

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

SCD

VASCAMEN

tablets

Contains sugar: Each tablet contains 244 mg lactose and 8 mg fructose.

COMPLEMENTARY MEDICINE

COMBINATION PRODUCT: WESTERN HERBAL MEDICINE / HEALTH SUPPLEMENT

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.

VASCAMEN is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to take 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 healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

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

1. What VASCAMEN is and what it is used for

VASCAMEN is a complementary medicine intended to improve the general quality of life in men by improving blood circulation in the body.

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 (see section 6).
- If you are taking blood thinning medicines or herbal supplements (see section 4.5).
- If you are allergic to poison ivy, poison oak, poison sumac, mango rind and/or cashew shell oil, due to a cross-sensitivity with ginkgo.
- If you have low blood pressure or a liver disease.

Warnings and precautions

Take special care with VASCAMEN:

- If you have a bleeding disorder, VASCAMEN should be discontinued at least 2 weeks before surgical procedures.
- If you have heart problems.
- If you have diabetes (high blood sugar) and you are taking medicines to control your blood sugar levels.
- If you have epilepsy (seizure disorder).
- If you have low blood pressure.
- If you have been diagnosed or are suspected to suffer from prostate cancer.
- If you want to take VASCAMEN for longer than 8 months.

Other medicines and VASCAMEN

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

Tell your doctor or pharmacist if you are currently using:

- Anticoagulant/antiplatelet medicines (used to thin your blood), or herbal supplements with blood thinning effects.
- Antihypertensive medicines (used for high blood pressure), or herbal supplements with blood pressure lowering effects.
- A heart medicine known as digoxin.
- Antidiabetic medicines (used to treat high blood sugar levels), or herbal supplements which can influence blood sugar levels.
- Anticonvulsant medicines (used to treat epilepsy and/or fits).
- Antidepressant medicines (used to treat depression) or lithium (used to stabilise the mood).

Pregnancy and breastfeeding

VASCAMEN is intended for use by men. However, if you are a woman and are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking VASCAMEN.

Do not take VASCAMEN while pregnant or breastfeeding, as the safety has not yet been established.

Driving and using machines

VASCAMEN may cause side effects, such as dizziness and tiredness and can affect your ability to drive a vehicle and use machines (see section 4). Do not drive or operate machinery until you know how VASCAMEN affects you.

VASCAMEN contains sugar

VASCAMEN contains 244 mg lactose and 8 mg fructose per tablet.

If your doctor has told you that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you take VASCAMEN.

3. How to take VASCAMEN

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.

Adults:

Take two tablets in the morning and one at night after meals.

If you take more VASCAMEN than you should

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

Take this leaflet and the rest of the VASCAMEN with you so the doctor will know what you have taken.

If you forget to take VASCAMEN

Take your next dose at the usual time.

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

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 you experience any untoward effects while taking VASCAMEN please consult your healthcare provider for advice.

If any of the following happens, stop taking VASCAMEN and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to VASCAMEN. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequency unknown:

- Changes in the way your heart beats, for example, if you notice it beating faster than normal.
- Difficulty breathing or shortness of breath.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequency unknown:

- Bleeding, nose bleeds.
- Dizziness, headache, irritation.
- Stomach pain, nausea, vomiting, diarrhoea, gassiness, constipation.
- Increased sweating.

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 **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 VASCAMEN.

5. How to store VASCAMEN

- Store at or below 25 °C in a dry place.
- Protect from direct sunlight and moisture.
- Keep the container tightly closed.
- 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 VASCAMEN contains

Each tablet contains:

<i>Crataegus pinnatifida</i> Bunge (Hawthorn) [fruit, as 10 mg of a 10:1 extract]	100 mg
<i>Epimedium brevicornum</i> Maxim (Horny goat weed) [stem & leaf, as 3,75 mg of a 20:1 extract]	75 mg
<i>Ginkgo biloba</i> L. (Maidenhair Tree) [leaf, as 10 mg of a 5:1 extract]	50 mg
<i>Tribulus terrestris</i> L. (Devil's thorn) [fruit, as 0,7 mg of a 50:1 extract]	35 mg
<i>Serenoa repens</i> (W.Bartram) Small (Saw palmetto) [fruit, as 3,125 mg of an 8:1 extract]	25 mg
Zinc sulphate providing zinc (elemental)	22 mg 5 mg
Selenium amino acid chelate (ACC) 2 % providing selenium	1 mg 20 µg
Lycopene 10 %	1 mg

The other ingredients are fructose, greyish brown colour (V8 PBL32454), lactose, magnesium stearate (E572), maize starch (E1400), microcrystalline cellulose (E460), povidone K25, silicone dioxide (E551) and sodium starch glycolate A.

What VASCAMEN looks like and contents of the pack

Round, brown, speckled, uncoated tablets.

90 tablets are packed in a blue securitainer with a blue screw-on cap. Each securitainer contains a silica gel sachet and sponge.

Holder of certificate of registration



LOOCK PHARMACEUTICALS

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011 480 4916

This leaflet was last revised in

June 2021.

