

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

Unscheduled

PROPRIETARY NAME AND DOSAGE FORM:

VASCAMEN tablets

Read all of this leaflet carefully because it contains important information for you. VASCAMEN is available without a doctor's prescription, for you as a health supplement. Nevertheless, you still need to use VASCAMEN carefully to get the best results from it.

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

WHAT VASCAMEN CONTAINS:

Each VASCAMEN tablet contains:

<i>Ginkgo biloba</i> (Ginkgo) [leaf, as 10 mg of a 5:1 extract]	50 mg
<i>Epimedium brevicornum</i> (Horny goat weed) [stem & leaf, as 3.75 mg of a 20:1 extract]	75 mg
<i>Crataegi fructus</i> (Hawthorn) [fruit]	100 mg
<i>Serenoa repens</i> (Saw palmetto) [fruit, as 3.125 mg of a 8:1 extract]	25 mg
<i>Tribulus terrestris</i> (Devil's thorn) [fruit, as 0.7 mg of a 50:1 extract]	35 mg
Zinc sulphate	22 mg
providing Zinc (elemental)	5 mg
Selenium AAC 2%	1 mg
providing Selenium	20 µg
Lycopene 10%	1 mg

Contains sugar as Lactose (154 mg) and Fructose (8 mg)

Complementary Medicine: Health Supplement.

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

1. What VASCAMEN is and what it is used for

VASCAMEN is a health supplement that may improve general quality of life in men by improving blood circulation in the body. VASCAMEN contains several plant-derived ingredients as well as minerals and trace elements.

2. What you need to know before you take VASCAMEN

Do not take VASCAMEN

- If you are hypersensitive (allergic) to any of the ingredients of VASCAMEN
- If you have uncontrolled high blood pressure
- If you are pregnant or breastfeeding your baby
- If you are taking digoxin, nitro-glycerine or anticoagulants

Warnings and precautions

If you have a medical condition, seek advice from your health care provider.

Take special care with VASCAMEN:

- If you have diabetes
- If you have epilepsy
- If you have arrhythmias

Other medicines and VASCAMEN:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Drug interactions

Ginkgo Biloba:

- **NSAIDS** (Nonsteroidal Anti-inflammatory Drugs) – in combination with Ginkgo this may enhance blood thinning effects of either medications.
- **Anti-coagulants** – (Warfarin, Clopidogrel, Enoxaparin, etc.) - in combination with Ginkgo this may enhance blood thinning effects of either medications.
- **Alprazolam** – Ginkgo may decrease the effectivity of Alprazolam
- **Efavirenz** – Ginkgo might decrease the absorption and thus effectivity of Efavirenz
- **Medicine metabolized in the liver** – Ginkgo will compete with other drugs to be metabolised in the liver. Thus, this might have an effect on how quickly those drugs are metabolized and thus patients may experience increased side effects from those drugs.
- **Anti-diabetic medication** – Ginkgo may have an effect on blood glucose levels of type 2 diabetic patients. Simultaneous use with other hyperglycaemic medication is not recommended.

Crataegi fructus:

- **Digoxin** – Might increase the side effects of Digoxin.
- **High-blood pressure medication** (Calcium Channel Blockers and Beta-blockers) – Might lead to hypotension

Serenoa repens:

- **Oestrogen** – May decrease the effect of oestrogen or oestrogen containing products such as birth control tablets.

Epimedium brevicornum:

- **Antihypertensive medication and nitro-glycerine** – May cause severe hypotension

VASCAMEN with food, drink and alcohol

VASCAMEN must be taken with food

Pregnancy, breastfeeding and fertility

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

Safety during pregnancy and breastfeeding has not been established

Driving and using machines

VASCAMEN is unlikely to affect your ability to drive or operate machinery / equipment. It is not always possible to predict to what extent VASCAMEN may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which VASCAMEN affects them.

VASCAMEN contains sugar in the form of lactose and fructose

3. How to take VASCAMEN:

Do not share medicines prescribed for you with any other person. Always take VASCAMEN 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.

Take two tablets in the morning and one tablet at night after meals. This product is intended for continuous use to maintain quality of life in men.

