PATIENT INFORMATION LEAFLET
SCHEDULING STATUS
S0

VASCAFEM tablets

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

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.
VASCAFEM is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to take VASCAFEM carefully to get the best results from it.
· Keep this leaflet. You may need to read it again.
· Do not share VASCAFEM with any other person.
· Ask your healthcare provider or pharmacist if you need more information or advice.

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

1. What VASCAFEM is and what it is used for

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 your heart, blood vessels and bones.

2. What you need to know before you take VASCAFEM

Do not take VASCAFEM:
· If you are hypersensitive (allergic) to any of the ingredients of VASCAFEM (see section 6).

Warnings and precautions
Take special care with VASCAFEM:
· If you are going to have an operation. VASCAFEM should be discontinued at least 2 weeks before surgical procedures.
· If you have heart problems.

Other medicines and VASCAFEM
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.
· Antihypertensive medicines (used to treat high blood pressure), or herbal supplements with blood pressure lowering effects.
· Digoxin (used to treat heart failure).
· Lithium (used in bipolar depression).
· Antibiotics (used to treat bacterial infections). Take your antibiotic at least 2 hours before, or 4 to 6 hours after taking VASCAFEM.
· Antiretroviral medicine (used to treat HIV-infection). If you use medicine that contains dolutegravir or raltegravir, take it at least 2 hours before, or 4 to 6 hours after VASCAFEM.
· Levothyroxine (used to treat an under active thyroid). Take VASCAFEM and levothyroxine at least 4 hours apart.

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

Driving and using machines
VASCAFEM 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 VASCAFEM affects you.

VASCAFEM contains sugar
VASCAFEM contains 24 mg fructose and 10 mg sucrose 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 VASCAFEM.

3. How to take VASCAFEM

Always take VASCAFEM 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. The tablet should be taken orally, with or directly after food.

Children:
VASCAFEM is not indicated for use in children younger than 18 years of age.

If you take more VASCAFEM 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 VASCAFEM with you so that the doctor will know what you have taken.

If you forget to take VASCAFEM
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

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

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

· Swelling of your hands, feet, ankles, face, lips, mouth or throat.
· Difficulty breathing or swallowing.
· Rash or itching.
· Fainting

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to VASCAFEM. 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.
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) or drowsiness.
· Dizziness, headache.
· Feeling agitated.
· Tiredness.
· Paraesthesia (numbing sensation of your skin, "pins and needles").
· Pain, cramps or discomfort of your stomach area, nausea, vomiting, diarrhoea, excessive gas, constipation, heart burn, upset stomach.
· Loss of appetite.
· Metallic taste in your mouth.
· 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 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**, found online on SAHPRA's website, www.sahpra.org.za, or download it from your mobile phone's app store. By reporting side effects, you can help provide more information on the safety of VASCAFEM.

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**, found online on SAHPRA's website, www.sahpra.org.za, or download it from your
mobile phone's app store. By reporting side effects, you can help provide more information on the safety of VASCAFEM.

5. How to store VASCAFEM

· 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:

Crataegus pinnatifida Bunge (Hawthorn) [fruit; as 60 mg of a 10:1 extract]	600 mg
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)

The other ingredients are fructose, sucrose, greyish brown colour (PBL32454), magnesium stearate (E572), maize starch (E1400), microcrystalline cellulose (E460), shellac blond and sodium starch glycollate A.

What VASCAFEM looks like and contents of the pack
Mild brown caplet shaped tablet with a break line.
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.

LOOCK PHARMACEUTICALS

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
September 2023.

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.vascafem.co.za.

PASIËNTINLIGTINGSBLAD
SKEDULERINGSTATUS
S0

VASCAFEM tablette

Formule met verskeie bestanddele.
Bevat suiker: Elke tablet bevat 24 mg fruktose en 10 mg sukrose.

KOMPLEMENTÊRE MEDISYNE
KOMBINASIEPRODUK: WESTERSE KRUIEMEDISYNE / GESONDHEIDSAANVULLING
Hierdie ongeregistreerde medisyne is nie deur SAHPRA geëvalueer vir gehalte, veiligheid of beoogde gebruik, nie.

Lees die volledige inligtingsblad aandagtig deur want dit bevat belangrike inligting vir jou.
VASCAFEM is beskikbaar sonder 'n dokter se voorskrif, sodat jy jou gesondheid in stand kan hou. Jy moet VASCAFEM nogtans met sorg neem om die beste resultate te verkry.
· Bewaar hierdie inligtingsblad. Dit mag nodig wees om dit later weer te lees.
· Moenie VASCAFEM met enige ander persoon deel nie.
· Vra gerus jou gesondheidsorgverskaffer of apteker indien jy verdere inligting of advies nodig het.

