Professional Information for VASCAFEM 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

VASCAFEM tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Crataegus pinnatifida Bunge (Hawthorn)	600 mg
[fruit; as 60 mg of a 10:1 extract]	
Calcium carbonate	1258 mg
providing calcium (elemental)	504 mg
Pyridoxine hydrochloride	67,1 mg
providing pyridoxine (vitamin B_6)	50 mg
Calcium lactate gluconate	193 mg
providing calcium (elemental)	24,72 mg
Zinc sulphate heptahydrate	60 mg
providing zinc (elemental)	13,63 mg
Folic acid	500 µg
Vitamin K_2	40 µg
Colecalciferol (Vitamin D_3)	1 000 IU

	(25 µg)
Selenium amino acid chelate 2 %	175 µg
providing selenium (elemental)	3,5 µg
and amino acids (1,908 µg glutamic acid, 0,910 µg leucine, 0,875 µg arginine, 0,840 µg aspartic acid, 0,718 µg valine, 0,595 µg alanine, 0,543 µg phenylalanine, 0,525 µg cystine, 0,490 µg glycine, 0,438 µg proline, 0,403 µg isoleucine, 0,403 µg lysine, 0,385 µg serine, 0,368 µg tyrosine, 0,350 µg methionine, 0,245 µg threonine, 0,228 µg histidine, 0,193 µg tryptophan)	

Contains sugar: Each tablet contains 24 mg fructose and 10 mg sucrose.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets.

Mild brown caplet shaped tablet with a break-line.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

VASCAFEM is classified as a complementary medicine, formulated for women to add to their general health. VASCAFEM provides a carefully selected combination of vitamins, minerals and plant extracts that focus on the protection of the heart, blood vessels and bones.

4.2 Posology and method of administration

Adults: Take one tablet daily. The tablet should be taken orally, with, or directly after food.

Children:

Not intended for use by 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.

4.4 Special warnings and precautions for use

Surgery:

Patients should be advised to discontinue VASCAFEM TABLETS at least 2 weeks prior to surgical procedures (see section 4.5).

Hereditary fructose intolerance (HFI):

Patients with rare hereditary fructose intolerance (HFI) should not take VASCAFEM.

4.5 Interaction with other medicines and other forms of interaction

Anticoagulant/antiplatelet medicines:

VASCAFEM 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:

VASCAFEM may lower blood pressure and heart rate due to vasodilatory effects. Caution should be taken with concomitant use of VASCAFEM with antihypertensive medicines (including beta-blockers, calcium channel blockers and nitrates) and herbal supplements with hypotensive effects.

Heart medicines:

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

Antibiotics:

VASCAFEM may decrease the absorption of antibiotics. Absorption of tetracyclines and fluoroquinolones is impaired by multivalent cations including Ca^{2+}, Zn^{2+}, Mg^{2+}, Fe^{2+}, Al^{3+}. Doses should be separated by at least 2 hours prior to, or 4 to 6 hours after taking VASCAFEM.

Antiretrovirals:

Calcium may reduce the absorption of certain antiretroviral medicine through chelation. Dolutegravir and raltegravir should be taken at least 2 hours before, or 4 to 6 hours after taking VASCAFEM.

Levotyroxine:

Calcium, as in VASCAFEM, may reduce the absorption and effectiveness of levothyroxine. Patients should take VASCAFEM and levothyroxine at least 4 hours apart.

Lithium:

Concomitant use of lithium and calcium, as in VASCAFEM, may increase the risk of hypercalcemia.

4.6 Fertility, pregnancy and lactation

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

4.7 Effects on ability to drive and use machines

VASCAFEM 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).

Be careful before driving a vehicle or operating machinery until the effects of VASCAFEM are known.

4.8 Undesirable effects

Psychiatric disorders:

Frequency unknown: insomnia, somnolence.

Nervous system disorders:

Frequency unknown: dizziness, headache, agitation, fatigue, paraesthesia.

Cardiac disorders:

Frequency unknown: tachycardia, palpitations.

Respiratory, thoracic and mediastinal disorders:

Frequency unknown: dyspnoea.

Gastrointestinal disorders:

Frequency unknown: abdominal discomfort, nausea, vomiting, abdominal pain or cramps, constipation, diarrhoea, flatulence, heartburn, loss of appetite, upset stomach, metallic taste.

Skin and subcutaneous tissue disorders:

Frequency unknown: skin rash, diaphoresis.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of VASCAFEM is important. It allows continued monitoring of the benefit/risk balance of VASCAFEM. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via **The Med Safety App,** which can be

found online on SAHPRA's website www.sahpra.org.za, or download from your mobile phone's app store.

4.9 Overdose

In the case of 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.

VASCAFEM is formulated for women to add to their general health. VASCAFEM provides a carefully selected combination of vitamins, minerals and plant extracts that focus on the protection of the heart, blood vessels and bones.

5.2 Pharmacokinetic properties

The procyanidins of the hawthorn berry have a higher degree of polymerisation, and a lower concentration of flavonoids and procyanidins.

Calcium absorption is affected by several factors including age, race, environmental and dietary conditions. Calcium is distributed in the bones and teeth and is excreted via the urine and faeces.

After folic acid is absorbed, it is reduced to tetrahydrofolate and then enters a methylation cycle, where it is further converted to L-methylfolate. Folic acid is excreted mainly in the urine.

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. The metabolism of selenium by the brain differs from other organs in that at times of deficiency, the brain retains selenium to a greater extent. Selenium is excreted in the urine.

Vitamin B_6 is passively absorbed from the upper gastrointestinal tract, converted in the liver to coenzyme pyridoxal phosphate and excreted in the urine.

Vitamin D is well absorbed and requires hydroxylation in the body to form the active metabolite, calcitriol.

Zinc is mostly absorbed in the small intestines, distributed in the body in skeletal muscle and bone, and mainly excreted through the faeces.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Fructose

Greyish brown colour (PBL32454)

Magnesium stearate (E572)

Maize starch (E1400)

Microcrystalline cellulose (E460)

Shellac blond

Sodium starch glycollate.

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 purple vitamin jar with a purple 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

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

September 2023.