If you take more VASCAMEN than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take VASCAMEN:

Take your missed dose as soon as you remember, if within a few hours after missing a dose. If you only remember about the missed dose the following day, do not take a double dose to make up for the forgotten individual doses. In this case just continue taking two tablets in the morning and one tablet at night after meals.

If you stop taking VASCAMEN:

If you have stopped taking VASCAMEN for any reason, particularly because you think you are having side effects or for other illness, it is important that you contact your doctor before restarting.

4. Possible side effects

VASCAMEN can have side effects. Not all side effects reported for VASCAMEN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking VASCAMEN, please consult your health care provider for advice.

VASCAMEN may cause the following side effects:

Minor side effects such as stomach upset, headache, dizziness, constipation, forceful heartbeat, allergic skin reactions, nausea, fatigue, sweating, palpitations, nosebleeds, insomnia, agitation and dry mouth.

Ginkgo and Hawthorn may have a blood thinning effect which may lead to easy bruising and increased risk of bleeding.

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction 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 VASCAMEN.

5. How to store VASCAMEN:

- Store at or below 25 °C
- Protect from direct sunlight and moisture
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN
- Do not use after the expiry date stated on the outer packaging
- Return all unused or expired medicine to your pharmacist
- Do not dispose of unused or expired medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What VASCAMEN contains

The active substances are *Ginkgo biloba*, *Epimedium brevicornum*, *Crataegi fructus*, *Serenoa repens*, *Tribulus terrestris*, zinc, lycopene 10%, selenium. The other ingredients are micro crystalline cellulose, maize starch, povidone, sodium starch, magnesium stearate.

Contains sugar as lactose and fructose.

What VASCAMEN looks like and contents of the pack

Vascamen are medium, round, brown, speckled tablets. Available in securitainer bottles containing 90 tablets.

Registration number:

To be allocated by Council upon registration.

Holder of Certificate of registration

Manufactured by Hersol Manufacturing Laboratories (Pty) Ltd on behalf of Look Pharmaceuticals (Pty) Ltd.



LOOK PHARMACEUTICALS
REG NO: 2001/002217/07 (PTY) LTD

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Complementary Medicine: Health Supplement. Category D.

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

This leaflet was last revised in 10 December 2019

PASIËNTINLIGTINGSVOUBILJET

SKEDULERINGSSTATUS:

Ongeskeduleerd

HANDELSNAAM EN DOSERINGSVORM

VASCAMEN tablette

Lees al die inligting in die voubiljet noukeurig deur, want dit bevat belangrike inligting vir jou. VASCAMEN is beskikbaar vir jou as 'n gesondheidsaanvulling sonder 'n voorskrif van die dokter. Nogtans moet jy VASCAMEN noukeurig gebruik om die beste resultate daaruit te kry.

- Hou hierdie voubiljet. Jy mag dit later weer wil lees.
- Moet nie VASCAMEN met enige ander persoon deel nie.
- Vra jou apteker of gesondheidsorgverskaffer as jy meer inligting of advies benodig.

WAT BEVAT VASCAMEN:

Elke VASCAMEN tablet bevat:

<i>Ginkgo biloba</i> (Ginkgo) [blaar, as 10 mg van 'n 5:1 ekstrak]	50 mg
<i>Epimedium brevicornum</i> (Geile bokkruid) [stam & blaar, as 3.75 mg van 'n 20:1 ekstrak]	75 mg
<i>Crataegi fructus</i> (Haagdoring) [vrug]	100 mg
<i>Serenoa repens</i> (Saagpalm) [vrug, as 3.125 mg van 'n 8:1 ekstrak]	25 mg
<i>Tribulus terrestris</i> (Duiwelsdoring) [vrug, as 0.7 mg van 'n 50:1 ekstrak]	35 mg
Sinksulfaat	22 mg
verskaf Sink (elementeel)	5 mg
Selenium AAC 2%	1 mg
verskaf Selenium	20 µg
Likopeen 10%	1 mg

Bevat suiker as Laktose (154 mg) en Fruktose (8 mg)

Aanvullende Medisyne: Gesondheidsaanvulling

Hierdie ongeregisteerde medisyne is nie deur die SAHPRA geëvalueer vir die kwaliteit, veiligheid of beoogde gebruik daarvan nie.