Wat is in hierdie inligtingsblad?
1. Wat is VASCAFEM en waarvoor word dit gebruik.
2. Wat jy moet weet voordat jy VASCAFEM neem.
3. Hoe om VASCAFEM te neem.
4. Moontlike newe-effekte.
5. Hoe om VASCAFEM te stoor.
6. Inhoud van die verpakking en ander inligitng

1. Wat is VASCAFEM en waarvoor word dit gebruik?
VASCAFEM is geklassifiseer as 'n komplementêre medisyne wat geformuleer is vir vroue om by te dra tot hul algemene gesondheid. VASCAFEM verskaf 'n noukeurig geselekteerde kombinasie van vitamiene, minerale en plantekstrakte wat fokus op die beskerming van die hart, bloedvate en bene.

2. Wat jy moet weet voordat jy VASCAFEM neem
Moenie VASCAFEM neem
· Indien jy hipersensitief (allergies) is vir enige van die bestanddele van VASCAFEM (sien afdeling 6) nie.

Waarskuwings en voorsorgmaatreëls
Wees veral versigtig met VASCAFEM:
· Indien jy vir 'n operasie moet gaan. Hou ten minste twee weke voor enige sjirurgiese prosedure op om VASCAFEM te neem.
· Indien jy hartprobleme het.

Ander medikasie en VASCAFEM
Stel altyd jou gesondheidsorgverskaffer in kennis indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)
Sê vir jou dokter of apteker indien jy tans die volgende gebruik:
· Antikoagulantmedisyne (word gebruik om bloed te verdun), of kruie-aanvullings wat bloedverdunnende effekte het.
· Antihipertensiewe medisyne (word gebruik om hoë bloeddruk te behandel), of kruie-aanvullings met bloeddrukverlagende effekte.
· Digoksien (word gebruik om hartversaking te behandel).
· Litium (word gebruik vir bipolêre depressie).
· Antibiotika (word gebruik om bakteriële infeksies te behandel). Jy moet jou antibiotika ten minste 2 ure voor, of 4 tot 6 ure na VASCAFEM neem.
· Antiretrovirale middels (word gebruik vir MIV-besmettting). Indien jy dolutegravir of raltegravir gebruik, neem dit ten minste 2 ure voor, of 4 tot 6 ure na VASCAFEM.
· Levotiroksien (word gebruik om 'n onderaktiewe skildklier te behandel). Neem VASCAFEM en levotiroksien ten minste 4 ure uitmekaar.

Swangerskap en borsvoeding
Indien jy swanger is of borsvoed, of vermoed dat jy swanger is, of beplan om swanger te raak, raadpleeg asseblief jou dokter, apteker of gesondheidsorgverskaffer voordat jy VASCAFEM neem.
Moenie VASCAFEM neem terwyl jy swanger is of borsvoed nie, aangesien die veiligheid daarvan nog nie vasgestel is nie.

Bestuur en die gebruik van masjinerie
VASCAFEM kan newe-effekte soos duiseligheid 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 VASCAFEM jou affekteer nie.

VASCAFEM bevat suiker
VASCAFEM bevat 24 mg fructose en 10 mg sukrose per tablet.
Indien jou dokter jou ingelig het dat jy vir sommige suikers 'n intoleransie het, of as 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 VASCAFEM neem.

3. Hoe om VASCAFEM te neem
Gebruik VASCAFEM altyd presies soos dit in hierdie inligtingsblad aangedui word, of soos wat jou dokter of apteker aanbeveel het. Vra gerus jou dokter of apteker indien jy onseker is.

Volwassenes:
Die normale dosis is een tablet daagliks. Die tablet moet mondeliks saam, of direk na voedsel geneem word.

Kinders:
VASCAFEM is nie aangedui vir gebruik deur kinders jonger as 18 jaar nie.

Indien jy meer VASCAFEM geneem het as wat jy moet
In die geval van 'n 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 oorblywende VASCAFEM saam sodat die dokter weet wat jy geneem het.

Indien jy vergeet om VASCAFEM te neem
Neem jou volgende dosis op die gewone tyd.
Moenie 'n dubbele dosis neem om te vergoed vir die individuele dosisse wat gemis is nie.

4. Moontlike newe-effekte
VASCAFEM kan newe-effekte hê.
Nie alle newe-effekte wat vir VASCAFEM gerapporteer is, word in hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid verswak of jy enige ongunstige effekte ondervind terwyl VASCAFEM geneem word, raadplaag asseblief jou gesondheidsorgverskaffer.

Indien enige van die volgende gebeur, hou op om VASCAFEM te neem en kontak jou dokter onmiddelik, of gaan na die ongevalle afdeling by die naaste hospitaal:
· Swelling van jou hande, voete, enkels, gesig, lippe, mond of keel.
· Probleme met sluk of asemhaling.
· Veluitslag of jeuk.
· Floute.

