Professional Information for VASCAMEN ULTRA 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 ULTRA tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Crataegus pinnatifida Bunge (Hawthorn)	300 mg
[fruit; as 30 mg of a 10:1 extract]	
Camellia sinensis L. (Kuntze) (Green tea)	250 mg
[leaf; as 25 mg of an extract standardised to 45 % EGCG, 75 % catechins and 95 % polyphenol]	
Epimedium brevicornu Maxim. (Horny goat weed)	225 mg
[stem & leaf; as 11.25 mg of a 20:1 extract]	
Panax ginseng C.A. Mey (Panax ginseng)	200 mg
[root; as 13,33 mg of a 15:1 extract]	
Tribulus terrestris L. (Devil's thorn)	105 mg
[fruit; as 2,1 mg of a 50:1 extract]	
Zinc sulphate heptahydrate	66 mg

	providing zinc elemental	15 mg
Lycopene	10 %	6.5 mg
Selenium amino acid chelate 2 %		3 mg
	providing elemental selenium	60 µg
	and amino acids (32,7 µg glutamic acid, 15,6 µg leucine, 15,0 µg arginine, 14.4 µg aspartic acid, 12,3 µg valine, 10,2 µg alanine, 9,3 µg phenylalanine, 9,0 µg cystine, 8,4 µg glycine, 7,5 µg proline, 6,9 µg isoleucine, 6,9 µg lysine, 6,6 µg serine, 6,3 µg tyrosine, 6,0 µg methionine, 4,2 µg threonine, 3,9 µg histidine, 3,3 tryptophan).	

Excipients with known effect:

Contains sugar: Each tablet contains 110 mg lactose monohydrate and 8 mg fructose.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.

Round, brown speckled tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

VASCAMEN ULTRA is a complementary medicine intended to maintain and improve the general quality of life in men by providing cardiovascular protection, improving sexual health and energy levels, and maintaining immune function.

4.2 Posology and method of administration

Posology:

Adults:

Take one tablet in the morning after a meal. The absorption of VASCAMEN ULTRA may be improved when taken with fatty food or milk.

Children:

Not intended for children younger than 18 years.

Method of administration:

The tablet should be taken orally, with or directly after fatty food or milk.

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).
- Liver deficiency (see section 4.4).

4.4 Special warnings and precautions for use

Bleeding disorders:

VASCAMEN ULTRA tablets may have antiplatelet effects and may increase the risk of bruising and bleeding when used in patients with bleeding disorders. (see section 4.5)

Surgery:

VASCAMEN ULTRA may inhibit platelet aggregation and increase the risk of postoperative bleeding. Patients should be advised to discontinue VASCAMEN ULTRA tablets at least 2 weeks prior to surgical procedures (see section 4.5).

Diabetes:

VASCAMEN ULTRA may reduce blood glucose levels. VASCAMEN ULTRA may increase the risk for hypoglycaemia, especially in patients on insulin or oral hypoglycaemic medication. Diabetes should use VASCAMEN ULTRA with caution, and blood glucose levels should be monitored closely (see section 4.5).

Hypotension:

VASCAMEN ULTRA may have hypotensive effects and may exacerbate hypotension in people with existing low blood pressure. Caution is advised (see section 4.5).

Liver disease

Patients with liver disease should consult with their healthcare provider before taking VASCAMEN ULTRA (see section 4.3).

Contains caffeine.

VASCAMEN ULTRA contains caffeine because of the green tea extract. Rare, unpredictable cases of liver injury associated with green tea extract-containing products have been reported. Patients should stop use and consult a relevant healthcare provider if they develop symptoms of liver trouble such as yellowing of the skin/eyes (jaundice), stomach pain, dark urine, sweating, nausea, unusual tiredness and/or loss of appetite.

Patients should consult a relevant healthcare provider:

• for use beyond 12 weeks.

• prior to use if they are pregnant or breastfeeding; or

• if they have a liver disorder or an iron deficiency.

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 ULTRA.

Patients should consult a healthcare provider for use of VASCAMEN ULTRA beyond 6 months.

4.5 Interaction with other medicines and other forms of interaction

Anticoagulant/antiplatelet medicines:

VASCAMEN ULTRA may enhance the effects of anticoagulant/antiplatelet medicines or herbal supplements. Concomitant use may increase the risk of bruising and bleeding (see section 4.3 and 4.4).

Antihypertensive medicines:

VASCAMEN ULTRA may lower blood pressure due to vasodilatory effects. Concomitant use of VASCAMEN ULTRA with antihypertensive medicines (including beta-blockers, calcium channel blockers, ACE-inhibitors, diuretics and nitrates) and herbal supplements with hypotensive effects, may increase the risk of hypotension. Caution is advised (see section 4.4).

Heart medicines:

VASCAMEN ULTRA may potentiate the effects of digoxin and may require digoxin dose reduction. Concomitant use of VASCAMEN ULTRA with betablockers, calcium channel blockers and digoxin may cause additive effects on lowering heart rate. Caution is advised.

