOGEN VEIN-VINE.

Pregnancy, breastfeeding and fertility

Not recommended for use during pregnancy or lactation.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Driving and using machinery

No studies on the effects on the ability to drive or use machinery have been performed. Patients should exercise caution before driving or use of machinery until they are reasonably certain BIOGEN VEIN-VINE does not adversely affect their performance.

3. How to take BIOGEN VEIN-VINE

Do not share your medicines with any other person.

Always take BIOGEN VEIN-VINE exactly as described in this leaflet or as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

Adults:

Take 1 (one) capsule in daily before breakfast, or as recommended by your healthcare provider. Dose may be increased to 2 capsules in the morning. Do not exceed with recommended daily dose.

The safety and efficacy of BIOGEN VEIN-VINE in children has not yet been established. Not allowed in children under 18 years.

If you take more BIOGEN VEIN-VINE than you should

No known information. In the event of an over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Take this leaflet and the rest of the BIOGEN VEIN-VINE capsules with you so the doctor will know what you have taken.

If you forget to take BIOGEN VEIN-VINE

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

BIOGEN VEIN-VINE can have side effects.

Not all side effects reported for BIOGEN VEIN-VINE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BIOGEN VEIN-VINE, please consult your healthcare provider for advice.

Side effects associated:

Dermatologic

Rare: mild hair thinning has been reported in a patient taking red vine leaf extract. Urticaria (hives) has also been reported with this same extract.

Gastrointestinal

Unknown frequency: Abdominal pain and nausea and intermittent nausea, vomiting, and diarrhea when taking red vine leaf extract has been reported.

Rare: Flatulence, mild constipation, gastrointestinal discomfort, diarrhea, dyspepsia, dry mouth, and retching.

Musculoskeletal

Unknown frequency: Musculoskeletal disorders, including back pain, have been reported with use of red vine leaf extract.

Neurologic/CNS

Unknown frequency: Dizziness, tiredness, headache, and sleep problems has been reported with use of red vine leaf extract.

Pulmonary/Respiratory

Frequent: Nasopharyngitis and oropharyngeal pain have been reported with use of Red vine leaf extract.

Rare: Sore throat, cough, allergic rhinitis, and nasopharyngitis have been reported with use of red vine leaf extract.

Should your general health worsen or if you experience any untoward effects while BIOGEN VEIN-VINE, please consult your doctor, pharmacist or other healthcare practitioner for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you experience side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications:

<http://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of BIOGEN VEIN-VINE.

5. How to store BIOGEN VEIN-VINE

- Store at or below 25 °C.
- Protect from light and moisture.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information What BIOGEN VEIN-VINE contains

What BIOGEN VEIN-VINE contains

Active ingredients per capsule.

Red vine leaf extract 360,00 mg.

The other ingredients are magnesium stearate and microcrystalline cellulose.

What BIOGEN VEIN-VINE looks like and contents of the pack

50 Red Capsules packed in blisters of 10's in a unit carton.

Holder of certificate of registration

BIOGEN
23 Stag Road, Glen Austin, South Africa

info@biogen.co.za

www.biogen.co.za

Tel: 0860 347243

This leaflet was last revised in

June 2022.

Registration Number

Will be allocated by SAHPRA upon registration.

PASIËNTINLIGTINGSBLAD

SKEDULERINGSSTATUS: **[S0]**

PRODUKNAAM
BIOGEN VEIN-VINE

Elke groentekapsule bevat:

Vitis vinifera L. (Rooi Wingerdblaar) [Blaar; 10:1 ekstrak gestandaardiseer tot 7,0 % Flavonoïede] 360,00 mg

Suikervry.

D 33.6 Westerse kruie medisyne. Komplementêre medisyne.
Hierdie ongeregistreerde medisyne is nie deur die SAHPRA geëvalueer vir gehalte, veiligheid of beoogde gebruik nie.

Lees hierdie inligtingsblad noukeurig deur want dit bevat inligting wat belangrik is vir u.
BIOGEN VEIN-VINE is beskikbaar sonder 'n dokter se voorskrif, sodat u u gesondheid kan onderhou. U moet BIOGEN VEIN-VINE nietemin steeds versigtig neem om die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat u dit weer lees.
- Moenie BIOGEN VEIN-VINE met enigiemand anders deel nie.
- Vra gerus u gesondheidsorgverskaffer of apteker indien u verdere inligting of advies nodig het.

Wat is in hierdie pamflet

1. Wat is BIOGEN VEIN-VINE en waarvoor word dit gebruik.
2. Wat u moet weet voordat u BIOGEN VEIN-VINE neem.
3. Hoe om BIOGEN VEIN-VINE te neem.
4. Moontlike nuwe-effekte.
5. Hoe om BIOGEN VEIN-VINE te bêre.
6. Inhoud van die verpakking en ander inligting.