Registration number

Will be allocated by SAHPRA upon registration.

PASIËNTINLIGTINGSBLAD

SKEDULERINGSSTATUS

S0

VASCAMEN

tablette

Bevat suiker: Elke tablet bevat 244 mg laktose en 8 mg fruktose.

KOMPLEMENTÊRE MEDISYNE

KOMBINASIEPRODUK: WESTERSE KRUIEMEDISYNE / GESONDHEIDSAANVULLING

Hierdie ongeregistreerde medisyne is nie vir gehalte, veiligheid of beoogde gebruik deur SAHPRA geëvalueer nie.

Lees hierdie hele inligtingsblad aandagtig deur want dit bevat inligting wat belangrik is vir jou.

VASCAMEN is beskikbaar sonder 'n dokter se voorskrif, sodat jy jou gesondheid in stand kan hou. Jy moet VASCAMEN nogtans met sorg neem om die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit mag nodig wees dat jy dit weer lees.
- Moenie VASCAMEN met enigiemand anders deel nie.
- Vra gerus jou apteker indien jy verdere inligting of advies nodig het.

Wat is in hierdie inligtingsblad

1. Wat is VASCAMEN en waarvoor word dit gebruik.
2. Wat jy moet weet voordat jy VASCAMEN neem.
3. Hoe om VASCAMEN te neem.
4. Moontlike nuwe-effekte.
5. Hoe om VASCAMEN te bêre.
6. Inhoud van die pak en ander inligting.

1. Wat is VASCAMEN en waarvoor word dit gebruik

VASCAMEN is 'n komplementêre medisyne aangedui om die algemene lewensgehalte van mans te verbeter deur die bloedsirkulasie in die liggaam te verbeter.

2. Wat jy moet weet voordat jy VASCAMEN neem

Moenie VASCAMEN neem nie

- Indien jy hipersensitief (allergies) is vir enige van die bestanddele van VASCAMEN (gelys by afdeling 6).
- Indien jy medisyne of kruië-aanvullings neem om die bloed te verdun (sien afdeling 4.5).
- Indien jy allergies is vir gif-klimpop, gif-eikehout, gifsoom, mango-skil en / of kasjo-olie, as gevolg van 'n kruis sensitiviteit met ginkgo.
- Indien jy lae bloeddruk of 'n lewersiekte het.

Waarskuwings en voorsorgmaatreëls

Wees veral versigtig met VASCAMEN:

- Indien jy 'n bloedversteuring het en vir 'n operasie moet gaan. Hou twee weke voor enige chirurgiese prosedure (operasie) op om VASCAMEN te neem.
- Indien jy hartprobleme het.
- Indien jy diabetes (hoë bloedsuiker) het en jy medisyne gebruik om jou bloedsuikervlakke te beheer.
- Indien jy ly aan epilepsie (valsiekte).
- Indien jy lae bloeddruk het.
- Indien jy gediagnoseer is of vermoed dat jy prostaatanker het.
- Indien jy VASCAMEN vir langer as 8 maande wil gebruik.

Ander medisyne en VASCAMEN

Sê altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)

Sê vir jou dokter of apteker indien jy tans die volgende gebruik:

- Antikoagulantmedisyne (word gebruik om jou bloed dun te hou) of kruië-aanvullings met bloedverdunnende effekte.
- Antihypertensiewe medisyne (word gebruik om hoë bloeddruk te behandel), of kruië-aanvullings met bloeddruk verlagende effekte.
- 'n Hartmedisyne genaamd digoksien.
- Antidiabetiese medisyne (gebruik om hoë bloedsuikervlakke te behandel) of kruië-aanvullings met bloedsuiker verlagende effekte.

- Antikonvulsante (gebruik vir die behandeling van epilepsie en/of aanvalle).
- Antidepressante (gebruik om depressie te behandel) of litium (gebruik om die gemoed te stabiliseer).

Swangerskap en borsvoeding

VASCAMEN is aangedui vir mans. As jy egter 'n vrou is en swanger is of jou baba borsvoed, dink dat jy swanger mag wees of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer voordat jy VASCAMEN neem.

Moenie VASCAMEN neem indien jy swanger is of jou baba borsvoed nie, aangesien die veiligheid nog nie vasgestel is nie.

Bestuur en die gebruik van masjiene

VASCAMEN kan nuwe-effekte soos duiseligheid en moegheid veroorsaak wat jou vermoë om 'n voertuig te bestuur en masjiene te gebruik kan belemmer (sien afdeling 4). Moenie 'n voertuig bestuur of masjinerie hanteer totdat jy weet hoe VASCAMEN jou affekteer nie.

VASCAMEN bevat suiker

VASCAMEN bevat 244 mg laktose en 8 mg fruktose per tablet.

Indien jou dokter jou ingelig het dat jy vir sommige suikers onverdraagsaam is of dat jy gediagnoseer is met oorerflike fruktose-intoleransie (HFI), 'n seldsame genetiese afwyking waarin iemand nie fruktose kan afbreek nie, moet jy met jou dokter praat voordat jy VASCAMEN neem.

