

PATIENT INFORMATION LEAFLET

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS

S0

LADY PRELOX® MENOPAUSE Caplets

Western Herbal Medicine/Health Supplement

Each LADY PRELOX® caplet contains:

40 mg	Pycnogenol® – French maritime pine bark extract (<i>Pinus Pinaster</i>)
100 mg	Rosvita® – Rose Hip (<i>Rosa Canina</i>) extract
400 mg	L-Arginine HCl
400 mg	L-Citrulline

The caplets are Halaal certified and suitable for Vegans

Read all of this leaflet carefully before you start taking LADY PRELOX®

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- LADY PRELOX® has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.
- Read this entire leaflet carefully because it contains important information for you.

What is in this leaflet?

1. What LADY PRELOX® is and what it is used for
2. What you need to know before you take LADY PRELOX®
3. How to take LADY PRELOX®
4. Possible side effects
5. How to store LADY PRELOX®
6. Contents of the pack and other information

1. What is LADY PRELOX® and what it is used for

- LADY PRELOX® assists in the relief of the various symptoms associated with menopause and post menopause.
- LADY PRELOX® is an antioxidant and support blood circulation, to improve female sexual function and health.
- When taken at the recommended dose, 2 caplets per day of LADY PRELOX® will provide 80 mg French maritime pine bark extract (*Pinus Pinaster*), 200mg Rosvita® – Rose Hip (*Rosa Canina*) extract, 800mg L-Arginine HCl and 800mg L-Citrulline.

Pycnogenol® – French maritime pine bark extract (Pinus Pinaster)

- Research into Pycnogenol® for blood flow was the stimulus behind the development of LADY PRELOX®.
- Pycnogenol® is a patented, botanical extract from the bark of the French maritime pine tree and is known for its antioxidant properties.
- It is supported by 40 years of research, including 300 scientific publications, 100 clinical trials and 7,000 study participants.
- Proven to expand and support healthy blood vessels, proven to support and restore production of nitric oxide which encourages better blood flow.

Rosvita® – Rose Hip (Rosa Canina) extract

- Rosvita® is a branded, patented rose hip extract that originate from the blossoms/fruit of the wild rose plant.
- An antioxidant, and contains vitamin C, which contributes to normal psychological function and reduction of tiredness and fatigue.
- Researched for gut health properties and increasing blood flow to the limbs.

L-Arginine HCl

- L-Arginine is an amino acid that plays an important role in nitric oxide mechanisms in the body.
- It is an essential precursor for the generation of nitric oxide, a messenger molecule which plays a key role for regulation of blood circulation.
- Nitric oxide is crucial for regulation of blood flow to the genital area.

L-Citrulline

- L-Citrulline is a naturally occurring amino acid. As a precursor of L-Arginine, it has been shown to help open up arteries to improve blood flow and reduce blood pressure.
- Our bodies change L-Citrulline into another amino acid called L-Arginine (mentioned above) and also to nitric oxide.

2. What you need to know before you take LADY PRELOX®

- Do not take LADY PRELOX® if you are hypersensitive (allergic) to any of the ingredients of LADY PRELOX® (listed in section 6).
- Postmenopausal women: Ensure that you are up-to-date on appointed clinical tests such as mammograms and endometrial ultrasounds or biopsies before using this product.

Warnings and precautions

- If you are on any medication or suffering from any medical condition, it is advisable to seek medical advice before starting any new medicine.
- Nutritional supplements should not be used as a substitute for a varied diet or healthy lifestyle.

Specified warnings:

Consult a relevant health care provider:

- to use if you suffer from a cardiovascular disease and are attempting an increase in physical activity.
- prior to use if you are taking medication for cardiovascular diseases and/or blood thinners
- if your cardiovascular condition worsens.
- prior to use if you have a renal/kidney disease or if you are following a low protein diet.

Children and adolescents

- Not suitable for children.

Other medicines and LADY PRELOX®

- There is no evidence to show any negative interaction with medicines.
- When taking any dietary supplement alongside other medication, it is always advisable to consult your doctor/ pharmacist.

LADY PRELOX® with food and drink

- LADY PRELOX® is not affected by taking it with food or drink.

Pregnancy and breastfeeding

- Safety and effectiveness of LADY PRELOX® during pregnancy and lactation have not been established.
- 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 health care provider for advice before taking this medicine.

Driving and using machines

- LADY PRELOX® should not have any effect on your ability to drive or to use machines.

3. How to take LADY PRELOX®

- The usual dose is two (2) caplets per day, preferably with a meal.
- Take LADY PRELOX® once a day, every day, at about the same time each day.
- Taking your medicine at the same time each day will help you remember to take it.
- Do not share medicines prescribed for you with any other person.
- Always take LADY PRELOX® exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your health practitioner if you are not sure.