1. Wat is BIOGEN VEIN-VINE en waarvoor word dit gebruik

BIOGEN VEIN-VINE, kan help met die verligting van simptome wat verband hou met chroniese veneuse ontoereikendheid (CVO), in verband met spatate, insluitend swelling van die onderbeen, swaar of moeë bene, en sensasie van spanning, tinteling en pyn.

2. Wat u moet weet voordat u BIOGEN VEIN-VINE neem

Moenie BIOGEN VEIN-VINE neem nie:

- As jy 'n hipersensitieweit het vir Rooi wingerdblaarekstrak of enige van die ander bestanddele gelys (sien afdeling 6).
- Nie aanbeveel tydens swangerskap en laktasie nie.

Waarskuwings en voorsorgmaatreëls

Spesiale sorg moet toegepas word met die gebruik van BIOGEN VEIN-VINE.

Raadpleeg u gesondheidspraktisyn voordat u hierdie medisyne neem as u voorgeskrewe medisyne gebruik.

Let asseblief op die volgende:

- Raadpleeg 'n gesondheidsorgverskaffer voor gebruik indien simptome vererger.
- Raadpleeg 'n gesondheidsorgverskaffer voor gebruik as jy swanger is of borsvoed.
- BIOGEN VEIN-VINE word nie aanbeveel vir gebruik by kinders onder die ouderdom van 18 jaar nie.

Voedingsaanvullings moet nie 'n gebalanseerde dieet vervang nie. Moet nie die aanbevole dosis oorskry sonder om 'n gesondheidsorgverskaffer te raadpleeg nie.

Kinders en adolessente

BIOGEN VEIN-VINE word nie vir kinders onder die ouderdom van 18 jaar aanbeveel nie.

Ander medisyne en BIOGEN VEIN-VINE

Lig altyd u gesondheidspraktisyn in wanneer u medisyne om 'n gereelde basis neem, insluitend komplementêre of tradisionele medisyne.

Dit word aanbeveel om u dokter te raadpleeg as u BIOGEN VEIN-VINE wil kombineer saam met ander medisyne of behandelinge soos:

- Rooi wingerdblaarekstrak kan antiplaatjie-effekte hê en kan die risiko van bloeding verhoog indien dit saam met antikoagulanate of antiplaatjie-middels gebruik word.
- Rooi wingerdblaarekstrak inhibeer CYP2C9, kan die vlakke van CYP2D6 en CYP2E1 substrate verhoog.
- Rooi wingerdblaarekstrak geneem teen hoë dosisse van 'n 1 000 mg daagliks met 500 mg vitamien C daagliks verhoog sistoliese en diastoliese bloeddruk aansienlik, sowel as dag- en nagbloeddrukeranderlikheid by pasiënte met hipertensie en versigtigheid word aangerai.

Ander siektes / gestremdhede en BIOGEN VEIN-VINE

- Rooi wingerdblaar ekstrak kan die risiko van bloeding en kneusing verhoog by individue met bloedingstoestand.
- Rooi wingerdblaar ekstrak kan die risiko van oormatige bloeding en kneusing verhoog indien dit voor die operasie gebruik word. Pasiënte word aangerai om die gebruik van rooi wingerdblaarekstrak ten minste 2 weke voor elektiewe chirurgiese prosedures te staak.

BIOGEN VEIN-VINE met kos en drinkgoed

- Vitamiene, minerale en voedingsowwe verkry uit ander bronne moet in ag geneem word wanneer BIOGEN VEIN-VINE voorgeskryf/voorgeskryf word.

Swangerskap, borsvoeding en vrugbaarheid

Nie aanbeveel vir gebruik tydens swangerskap en laktasie nie.

Indien u swanger is of u baba borsvoed, dink dat u swanger is, of van plan is om 'n baba te hê, raadpleeg u dokter, apteker of gesondheidsorgwerker voordat u hierdie medisyne gebruik.

Bestuur en die gebruik van masjinerie

Geen studies is uitgevoer oor die uitwerking op die vermoë om te bestuur of masjinerie te gebruik nie. Dit is moontlik dat BIOGEN VEIN-VINE die vermoë om te bestuur of gebruik van masjinerie kan beïnvloed, aangesien BIOGEN VEIN-VINE vertraagde reaksies, lomerigheid en sedasie kan veroorsaak. Wees asseblief versigtig totdat u seker is dat u vermoë om sulke aktiwiteite uit te voer nie beïnvloed word nie.

3. Hoe om BIOGEN VEIN-VINE te neem

Moenie u medisyne met enigiemand anders deel nie.

Neem, BIOGEN VEIN-VINE altyd presies soos wat in hierdie inligtingsblad aangedui word, of soos wat u dokter of apteker vir u aanbeveel het. Vra gerus u dokter of apteker indien u onseker is.

Volwassenes:

Neem 1 (eem) kapsule daagliks voor ontbyt, of soos aanbeveel deur u gesondheidsorgpraktisyn. Dosis mag verhoog word na 2 kapsules in die oggend. Moenie die aanbevele dosis oorskry nie.