3. Hoe om VASCAMEN te neem

Gebruik VASCAMEN altyd presies soos wat in hierdie inligtingsblad aangedui word, of soos wat jou dokter of apteker vir jou gesê het. Vra gerus jou dokter of apteker indien jy onseker is.

Volwassenes:

Neem twee tablette soggens en een tablet saans na etes.

Wat om te doen indien jy meer VASCAMEN geneem het as wat jy moet

In geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Neem hierdie pamflet en die res van die VASCAMEN saam sodat die dokter weet wat jy geneem het.

Indien jy vergeet om VASCAMEN te neem

Neem jou volgende dosis op die gewone tyd.

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

4. Moontlike nuwe-effekte

VASCAMEN kan nuwe-effekte hê.

Nie alle nuwe-effekte wat vir VASCAMEN gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak of jy enige ongunstige effekte ondervind terwyl VASCAMEN geneem word, raadpleeg asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, hou op om VASCAMEN te neem en sê dadelik vir jou dokter, of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- Swelling van jou hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak met sluk en asemhaling.
- Uitslag of gejeuk.
- Floute.

Hierdie is baie ernstige nuwe-effekte. Indien jy enige daarvan ondervind, mag jy 'n ernstige allergie sereaksie op VASCAMEN gehad het. Jy mag dringende mediese bystand of hospitalisasie benodig.

Sê dadelik vir jou dokter of gaan na die ongevalle-afdeling van die naaste hospitaal indien jy die volgende opmerk:

Onbekende frekwensie:

- 'n Verandering in die manier waarop jou hart klop, bv. as jy agterkom dit klop vinniger as normaal.
- Moeilike asemhaling of kortasem.
- Hierdie is ernstige nuwe-effekte. Jy mag dringende mediese bystand benodig.

Sê vir jou dokter indien jy enige van die volgende opmerk:

Onbekende frekwensie:

- Bloeding, neusbloeding.
- Slaaploosheid, moegheid.

- Duiseligheid, hoofpyn, irritasie.
- Maagpyn, naarheid, braking, diarree, winderigheid, hardlywigheid.
- Toename in sweet.

Indien jy enige nuwe-effekte opmerk wat nie in hierdie inligtingsblad genoem word nie, sê asseblief vir jou dokter of apteker daarvan.

Aanmelding van nuwe-effekte

Indien enige nuwe-effekte ondervind word, bespreek dit met jou dokter of apteker. Jy kan ook nuwe-effekte aan SAHPRA rapporteer via die vorm om ongunstige geneesmiddelreaksies te rapporteer, wat aanlyn by SAHPRA se publikasies beskikbaar is: <http://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte te rapporteer kan jy help om meer inligting rakende die veiligheid van VASCAMEN te verskaf.

5. Hoe om VASCAMEN te bêre

- Bêre by of onder 25 °C op 'n droë plek.
- Beskerm van direkte sonlig en vog.
- Hou die houër dig toe.
- Bêre alle medisyne buite bereik van kinders.
- Moenie gebruik na die vervaldatum wat op die houër gedruk is nie.
- Neem alle ongebruikte medisyne terug na jou apteker.
- Moenie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting

Wat VASCAMEN bevat

Elke tablet bevat:

<i>Crataegus pinnatifida</i> Bunge (Haagdoorn) [vrug, as 10 mg van 'n 10:1 ekstrak]	100 mg
<i>Epimedium brevicornum</i> Maxim (Geile bokkruid) [stam & blaar; as 3,75 mg van 'n 20:1 ekstrak]	75 mg
<i>Ginkgo biloba</i> L. (Vrekkboom) [blaar; as 10 mg van 'n 5:1 ekstrak]	50 mg
<i>Tribulus terrestris</i> L. (Duiwelsdoring) [vrug; as 0,7 mg van 'n 50:1 ekstrak]	35 mg
<i>Serenoa repens</i> (W.Bartram) Small (Saagpalm) [vrug; as 3,125 mg van 'n 8:1 ekstrak]	25 mg
Sinksulfaat verskaf sink (elementêr)	22 mg 5 mg
Selenium aminosuurchelaat (ACC) 2 % verskaf selenium	1 mg 20 µg
Likopeen 10 %	1 mg

Die ander bestanddele is fruktose, grysbruin kleur (V8 PBL32454), laktose, magnesiumstearaat (E572), meliestysel (E1400), mikrokristallyne sellulose (E460), povidoon K25, silikondioksied (E551) en natriumstyselglikolaat A.

Hoe VASCAMEN lyk en inhoud van die verpakking

Ronde, bruin, gespikkelde, onbedekte tablette.

90 tablette is verpak in 'n blou sekuriteitshouer met 'n blou skroefop. Elke sekuriteitshouer bevat 'n silikagelsakkie en spons.

Houer van die Registrasiesertifikaat



LOCK PHARMACEUTICALS

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011 480 4916

Hierdie inligtingsblad is laas hersien in

Junie 2021.

Registrasienommer

Moet toegeken word deur SAHPRA tydens registrasie.