If you take more LADY PRELOX® than you should

- You can experience mild nausea, diarrhoea or gastro-intestinal discomfort if you exceed the dosage.
- In the event of over dosage, consult your doctor or pharmacist.
- If neither is available, contact the nearest hospital or poison control centre.

If you forget to take LADY PRELOX® Take a dose as soon as you remember.

- Do not take a double dose to make up for forgotten individual doses.

If you stop taking LADY PRELOX®

- There is no known data available for withdrawal or any other effects when treatment is interrupted or ended early.

4. Possible side effects

- LADY PRELOX® can have side effects.
- No serious side effects or intolerance problems were reported or observed.
- Not all side effects reported for LADY PRELOX® are included in this leaflet.
- Should your general health worsen or if you notice any side effects not mentioned in this leaflet while taking LADY PRELOX®, please inform your doctor or pharmacist.

Contraindication:

- Do not use if you have had a heart attack/myocardial infarction

Known Adverse Reaction:

- Some people may experience gastrointestinal discomfort (such as diarrhoea)

Reporting of side effects

- If you get side effects, talk to your doctor, pharmacist or nurse.
- You can also report side effects directly to medical@lamelle.co.za
- Additionally you can report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>
- By reporting side effects, you can help provide more information on the safety of LADY PRELOX®.

5. How to store LADY PRELOX®

- Store all medicines out of reach of children
- Store in the original package
- Store in a cool, dry place below 25°C
- Protect from light and moisture
- Do not store in a bathroom
- Do not use after the expiry date stated on the label
- Do not use LADY PRELOX® if you notice visible colour or composition change
- Return all unused medicine to your pharmacist
- Do not dispose of unused medicine in drains or sewerage systems

6. What LADY PRELOX® contains

- The active substances in LADY PRELOX® are Pycnogenol®, French maritime pine bark extract (*Pinus Pinaster*), Rosvita® – Rose Hip (*Rosa Canina*) extract, L-Arginine HCl and L-Citrulline.
- The other ingredients are Di Calcium Phosphate DC, Microcrystalline Cellulose Avicel PH101, Povidone VA64, CMC, Silicon Dioxide, Magnesium Stearate, Flexicoat Clear PHA1000 (3%) and Flexicoat Blush PHA9085 (6%).

What LADY PRELOX® looks like and contents of the pack

- Light pink-coloured, oval-shaped, scored caplets with a logo imprinted on both sides.
- 15 Caplets are packed into a blister strip made of clear PVC/PVDC film and Alu foil.
- 4 Blister strips are included per light pink outer cardboard carton, therefore pack contains 60 capsules.

Holder of Certificate of Registration

Lamelle Pharmaceuticals (Pty) Ltd
Building C1, Northlands Deco Park,
Newmarket Road, North Riding

This leaflet was last revised in

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Registration/Application number

To be allocated

PASIËNT INLIGTINGS PAMFLET

Hierdie ongeregistreerde medisyne is nie deur die SAHPRA geëvalueer vir die kwaliteit, veiligheid of beoogde gebruik daarvan nie.

SKEDULERINGS STATUS

SO

LADY PRELOX® MENOPAUSE Kaplette

Westerse Kruiemedyne/Gesondheidsaanvulling

Aktiewe bestanddele per kaplet:

40 mg	Pycnogenol® – French maritime pine bark ekstrak (<i>Pinus Pinaster</i>)
100 mg	Rosvita® – Rose Hip (<i>Rosa Canina</i>) ekstrak
400 mg	L-Arginine HCl
400 mg	L-Citrulline

Die kaplette is Halaal gesertifiseer en geskik vir Vegans.

LEES HIERDIE PAMFLET NOUKEURIG DEUR WANT DIT HOU BELANGRIKE INLIGTING VIR JOU IN

- Bewaar hierdie pamflet, want jy gaan dit waarskynlik weer lees.
- As u verdere vrae het, kan u dit vir u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer vra.
- LADY PRELOX® is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al is hulle simptome dieselfde as joune.
- Lees hierdie hele pamflet aandagtig deur want dit bevat belangrike inligting vir jou.

Wat is in hierdie pamflet?

1. Wat is LADY PRELOX® en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy LADY PRELOX® neem
3. Hoe om LADY PRELOX® te neem
4. Moontlike nuwe-effekte
5. Hoe om LADY PRELOX® te stoor
6. Inhoud van die pakkie en ander inligting.

1. Wat is LADY PRELOX® en waarvoor dit gebruik word

- LADY PRELOX® help met die verligting van die verskeie simptome wat met menopause en post-menopause geassosieer word.
- LADY PRELOX® is 'n antioksidant, wat bloedsomloop ondersteun en vroulike seksuele funksie en gesondheid bevorder.
- Wanneer LADY PRELOX® teen die aanbevole dosis van 2 kaplette per dag geneem word, voorsien dit 80 mg French maritime pine bark ekstrak (*Pinus Pinaster*), 200 mg Rosvita® – Rose Hip (*Rosa Canina*) ekstrak, 800 mg L-Arginine HCl en 800 mg L-Citrulline.

