

VASCAMEN ULTRA
PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S0

VASCAMEN ULTRA tablets

Multiple ingredient formulation.

Contains sugar: Each tablet contains 110 mg lactose monohydrate 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 ULTRA is available without a doctor's prescription, for you to maintain your health.

Nevertheless, you still need to take VASCAMEN ULTRA carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share VASCAMEN ULTRA 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 ULTRA is and what it is used for.
2. What you need to know before taking VASCAMEN ULTRA.
3. How to take VASCAMEN ULTRA.
4. Possible side effects.
5. How to store VASCAMEN ULTRA.
6. Contents of the pack and other information.

1. What VASCAMEN ULTRA is and what it is used for

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.

2. What you need to know before you take VASCAMEN ULTRA

Do not take VASCAMEN ULTRA

- If you are hypersensitive (allergic) to any of the ingredients of VASCAMEN ULTRA (see section 6).
- If you are taking blood thinning medicines or supplements with blood thinning effects (see Other medicines and VASCAMEN ULTRA).
- If you have liver problems (see Warnings and precautions).

Warnings and precautions

Take special care with VASCAMEN ULTRA:

- If you suffer from a bleeding disorder.
- If you are going to have an operation. VASCAMEN ULTRA should be discontinued at least 2 weeks before surgical procedures.
- If you have diabetes (high blood sugar) and use medicine or insulin to control your blood sugar levels (see Other medicines and VASCAMEN ULTRA).
- If you have low blood pressure (see Other medicines and VASCAMEN ULTRA).
- If you have liver problems (see Do not take VASCAMEN ULTRA).
- VASCAMEN ULTRA contains caffeine because it contains green tea extract. Stop use and consult a relevant healthcare provider if you develop symptoms of liver trouble (See section 4).

You should consult a healthcare provider for use beyond 6 months.

Children

VASCAMEN ULTRA is not intended for use in children younger than 18 years of age.

Other medicines and VASCAMEN ULTRA

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

Inform your doctor or pharmacist if you are currently using:

- Anticoagulant/antiplatelet medicines (used to thin your blood), or herbal supplements with blood thinning effects, because VASCAMEN ULTRA can increase the blood thinning effect.
- Antihypertensive medicines (used to treat high blood pressure), or herbal supplements with blood pressure lowering effects, because VASCAMEN ULTRA can lower your blood pressure and increase your risk for developing low blood pressure.
- Digoxin (used to treat heart failure). Your doctor might adjust your dose.
- Insulin and other medicine used to control blood sugar levels, or herbal supplements that can influence your blood sugar levels. VASCAMEN ULTRA can lower your blood sugar levels and increase the risk for blood sugar levels to drop too low (hypoglycaemia).
- Antibiotics (used to treat bacterial infections) because VASCAMEN ULTRA can decrease the absorption of certain antibiotics. Take your antibiotic medicine at least 2 hours before, or 4 to 6 hours after taking VASCAMEN ULTRA.
- Antiretroviral medicine (used to treat HIV-infection), because VASCAMEN ULTRA may decrease the absorption of certain antiretroviral medicine. Take your antiretroviral medicine at least 2 hours before, or 4 to 6 hours after VASCAMEN ULTRA.
- Lithium (used in bipolar depression), because VASCAMEN ULTRA may increase the levels of lithium. Your doctor might adjust your dose.
- Phosphodiesterase-5 inhibitors (used to treat erectile dysfunction), because VASCAMEN ULTRA may potentiate the effect of phosphodiesterase-5 inhibitors. Do not use them together.

- Medicine that is metabolised by the enzyme cytochrome P450 (CYP1A2 and CYP2B6).
VASCAMEN ULTRA may increase its effect.
- Medicine to treat irregular heartbeats because VASCAMEN ULTRA may increase your risk to develop irregular heartbeats.

Pregnancy and breastfeeding

VASCAMEN ULTRA is intended for use by men. However, if you are a woman and 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 ULTRA.

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

Driving and using machines

VASCAMEN ULTRA may cause side effects, such as dizziness 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 ULTRA affects you.

VASCAMEN ULTRA contains sugar

VASCAMEN ULTRA contains 110 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 taking VASCAMEN ULTRA.

3. How to take VASCAMEN ULTRA

Always take VASCAMEN ULTRA exactly as described in this leaflet or as instructed by your doctor or pharmacist. Check with your doctor or pharmacist if you are not sure.

Adults:

The usual dose is one tablet once daily. Take the tablet orally, with or directly after food. The absorption may be increased when taken with fatty food or milk.

If you take more VASCAMEN ULTRA than you should

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

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

If you forget to take VASCAMEN ULTRA

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 ULTRA may have side effects.

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

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

- Swelling of your hands, feet, ankles, face, lips, and 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 reaction to VASCAMEN ULTRA. 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:

- Changes in the way your heart beats, for example, if you notice it beating faster than normal.
- Difficulty breathing or shortness of breath.
- Liver trouble such as yellowing of the skin/eyes (jaundice), dark urine, sweating, unusual tiredness and/or loss of appetite.

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

Tell your doctor if you notice any of the following:

Frequency unknown:

- Difficulty sleeping (insomnia).
- Dizziness, headache.
- Feeling agitated.
- Pain, cramps or discomfort of your stomach area, nausea (feeling sick), vomiting (being sick), diarrhoea, excessive gas, constipation.
- Metallic taste in your mouth, thirst.
- Increased sweating.
- Nose bleeding.

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

Reporting of side effects

If you experience any side effects, including side-effects not mentioned in this leaflet, please inform your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of VASCAMEN ULTRA.

5. How to store VASCAMEN ULTRA

- Store at or below 25 °C in a dry place.
- Protect from direct sunlight and moisture.
- 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 for destruction.
- Do not dispose of unused medicine in drains and sewerage systems (e.g., toilets).

6. Contents of the pack and other information

Each tablet contains:

<i>Crataegus pinnatifida</i> Bunge (Hawthorn)	300 mg
[fruit; as 30 mg of a 10:1 extract]	
<i>Camellia sinensis</i> L. (Kuntze) (Green tea)	250 mg
[leaf; as 25 mg of an extract standardised to 45 % EGCG, 75 % catechins and 95 % polyphenol]	
<i>Epimedium brevicornu</i> Maxim. (Horny goat weed)	225 mg
[stem & leaf; as 11,25 mg of a 20:1 extract]	
<i>Panax ginseng</i> C.A. Mey (Panax ginseng)	200 mg
[root; as 13,33 mg of a 15:1 extract]	
<i>Tribulus terrestris</i> 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).

The other ingredients are lactose monohydrate, fructose, microcrystalline cellulose (PH 102), maize starch (E1400), povidone K25, ethanol 98%, sodium starch glycollate, magnesium stearate (E572) and shellac blond.

What VASCAMEN ULTRA looks like and contents of the pack

Round, brown speckled tablet.

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.

Holder of certificate of registration

Loock Pharmaceuticals

Postnet suite 223

Private bag X82245

Rustenburg

0300

Tel 066 302 8972

This leaflet was last revised in

June 2024.

Registration number

Will be allocated by SAHPRA upon registration.

Access to the corresponding Professional Information

For full prescribing information, refer to the Professional Information (PI) available at

www.vascamen.co.za, or contact Looock Pharmaceuticals at Tel 066 302 8972.