Hierdie is baie ernstige newe-effekte. Indien jy hierdie simptome het, mag jy 'n ernstige allergiese reaksie teenoor VASCAFEM gehad het. Jy mag dringende mediese bystand of hospitalisasie benodig.

Sê vir jou dokter of gaan na die ongevalle-afdeling by die naaste hospitaal indien jy een van die volgende opmerk:
· Veranderinge in jou hartklop, bv. as jou hart vinniger klop as normaalweg.
· Sukkel om asem te haal of kort van asem.
Dit is alles ernstige newe-effekte. Jy mag moontlik dringende mediese hulp benodig.

Stel jou dokter in kennis indien jy enige van die volgende opmerk:
Frekwensie onbekend:
· Slaaploosheid of lomerigheid.
· Duiseligheid, hoofpyn.
· Angstigheid.
· Moegheid.
· Parestesie (tintelende gevoel op die vel, "naalde-en-spelde")
· Pyn, krampe of ongemak van die abdominale area, naarheid, braking, diaree, oormatige winderigheid, hardlywigheid, sooibrand, omgekrapte maag.
· Verlies aan eetlus.
· Metaalsmaak in die mond.
· Toename in sweet.

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

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

Aanmelding van newe-effekte
Indien jy enige newe-effekte ervaar, insluitend newe-effekte wat nie in hierdie inligtingsblad genoem word nie, stel jou dokter of apteker daarvan in **kennis**. Jy kan ook newe-effekte aan SAHPRA rapporteer deur gebruik te maak van The Med Safety App wat aanlyn op SAHPRA se webtuiste beskikbaar is by www.sahpra.org.za, of laai dit van jou slimfoon se toepwinkel af.
Deur newe-effekte te rapporteer, kan jy help om meer inligting rakende die veiligheid van VASCAFEM te verskaf.

5. Hoe om VASCAFEM te bêre
· Bêre by of onder 25 °C op 'n droë plek.
· Beskerm teen direkte sonlig en vog.
· Bêre alle medisyne buite die bereik van kinders.
· Moenie gebruik na die vervaldatum, wat op die houer gedruk is nie.
· Neem alle ongebruikte medisyne terug na jou apteker sodat dit vernietig kan word.
· Moenie ongebruikte medisyne in dreine en rioolstelsels (bv toilette) afspoel nie.

6. Inhoud van die verpakking en ander inligting
Wat VASCAFEM bevat
Elke tablet bevat:

Crataegus pinnatifida Bunge (Haagdoorn) [vrug; as 60 mg van 'n 10:1 ekstrak]	600 mg
Kalsiumkarbonaat	1258 mg
verskaf kalsium (elementêr)	504 mg
Piridoksien hidrochloried	67,1 mg
verskaf piridoksien (vitamien B6)	50 mg
Kalsiumlaktaatglukonaat	193 mg
verskaf kalsium (elementêr)	24,72 mg
Sinksulfaatheptahidraat	60 mg
verskaf sink (elementêr)	13,63 mg
Foliensuur	500 µg
Vitamien K_2	40 µg
Colekalsiferol (vitamien D_3)	1 000 IE (25 µg)
Selenium aminosuur chelaat 2 %	175 µg
verskaf elementele selenium	3,5 µg

en aminosure (1,908 µg glutamiensuur, 0,910 µg leusien, 0,875 µg arginien, 0,840 µg asparaginsuur, 0,718 µg valien, 0,595 µg alanien, 0,543 µg fenielalanien, 0,525 µg sistien, 0,490 µg glisien, 0,438 µg prolien, 0,403 µg isoleusien, 0,403 µg lisien, 0,385 µg serien, 0,368 µg tirosien, 0,350 µg metionien, 0,245 µg treonien, 0,228 µg histidine, 0,193 µg triptofaan).

Die ander bestanddele is fruktose, grysbruin kleurstof (PBL32454), magnesiumstearaat (E572), mieliestysel (E1400), mikrokristallyne sellulose (E460), skilferlak blond en natriumstyselglikolaat A.

Hoe VASCAFEM lyk en die inhoud van die verpakking
Bruinerige kapletvorm-tablet met 'n breeklyn.
30 tablette is verpak in 'n pers vitamienhouer met 'n pers skroefdop. Elke vitamienhouer bevat 'n silikagelsakkie en 'n spons.

LOOCK PHARMACEUTICALS

Houer van die Registrasiesertifikaat
Loock Pharmaceuticals
Postnet suite 223
Privaatsak X82245
Waterfall Mall
Rustenburg 0300
Suid-Afrika
066 302 8972

Hierdie inligtingsblad is laas hersien in
September 2023

Registrasienommer
Moet toegeken word deur SAHPRA tydens registrasie.

Toegang tot ooreenstemmende Professionele Inligting
Vir volledige voorgeskrewe inligting, verwys na die Professionele Inligting (PI) beskikbaar by www.vascafem.co.za.