



## PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:** S0

### PRELOX® Male Fertility Capsules

Active substances per capsule:

40mg Pycnogenol® French maritime pine bark extract (Pinus Pinaster)  
780mg L-Arginine HCL

Halal certified  
Suitable for Vegans

Category DS: 32.16, Other, Complimentary Human Medicines  
Discipline Specific Combination Health Supplement/Western Herbal

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

### READ ALL OF THIS LEAFLET CAREFULLY BECAUSE IT CONTAINS IMPORTANT INFORMATION FOR YOU

- Keep this leaflet. You may need to read it again.
- PRELOX® Male Fertility is available without a doctor's prescription.
- Nevertheless you still need to use PRELOX® Male Fertility carefully to get the best results from.
- Do not share PRELOX® Male Fertility with other people.
- If you have further questions, please ask your doctor, pharmacist nurse or other health care provider.

#### 1. What is PRELOX® Male Fertility and what is it used for

- PRELOX® Male Fertility is a potent antioxidant that may assist blood circulation, sperm motility and quality.
- When taken at the recommended dose, PRELOX® Male Fertility provides 80mg of Pycnogenol® French maritime pine bark extract and 1560mg of L-Arginine HCL per day.

##### *Pycnogenol®*

- Pycnogenol® is a patented, botanical extract from the bark of the French maritime pine tree and is known for its potent 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.
- Research into Pycnogenol® for blood flow was the stimulus behind the development of PRELOX® Male Fertility.

##### *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 and increases sperm quality and motility by antioxidative effect.

#### 2. What you need to know before you take PRELOX® Male Fertility

Do not take PRELOX® Male Fertility if you are hypersensitive (allergic) to any of the ingredients of PRELOX® Male Fertility.

##### *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.

##### *Children and adolescents*

- Not suitable for children.

##### *Other medicines and PRELOX® Male Fertility*

- 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.

##### *Pregnancy, breastfeeding and fertility*

- PRELOX® Male Fertility is intended for use in males only.

#### 3. How to take PRELOX® Male Fertility

- It would be a good idea to fill out the International Index of Erectile Function (IIEF) questionnaire as a self-assessment.
- The usual dose is 2 capsules per day, preferably with breakfast.
- Take PRELOX® Male Fertility 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 PRELOX® Male Fertility 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 PRELOX® Male Fertility than you should*

- 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 PRELOX® Male Fertility*

- 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 PRELOX® Male Fertility*

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

#### 4. Possible side effects

*PRELOX® Male Fertility can have side effects.*

- No serious side effects or intolerance problems were reported or observed.
- Vertigo, headache, joint pain and palpitation might occur in rare cases.
- You can experience nausea if you exceed the dosage.
- Not all side effects reported for PRELOX® Male Fertility are included in this leaflet.
- Should your general health worsen or if you notice any side effects not mentioned in this leaflet while taking PRELOX® Male Fertility, please inform your doctor or pharmacist.

##### *Reporting of side effects*

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

#### 5. How to store PRELOX® Male Fertility

- 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 PRELOX® Male Fertility if you notice visible colour or composition changes.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems.

#### 6. Contents of the pack and other information

- The active substances in PRELOX® Male Fertility are Pycnogenol® and L-Arginine HCL.
  - The other ingredients are Magnesium Stearate and Aerosil 200Pharma.
- What PRELOX® Male Fertility looks like and contents of the pack*
- Blue and Red coloured oval-shaped size 00 vegi-capsules, with a logo on one side.
  - 10 Capsules are packed into a blister strip made of clear PVC/PVDC film and Alu foil.
  - 6 Blister strips are included per outer cardboard carton, therefore pack contains 60 capsules.

#### 7. Holder of Certificate of Registration

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

Pycnogenol® and PRELOX® are registered trademarks of Horphag Research Ltd and are protected by US and international patents.

#### Application number

D530471

#### This leaflet was last revised

March 2021





## PASIËNT INLIGTINGS PAMFLET

**KEDULERINGS STATUS:** SO

### PRELOX® Male Fertility Kapsules

Aktiewe bestanddele per kapsule:

40mg Pycnogenol® French maritime pine bark ekstrak (Pinus Pinaster)  
780mg L-Arginine HCL

Halal gesertifiseerd

Geskik vir Vegans

Kategorie DS: 32.16, Ander, Komplimentêre Medisyne vir menslike gebruik  
Disiplinespesifieke Kombinasie Gesondheidsaanvullings/Western Herbal

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

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

- Bewaar hierdie pamflet, want u gaan dit waarskynlik weer lees.
- PRELOX® Male Fertility is sonder 'n doktersvoorskrif beskikbaar.
- U moet PRELOX® Male Fertility egter steeds versigtig gebruik om die beste resultate daaruit te kry.
- Moenie PRELOX® Male Fertility met ander mense deel nie.
- As u verdere vrae het, kan u dit vir u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer vra.

