Professional information for VASCAMEN TABLETS

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.

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

VASCAMEN tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

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

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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.

Round, brown, speckled, uncoated tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Adults:

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

Children:

Not intended for children younger than 18 years.

4.3 Contraindications

- If you are hypersensitive (allergic) to any of the active or inactive ingredients listed in sections 2 and 6.1.
- If you are taking anticoagulant medicines or herbal supplements with blood thinning effects (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 hypotension or liver deficiency (see section 4.4).

4.4 Special warnings and precautions for use

Bleeding disorders:

VASCAMEN TABLETS may have antiplatelet effects and may increase the risk of bruising and bleeding when used in patients with bleeding disorders. Patients should be advised to discontinue VASCAMEN TABLETS at least 2 weeks prior to surgical procedures (see section 4.5).

Heart conditions:

VASCAMEN may increase the risk of heart failure. Caution is advised.

Diabetes:

VASCAMEN may alter insulin secretion and increase blood glucose levels. Diabetics should use VASCAMEN with caution, and blood glucose levels should be monitored closely.

Epilepsy:

VASCAMEN may increase the risk of seizures. Caution is advised with epileptics or those prone to seizures.

Hypotension:

VASCAMEN may have hypotensive effects, and my exacerbate hypotension in people with existing low blood pressure. Caution is advised (see section 4.3).

Prostate cancer:

Consult a healthcare provider prior to use of VASCAFEM if diagnosed or suspected to suffer from prostate cancer.

Sugar intolerance:

Patients with hereditary fructose intolerance (HFI) or rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take VASCAMEN.

Long-term use:

Consult a healthcare provider for use of VASCAMEN beyond 8 months.

4.5 Interaction with other medicines and other forms of interaction

Anticoagulant/antiplatelet medicines:

VASCAMEN may enhance the effects of anticoagulant/antiplatelet medicines or herbal supplements. Concomitant use may increase the risk of bruising and bleeding (see section 4.4).

Antihypertensive medicines:

VASCAMEN may lower blood pressure and heartrate due to vasodilatory effects. Caution is advised with concomitant use of VASCAMEN with antihypertensive medicines (including beta-blockers, calcium channel blockers and nitrates) and herbal supplements with hypotensive effects.

Heart medicines:

VASCAMEN may potentiate the effects of digoxin requiring digoxin dose reduction. Caution is advised.

Antidiabetic medicines:

VASCAMEN may affect blood glucose levels and adjustment of antidiabetic medicine or hypoglycaemic herbal supplements might be necessary (see section 4.4).

Anticonvulsant medicines:

VASCAMEN may reduce the effectiveness of anticonvulsants increasing the risk for convulsions. Caution is advised.

Antidepressant and mood stabilising medicines:

VASCAMEN may reduce the clinical effects of serotonergic antidepressants. VASCAMEN may also reduce the excretion of lithium thereby increasing levels of lithium. Caution is advised.

4.6 Fertility, pregnancy and lactation

VASCAMEN is intended for use by men. However, women should not take VASCAMEN while pregnant or breastfeeding, as the safety has not yet been established.

4.7 Effects on ability to drive and use machines

VASCAMEN may cause side effects such as dizziness and fatigue which can affect the ability to drive a vehicle and use machines (see section 4.8).

Caution is advised before driving a vehicle or operating machinery until the effects of VASCAMEN are known.

4.8 Undesirable effects

Blood and lymphatic system disorders:

Frequency unknown: bleeding, epistaxis.

Immune system disorders:

Frequency unknown: hypersensitivity, Stevens-Johnson syndrome.

Psychiatric disorders:

Frequency unknown: insomnia.

Nervous system disorders:

Frequency unknown: dizziness, headache, agitation, fatigue.

Cardiac disorders:

Frequency unknown: dysrhythmia, tachycardia, palpitations.

Respiratory, thoracic and mediastinal disorders:

Frequency unknown: dyspnoea.

Gastrointestinal disorders:

Frequency unknown: abdominal discomfort/pain, nausea, vomiting, constipation, diarrhoea, flatulence.

Skin and subcutaneous tissue disorders:

Frequency unknown: skin rash, diaphoresis.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of VASCAMEN is important. It allows continued monitoring of the benefit/risk balance of VASCAMEN. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the **Adverse Drug Reactions Reporting Form**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8). No known symptoms of overdosage have been recorded. Treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: D 33.7 Combination product.

Pharmacotherapeutic group: Multivitamins, other combinations.

ATC code: A11AB.

VASCAMEN contains herbal extracts, minerals and lycopene which is intended to improve the general quality of life in men by improving blood circulation in the body.

5.2 Pharmacokinetic properties

Overall, sufficient available data on the pharmacokinetic and pharmacodynamic properties of hawthorn is limited. The pharmacokinetics of another botanical (the common grape), whose constituents, like hawthorn, include procyanidins, have been reviewed elsewhere. In the common

grape, large quantities of procyanidins have been found unmetabolised in renal and intestinal elimination pathways, suggesting limited metabolic degradation. The procyanidins of the hawthorn berry are reported to have a higher degree of polymerisation, yet a lower concentration of flavonoids and procyanidins.

Ginkgolide A, ginkgolide B and bilobalide concentrations are found in the body after administration of ginkgo extracts with half-lives of 4, 6 and 3 hours, respectively. The amounts of each excreted unchanged in the urine were approximately 70 %, 50 % and 30 %, respectively.

Horny goat weed constituents are absorbed in the intestinal tract.

Peak plasma levels of the metabolite, icariside II, occurred at 4,1 – 4,3 hours after intake. The accumulation of the metabolite, desmethylicaritin, was biphasic with small and large peaks, respectively, after 5 and 24 hours. Peak levels lasted for up to 48 hours. The half-life of the icariin metabolite icariside II after oral intake of horny goat weed was 12 – 15 hours.

Saw palmetto has antiandrogenic, antiproliferative and anti-inflammatory properties and displays antiestrogenic activity in prostatic tissue of men with benign prostatic hypertrophy (BPH). After intake, saw palmetto reaches peak plasma levels at about 1,5 hours, and has a half-life of about 19 hours.

The protodioscin constituent of Tribulus increases levels of testosterone, luteinizing hormone (LH), dehydroepiandrosterone (DHEA) and dihydrotestosterone.

Zinc is a biologically essential trace element that is absorbed in the small intestines and is distributed in the body in skeletal muscle and bone. It is mainly excreted through the faeces.

After absorption from the gastrointestinal tract, selenium is incorporated into the enzyme glutathione peroxidase. It is excreted mainly in the urine.

Lycopene is a fat-soluble carotenoid and is incorporated into micelles containing bile salts, cholesterol and fatty acids in the intestine. Lycopene is absorbed into the enterocytes by passive diffusion or with the aid of a cholesterol membrane transporter into the lymphatic system before release into the blood. Lycopene is transported primarily by low-density lipoproteins (LDL) in the blood and is thought to undergo oxidation and enzymatic cleavage.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Fructose

Greyish brown colour (V8 PBL32454)

Lactose

Magnesium stearate (E572)

Maize starch (E1400)

Microcrystalline cellulose (E460)

Povidone K25

Silicon Dioxide (E551)

Sodium starch glycollate A.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

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

6.4 Special precautions for storage

Protect from direct sunlight and moisture.

6.5 Nature and contents of container

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

6.6 Special precautions for disposal and other handling

None.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Loock Pharmaceuticals

P.O Box 902

Waterfall Mall

Rustenburg 0323

South Africa

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF THE TEXT

June 2021.