Die veiligheid en doeltreffendheid van BIOGEN VEIN-VINE by kinders is nog nie vasgestel nie. Nie toegelaat by kinders nie onder 18 jaar.

Wat om te doen indien u meer BIOGEN VEIN-VINE geneem het as wat u moet

Geen bekende informasie. Indien u meer BIOGEN VEIN-VINE geneem het as wat u moes, of in die geval van 'n oordosis, raadpleeg u dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Neem hierdie inligtingsblad en die oorblywende BIOGEN VEIN-VINE olie saam sodat die dokter kan sien wat u ingeneem het.

Indien u vergeet om BIOGEN VEIN-VINE te neem

Moenie 'n dubbele dosis neem om te vergoed vir individuele dosisse wat vergeet is nie.

4. Moontlike nuwe-effekte

BIOGEN VEIN-VINE kan nuwe-effekte hê.

Nie alle nuwe-effekte wat aangemeld is vir BIOGEN VEIN-VINE is in hierdie voubljet ingesluit nie. Indien u algemene gesondheid vererger, of as u ongewenste gevolge ervaar tydens die gebruik van BIOGEN VEIN-VINE, raadpleeg u gesondheidsorgwerker vir advies.

Neuwe-effekte geassosieer:

Dermatologies

Skaars: ligte hare verdunning is aangemeld by 'n pasiënt wat rooi wingerdblaarekstrak neem. Urtikaria (korwe) is ook aangemeld met dieselfde uittreksel.

Gastroïntestinale

Onbekende frekwensie: Adominale pyn en naarheid en intermitterende naarheid, braking en diarree wanneer rooi wingerdblaarekstrak geneem word, is aangemeld.

Skaars: Winderigheid, ligte hardlywigheid, gastroïntestinale ongemak, diarree, dyspepsie, droë mond en kokhaling.

Muskuloskeletale

Onbekende frekwensie: Muskuloskeletale afwykings, insluitend ruggyn, is aangemeld met die gebruik van rooi wingerdblaarekstrak.

Neurologies/SSS

Onbekende frekwensie: Duiseligheid, moegheid, hoofpyn en slaapprobleme is aangemeld met die gebruik van rooi wingerdblaarekstrak.

Pulmonêre/respiratoriese

Dikwels: Nasofaryngitis en orofaringeale pyn is aangemeld met die gebruik van rooi wingerdblaarekstrak.

Skaars: Seer keel, hoës, allergiese rinitis en nasofaryngitis is aangemeld met die gebruik van rooi wingerdblaarekstrak.

Raadpleeg u dokter, apteker of ander gene-eseer vir advies indien u algemene gesondheid vererger of as u enige ongewenste effekte ervaar terwyl BIOGEN VEIN-VINE neem.

As u enige nuwe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie, moet u dokter of apteker daarvan in kennis gestel word.

Rapportering van nuwe-effekte

Praat met u dokter of apteker as u nuwe-effekte kry. U kan ook nuwe-effekte by SAHPRA aanmeld via die "6.04 Adverse Drug Reactions Reporting Form", wat aanlyn gevind kan word onder SAHPRA se publikasies:

<http://www.sahpra.org.za/Publications/Index/8>.

Deur nuwe-effekte te rapporteer kan u help om meer inligting rakende die veiligheid van BIOGEN VEIN-VINE te verskaf.

5. Hoe om BIOGEN VEIN-VINE te bêre

- Bêre by of onder 25 °C.
- Beskerm teen lig en vog.
- Bêre alle medisyne buite bereik van kinders.
- Moenie gebruik ná die vervaldatum wat op die produk gedruk is nie.
- Neem alle ongebruikte medisyne terug na u apteker.
- Moenie ongebruikte medisyne in dreine en rioolsisteme (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting

Wat BIOGEN VEIN-VINE bevat

Aktiewe bestanddele per kapsule.

Rooi wingerdblaar ekstrak 360,00 mg.

Die ander bestanddele is magnesiumsteraat en mikrokristallyne sellulose.

Hoe BIOGEN VEIN-VINE lyk en inhoud van die verpakking

50 Rooi Kapsules verpak in blase van 10'e in 'n eenheid karton.

Houer van die registrasiesertifikaat

BIOGEN
Stagweg 23, Glen Austin, Suid Afrika

info@biogen.co.za

www.biogen.co.za

Tel: 0860 347243

Hierdie inligtingsblad is laas hersien in

Junie 2022.

Registrasienuommer

Sal met registrasie deur SAHPRA toegeken word.

JOB: BPS_Vein-Vine_30s		SIZE: 210mm x 400mm	
STOCK: Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input checked="" type="checkbox"/> Other: <input type="checkbox"/>			
COLOURS:		FINISHING:	
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<input type="checkbox"/> Embossing			