1. Wat is VASCAMEN en waarvoor word dit gebruik

VASCAMEN is 'n gesondheidsaanvulling wat die algemene lewenskwaliteit in mans kan verbeter deur die bloedsomloop in die liggam te verbeter. VASCAMEN bevat verskeie plant-afgeleide bestanddele asook minerale en spoorelemente.

2. Wat jy moet weet voordat jy VASCAMEN gebruik

Moet nie VASCAMEN gebruik:

- As jy hipersensitief (allergies) is vir enige van die bestanddele van VASCAMEN
- Jy onbeheerde hoë bloeddruk het
- As jy swanger is of jou baba borsvoed
- As jy digoksien, nitrogliserien of anti-koagulante gebruik

Waarskuwings en voorsorgmaatreëls

As jy 'n mediese toestand het, raadpleeg jou gesondheidsorgverskaffer

Wees veral versigtig met VASCAMEN

- As jy diabetes het
- As jy epilepsie het
- As jy aritmieë (hartritme verstourings) het

Ander medisyne en vascamen:

Stel altyd jou gesondheidsorgverskaffer in kennis indien jy enige ander medikasie gebruik. (Dit sluit alle aanvullende of tradisionele medisyne in.)

Geneesmiddelinteraksies

Ginkgo biloba:

- **NSAIDS** (Non-steroïed Anti-inflammatoriese Middels) – In kombinsie met Ginkgo, kan dit die bloedverduunnende effek van beide middels verhoog.
- **Anti-koagulante** (Warfarien, Klopido-grel, Enoksaparien ens.) In kombinsie met Ginkgo, kan dit die bloedverduunnende effek van beide middels verhoog
- **Alprazolam** – Ginkgo kan die effektiwiteit van Alprazolam verminder
- **Efavirenz** – Ginkgo kan die absorpsie en dus effektiwiteit van Efavirenz verminder
- **Medisyne wat in die lewer gemetaboliseer word** – Ginkgo kan meeding met ander geneesmiddels wat in die lewer gemetaboliseer word. Dit kan dus 'n invloed hê op hoe vinnig hierdie medikasie gemetaboliseer word en pasiënte kan dalk meer nuwe-effekte ervaar
- **Anti-diabetes medikasie** – Ginkgo kan 'n invloed hê op bloedglukose vlakke van tipe-2 diabetiese pasiënte. Gelyktydige gebruik met ander hiperglysemiese medikasie word nie aanbeveel nie.

Crataegi fructus:

- **Digoksien** – Gesamentlike gebruik kan nuwe-effekte van digoksien verhoog
- **Hoë bloeddruk medikasie** (Kalsiumkanaal- en betablokkers) – Kan lei tot hipotensie

Serenoa repens:

- **Estrogeen** – Kan die effek van estrogeen of estrogeenbevattende produkte soos geboortebeperrings tablette verminder.

Epimedium brevicornum:

- **Antihypertensiewe medikasie en nitrogliserien** – Kan ernstige hipotensie veroorsaak

VASCAMEN met kos, drank en alkohol

VASCAMEN moet saam met voedsel geneem word

Swangerskap, borsvoeding en vrugbaarheid

As jy swanger is of borsvoed, dink dat jy swanger is of van plan is om 'n baba te hê, raadpleeg jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy hierdie medisyne gebruik.

Veiligheid tydens swangerskap en borsvoeding is nog nie vasgestel nie.

Bestuur en gebruik van masjiene

Dit is onwaarskynlik dat VASCAMEN jou vermoë om te bestuur of masjinerie / toerusting te gebruik sal beïnvloed. Dit is nie altyd moontlik om te voorspel tot in watter mate VASCAMEN in die daaglikse aktiwiteite van 'n pasiënt kan inmeng nie. Pasiënte moet seker maak dat hulle nie aan die bogenoemde aktiwiteite deelneem nie, totdat hulle bewus is van die mate waarop VASCAMEN hulle beïnvloed.

VASCAMEN bevat suiker in die vorm van laktose en fruktose.

3. Hoe om VASCAMEN te gebruik

Moet nie medisyne wat vir jou voorgeskryf is, met enige ander persoon deel nie. Gebruik VASCAMEN altyd presies soos beskryf in hierdie voubiljet, of soos deur jou dokter of apteker voorgesê is. Raadpleeg jou dokter of apteker indien jy nie seker is nie. Neem twee tablette in die oggend en een tablet in die aand na etes. Hierdie produk is bedoel vir voortdurende gebruik om lewensgehalte van mans te handhaaf.