Pycnogenol® – French maritime pine bark ekstrak (*Pinus Pinaster*)

- Die ondersoek na Pycnogenol® vir bloedvloei was die stimulus vir die ontwikkeling van LADY PRELOX®.
- Pycnogenol® is 'n gepatenteerde, botaniese ekstrak van die bas van die Franse maritime denneboom en is bekend vir antioksidant eienskappe.
- Dit word gerugsteun deur 40 jaar van navorsing, waaronder 300 wetenskaplike publikasies, 100 kliniese proewe en 7 000 deelnemers aan die studies.
- Studies toon dat beter bloedvloei aangemoedig word deur dat Pycnogenol® gesonde bloedvate verwyd, asook die produksie van stikstofoksied herstel en ondersteun.

Rosvita® – Rose Hip (*Rosa Canina*) ekstrak.

- Rosvita® is 'n gepatenteerde rosheip ekstrak handelsmerk wat afkomstig is van die bloeisel/vrugte van die wilde roosplant. Dit is 'n antioksidant en bevat vitamien C, wat bydra tot normale psigiese funksie wat moegheid en uitputting verminder.
- Volgens navorsing hou Rosvita® die ingewande gesond en verhoog bloedvloei na die ledemate.

L-Arginine HCl

- L-Arginine is 'n aminosuur wat 'n belangrike rol speel in stikstofoksiedmeganismes in die liggaam.
- Dit is 'n noodsaaklike voorloper in die vervaardiging van stikstofoksied, 'n boodskappermolekuul wat 'n sleutelrol speel in die regulering van die bloedsomloop.
- Stikstofoksied is van kardinale belang vir die regulering van bloedvloei na die geslagsdele.

L-Citrulline

- L-Citrulline is 'n aminosuur wat natuurlik voorkom. As voorloper van L-Arginine is getoon dat dit help om are te open om die bloedvloei te verbeter en bloeddruk te verlaag.
- Ons liggame verander L-Citrulline in 'n ander aminosuur naamlik L-Arginine (hierbo genoem) en ook na stikstofoksied.

2. Wat jy moet weet voordat jy LADY PRELOX® neem.

- Moenie LADY PRELOX® neem as jy oorgevoelig (allergies) is vir enige van die bestanddele van LADY PRELOX® nie (sien afdeling 6).
- Postmenopousale vroue: Maak seker dat u op datum is met aangestelde kliniese toetse soos mammogramme en endometriale ultraklanke of biopsies voordat u hierdie produk gebruik.

Waarskuwings en voorsorgmaatreëls

- As u enige medikasie gebruik of aan enige mediese toestand ly, is dit raadsaam om mediese advies in te win voordat u met 'n nuwe medisyne begin.
- Voedingsaanvullings moet nie as 'n plaasvervanger vir 'n gevarieerde dieet of gesonde leefstyl gebruik word nie.

Spesifieke waarskuwings:

Raadpleeg jou dokter, apteker of gesondheidswerker:

- om LADY PRELOX® te gebruik as jy aan 'n kardiovaskulêre siekte ly en 'n toename in fisiese aktiwiteit gaan hê.
- voor gebruik as jy medikasie vir kardiovaskulêre siekte en/of bloedverdunner neem
- as jou kardiovaskulêre toestand vererger
- voor gebruik as jy 'n nier-/niersiekte het of as jy 'n lae-proteïen dieet volg.

Kinders en adolessente

- Nie geskik vir kinders nie.

Ander medisyne en LADY PRELOX®

- Daar is geen bewyse dat LADY PRELOX® enige negatiewe interaksie met ander medisyne toon nie.
- As jy enige aanvulling saam met ander medisyne inneem, is dit altyd raadsaam om jou dokter / apteker te raadpleeg.

LADY PRELOX® met voedsel en vloeistof

- LADY PRELOX® word nie geaffekteer deur die inname van voedsel of vloeistof nie.

Swangerskap, borsvoeding en vrugbaarheid

- Die veiligheid en effektiwiteit van LADY PRELOX® tydens swangerskap en laktasie is nog nie vasgestel nie.
- Raadpleeg jou dokter, apteker of ander gesondheidswerker vir advies as jy swanger is of jou baba borsvoed terwyl jy LADY PRELOX® gebruik.

Bestuur en gebruik van masjiene

- LADY PRELOX® behoort geen effek te hê op jou vermoë om te bestuur of om masjiene te gebruik nie.