#### 1. Wat is PRELOX® Male Fertility en waarvoor word dit gebruik?

- PRELOX® Male Fertility is 'n kragtige antioksidant wat bloedsomloop, sperm motiliteit en kwaliteit kan bevorder.
- Wanneer dit teen die aanbevole dosis geneem word, voorsien PRELOX® Male Fertility 80mg Pycnogenol® en 1560mg L-Arginine HCL per dag.

##### *Pycnogenol®*

- Pycnogenol® is 'n gepatenteerde, botaniese ekstrak van die bas van die Franse maritime denneboom en is bekend vir kragtige 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.
- Die ondersoek na Pycnogenol® vir bloedvloei was die stimulus vir die ontwikkeling van PRELOX® Male Fertility.

##### *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 in die regulering van bloedvloei en verhoog die spermkwaliteit en -motiliteit deur antioksidatiewe effekte.

#### 2. Wat u moet weet voordat u PRELOX® Male Fertility neem

Moenie PRELOX® Male Fertility neem as u oorgevoelig (allergies) is vir enige van die bestanddele van PRELOX® Male Fertility nie.

##### *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

##### *Kinders en adolessente*

- Nie geskik vir kinders nie.

##### *Ander medisyne en PRELOX® Male Fertility*

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

##### *Swangerskap, borsvoeding en vrugbaarheid*

- PRELOX® Male Fertility is alleenlik vir gebruik by mans.

#### 3. Hoe om PRELOX® Male Fertility te neem

- Vir selfevaluering sal dit 'n goeie idee wees om die International Index of Erectile Function (IIEF) vraelys in te vul.
- Die aanbevole dosis is twee (2) kapsules daaglik, verkieslik met ontbyt.
- Neem PRELOX® Male Fertility een keer per dag, elke dag, op ongeveer dieselfde tyd elke dag.

- As u die medisyne elke dag op dieselfde tyd neem, sal dit u help onthou om dit te gebruik.
- Moenie medisyne wat vir u voorgeskryf is, met iemand anders deel nie.
- Neem PRELOX® Male Fertility altyd presies soos voorgeskryf in hierdie pamflet of soos u dokter, apteker of verpleegster vir u voorgeskryf het.
- Moenie die aanbevole dosis oorskry nie.

*As u meer PRELOX® Male Fertility neem as wat u behoort te gebruik*

- Raadpleeg u dokter of apteker in geval van 'n oordosis.
- Indien niemand beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

*As u vergeet om PRELOX® Male Fertility te neem*

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

*As u die gebruik van PRELOX® Male Fertility staak*

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

#### 4. Moontlike nuwe-effekte

*PRELOX® Male Fertility kan nuwe-effekte hê.*

- Geen ernstige nuwe-effekte of onverdraagsaamheidsprobleme is gerapporteer of waargeneem nie.
- U kan naardeer ervaar as u die dosis oorskry.
- Nie alle nuwe-effekte wat vir PRELOX® Male Fertility gerapporteer is word in hierdie pamflet ingesluit nie.
- As u algemene gesondheid versleg, of as u enige nuwe-effekte opmerk wat nie in hierdie pamflet genoem word terwyl u PRELOX® Male Fertility neem nie, moet u u dokter of apteker daarvan in kennis stel.

##### *Aanmelding van nuwe-effekte*

- Raadpleeg u dokter, apteker of verpleegster as u nuwe-effekte ondervind.
- U kan nuwe-effekte ook direk aanmeld by [medical@lamelle.co.za](mailto: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 u help om meer inligting oor die veiligheid van PRELOX® Male Fertility te verskaf.

#### 5. Hoe om PRELOX® Male Fertility 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 PRELOX® Male Fertility gebruik as u sigbare kleur- of samestellingsveranderinge opmerk nie.
- Handig alle ongebruikte medisyne by u apteek in.
- Moenie ongebruikte medisyne weggooi in drein of rioelstelsels nie.

#### 6. Inhoud van die verpakking en ander inligting

- Die aktiewe bestanddele in PRELOX® Male Fertility is Pycnogenol® en L-Arginine HCL.
- Die ander bestanddele is Magnesium Stearate en Aerosil 200Pharma.
- Hoe PRELOX® Male Fertility lyk en die inhoud van die verpakking*
- Blou en Rooi ovaal-vormige vegi-kapsules (grootte 00), met 'n PRELOX logo aan die een kant.
- 10 kapsules word verpak in 'n blisterstrook van deursigtige PVC / PVDC film en aluminiumfoelie.
- 6 blister stroke word in 'n kartonhouer verpak, 'n verpakking bevat dus 60 kapsules.

#### 7. Houer van Registrasiesertifikaat

Lamelle Pharmaceuticals (Edms.) Bpk.

Gebou C1, Northlands Deco Park,  
Newmarketweg, North Riding

Pycnogenol® en PRELOX® is geregistreerde handelsmerke van Horphag Research Ltd en word beskerm deur Amerikaanse en internasionale patente.

#### Aansoeknommer

D530471

#### Hierdie pamflet is hersien

Maart 2021