Antidiabetic medicines:

VASCAMEN ULTRA may enhance the blood glucose-lowering effects of hypoglycaemic medicines and herbs and supplements with hypoglycaemic potential. Monitor blood glucose levels closely.

Antibiotics:

VASCAMEN ULTRA may of decrease the absorption of certain antibiotics, including quinolones, tetracyclines, cephalexin and penicillamine. Doses should be separated by at least 2 hours prior to, or 4 to 6 hours after taking VASCAMEN ULTRA.

Antiretroviral medicines:

VASCAMEN ULTRA may reduce levels of antiretroviral medicines. Antiretrovirals should be taken at least 2 hours before, or 4 to 6 hours after taking VASCAMEN ULTRA.

Antidepressant and mood stabilising medicines:

VASCAMEN ULTRA may reduce excretion and thereby increase levels of lithium. Caution is advised. Dose adjustment may be required.

Phosphodiesterase-5 inhibitors:

VASCAMEN ULTRA may potentiate the vasodilative and hypotensive effects of phosphodiesterase-5 inhibitors. PDE-5 inhibitors include sildenafil, tadalafil and vardenafil. Concurrent use is not recommended.

Cytochrome P450 substrates:

VASCAMEN ULTRA may inhibit cytochrome P450 1A2 (CYP1A2) and 2B6 (CYP2B6) and therefor increase the effects and side-effects of CYP1A2 and CYP2B6 substrates.

QT Interval-prolonging medicines:

VASCAMEN ULTRA could have an additive effect when combined with medicines that prolong the QT interval and potentially increase the risk of ventricular arrhythmias.

4.6 Fertility, pregnancy, and lactation

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

4.7 Effects on ability to drive and use machines

VASCAMEN ULTRA may cause side effects such as dizziness and 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 ULTRA are known.

4.8 Undesirable effects

Blood and lymphatic system disorders:

Frequency unknown: bleeding, epistaxis.

Immune system disorders:

Frequency unknown: hypersensitivity.

Less frequent: Stevens-Johnson syndrome, anaphylaxis.

Psychiatric disorders:

Frequency unknown: insomnia, agitation.

Nervous system disorders:

Frequency unknown: dizziness, headache.

Cardiac disorders:

Frequency unknown: arrhythmia, tachycardia, palpitations.

Respiratory, thoracic and mediastinal disorders:

Frequency unknown: bronchitis, respiratory arrest.

Gastrointestinal disorders:

Frequency unknown: abdominal discomfort/pain, nausea, vomiting, constipation, diarrhoea, flatulence, thirst, dry mouth, metallic taste.

Less frequent: hepatotoxicity, nephrotoxicity.

Skin and subcutaneous tissue disorders:

Frequency unknown: skin rash, diaphoresis.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of VASCAMEN ULTRA is important. It allows continued monitoring of the benefit/risk balance of VASCAMEN ULTRA. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

4.9 Overdose

In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8). Large doses may cause hepato- and nephrotoxicity, respiratory arrest, and exaggeration of tendon reflexes to the point of spasm. Treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: D 33.7 Combination product.

VASCAMEN ULTRA contains a combination of carefully selected herbal extracts, minerals and lycopene which is intended to improve the general quality of life in men. It focuses on the prevention of cardiovascular disease, improving sexual health and energy levels, and maintaining immune function.

5.2 Pharmacokinetic properties

Green tea increases levels of plasma polyphenols, epigallocatechin gallate (EGCG) and other catechins. Systemic availability is increased when consumed together with a meal and nutrients such as ascorbic acid, selenium and N-acetylcysteine. Catechins accumulate in the protein-rich fraction of plasma, in low-density lipoproteins (LDL) and high-density lipoproteins (HDL). Metabolites of green tea are excreted in urine.

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.

Ginsenosides seem to have a low oral bioavailability. Intestinal microflora transforms ginsenosides by deglycosylation, which seems to improve absorption. Ginsenosides are mainly eliminated by first-pass biliary excretion.

Reliable information about the pharmacodynamics of Tribulus is limited. The protodioscin constituent of Tribulus increases levels of testosterone, luteinizing hormone (LH), dehydroepiandrosterone (DHEA) and dihydrotestosterone.

Zinc is mostly absorbed in the small intestines, distributed in the body in skeletal muscle and

bone, and mainly excreted through the faeces.

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.

Approximately 80 % of dietary selenium is absorbed. Selenium must travel via the gastrointestinal tract, cross the intestinal barrier, reach the blood circulation, and then be distributed to the different tissues of the body. It is excreted mainly in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose (PH 102)

Maize starch (E1400)

Lactose monohydrate

Fructose

Povidone K25

Ethanol 98%

Sodium starch glycollate

Magnesium stearate (E572)

Shellac blond

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

30 tablets are packed in a blue vitamin jar with a blue screw-on cap. Each vitamin jar 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

Postnet suite 223

Private bag X82245

Waterfall Mall

Rustenburg 0300

South Africa

Tel 066 302 8972

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 2024