As jy meer VASCAMEN neem as wat jy behoort:

In die geval van 'n oordosis, raadpleeg jou dokter of apteker. As nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

As jy vergeet om VASCAMEN te gebruik:

Neem jou gemiste dosis sodra jy dit onthou, binne 'n paar uur nadat jy 'n dosis gemis het. As jy slegs die volgende dag van die gemiste dosis onthou, moet nie 'n dubbele dosis neem om die vergete dosis aan te vul nie. In hierdie geval moet jy net voortgaan met die gebruik van twee tablette in die oggend en een tablet in die aand na etes.

As jy ophou om VASCAMEN te gebruik:

As jy om een of ander rede opgehou het om VASCAMEN te gebruik, veral omdat jy dink dat jy nuwe-effekte ervaar of weens ander siektes, is dit belangrik dat jy jou dokter kontak voordat jy dit weer begin gebruik.

4. Moontlike nuwe-effekte

VASCAMEN kan nuwe-effekte hê.

Nie alle nuwe-effekte wat vir VASCAMEN aangemeld is, word in die voubiljet genoem nie. Raadpleeg jou gesondheidsorgverskaffer vir advies indien jou algemene gesondheid versleg of as jy enige ander nuwe-effekte ervaar met die gebruik van VASCAMEN.

VASCAMEN kan die volgende nuwe-effekte veroorsaak:

Geringe nuwe-effekte soos maagongesteldheid, hoofpyn, duiseligheid, hardlywigheid, sterk hartklop, allergiese velreaksies, naarheid, moegheid, soet, hartkloppings, neusbloeding, slapeloosheid, roering en droë mond.

Ginkgo en haagdoring kan 'n bloedverduunnings-effek hê wat kan lei tot maklike kneusplekke en 'n groter risiko vir bloeding.

Indien jy enige nuwe-effekte opmerk wat nie in die voubiljet genoem word nie, stel jou dokter of apteker in kennis daarvan.

Rapportering van nuwe-effekte

Praat met jou dokter of apteker indien jy enige nuwe-effekte ervaar. Jy kan ook nuwe-effekte by SAHPRA aanmeld via die "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind kan word onder SAHPRA se publiskies: <http://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte te rapporteer, kan jy help om meer inligting oor die veiligheid van VASCAMEN te gee.

5. Hoe om VASCAMEN te berg:

- Berg teen of onder 25 °C
- Beskerm teen direkte sonlig en vog
- **BERG ALLE MEDISYNE BUIITE BEREIK VAN KINDERS**
- Moet nie gebruik na die vervaldatum wat op die buitenste verpakking aangedui is nie
- Vat alle ongebruikte of vervalde medisyne na jou apteker toe
- Moet nie ongebruikte of vervalde medisyne in dreine of rioelstelsels (bv. toilette) weggooi nie

6. Inhoud van die verpakking en ander inligting

Wat VASCAMEN bevat

Die aktiewe bestanddele is *Ginkgo biloba*, *Epimedium brevicornum*, *Crataegi fructus*, *Serenoa repens*, *Tribulus terrestris*, sink, likopeen 10% en selenium. Die ander bestanddele is mikrokristallynesellulose, mieliestysel, povidoon, natriumstysel en magnesiumstearaat.

Bevat suiker as laktose en fruktose.

Hoe VASCAMEN lyk en die inhoud van die verpakking

VASCAMEN is medium, rond, bruin, gespikkelde tablette. Beschikbaar in sekuriteitshouers wat 90 tablette bevat.

Registrasienuommer:

Word deur die Raad toegeken by registrasie.

Houer van registrasiesertifikaat

Vervaardig deur Hersol Manufacturing Laboratories (Edms) Bpk namens Look Pharmaceuticals (Edms) Bpk.



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Aanvullende Medisyne: Gesondheidsaanvulling. Kategorie D.

Hierdie ongeregisteerde medisyne is nie deur die SAHPRA geëvalueer vir die kwaliteit, veiligheid of beoogde gebruik daarvan nie.

Hierdie voubiljet is laas hersien op 10 Desember 2019