3. Hoe om LADY PRELOX® te neem.

- Die aanbevole dosis is twee (2) Kaplette daaglik, verkieslik met 'n maaltyd.
- Neem LADY PRELOX® een keer per dag, elke dag, op ongeveer dieselfde tyd elke dag.
- As jy die medisyne elke dag op dieselfde tyd neem, sal dit jou help onthou om dit te gebruik.
- Moenie medisyne wat vir jou voorgeskryf is, met iemand anders deel nie.
- Neem LADY PRELOX® altyd presies soos voorgeskryf in hierdie pamflet of soos jou dokter, apteker of verpleegster vir jou voorgeskryf het. Raadpleeg jou dokter as jy nie seker is nie.

As jy meer LADY PRELOX® neem as wat jy behoort te gebruik

- Jy kan effense naarheid, diaree of gastro-intestinale ongemak ervaar as jy die dosis oorskry.
- Raadpleeg jou dokter of apteker in geval van 'n oordosis.
- Indien niemand beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

As jy vergeet om LADY PRELOX® te neem

- Neem 'n dosis sodra jy dit onthou.
- Moenie 'n dubbele dosis neem om vir die vergete dosis op te maak nie.

As die gebruik van LADY PRELOX® gestaak word

- Daar is geen data beskikbaar vir wanneer die behandeling van LADY PRELOX® onderbreek of gestaak word nie.

4. Moontlike nuwe-effekte

- LADY PRELOX® kan nuwe-effekte hê.
- Geen ernstige nuwe-effekte of onverdraagsaamheidsprobleme is gerapporteer of waargeneem nie.
- Nie alle nuwe-effekte wat vir LADY PRELOX® gerapporteer word is in hierdie pamflet ingesluit nie.
- As jou algemene gesondheid versleg, of as jy enige nuwe-effekte opmerk wat nie in hierdie pamflet genoem word terwyl jy LADY PRELOX® neem nie, moet jou dokter of apteker daarvan in kennis gestel word.

Kontraindikasie:

- Moet nie gebruik as jy 'n hartaanval/miokardiale infarksie gehad het nie

Bekende nadelige reaksie:

- Sommige mense mag gastro-intestinale ongemak ervaar (soos diaree)

Aanmelding van nuwe-effekte

- Raadpleeg jou dokter, apteker of verpleegster as jy nuwe-effekte ondervind.
- Jy kan nuwe-effekte ook direk aanmeld by medical@lamelle.co.za
- Daarbenewens, aanlyn <https://www.sahpra.org.za/Publications/Index/8> onder SAHPRA se publikasies, vind u SAHPRA "6.04 Ongunstige geneesmiddelreaksie Verslagvorm"
- Deur nuwe-effekte aan te meld, kan jou help om meer inligting oor die veiligheid van LADY PRELOX® te verskaf.

5. Hoe om LADY PRELOX te bêre

- Hou alle medisyne buite bereik van kinders.
- Bêre in die oorspronklike verpakking.
- Bêre dit op 'n koel, droë plek onder 25 ° C.
- Beskerm teen lig en vog.
- Moet nie in 'n badkamer bêre nie.
- Moet dit nie gebruik na die vervaldatum wat op die etiket aangedui word nie. Moenie LADY PRELOX® gebruik as u sigbare kleur- of samestellingsveranderings opmerk nie.
- Handig alle ongebruikte medisyne by jou apteek in.
- Moenie ongebruikte medisyne weggooi in drein of rioolstelsels nie.

6. Inhoud van die verpakking en ander inligting

- Die aktiewe bestanddele in LADY PRELOX® is Pycnogenol®, French maritime pine bark ekstrak (*Pinus Pinaster*), Rosvita® – Rose Hip (*Rosa Canina*) ekstrak, L-Arginine HCl en L-Citrulline.
- Die ander bestanddele is Di Calcium Phosphate DC, Microcrystalline Cellulose Avicel PH101, Povidone VA64, CMC, Silicon Dioxide, Magnesium Stearate, Flexicoat Clear PHA1000 (3%) en Flexicoat Blush PHA9085 (6%).

Hoe LADY PRELOX® lyk en die inhoud van die verpakking

- Ligte Pienk ovaal-vormige kaplette met 'n logo aan albei kante.
- 15 Kaplette word verpak in 'n blisterstrook van deursigtige PVC / PVDC film en aluminiumfoelie.
- 4 Blister stroke word in 'n ligte pienk kartonhouer verpak, 'n verpakking bevat dus 60 kapsules.

Houer van Registrasiesertifikaat

Lamelle Pharmaceuticals (Edms.) Bpk.
Gebou C1, Northlands Deco Park,
Newmarketweg, North Riding

Hierdie pamflet is hersien

December 2024

Registrasie/ Aansoeknommer

TBA