

## PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline: Discipline Specific

33.4 Traditional Chinese Medicine

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM -

### SERENAGEN® , 60 & 120 Tablets

#### COMPOSITION

Each two (2) tablets of SERENAGEN® contains the following actives:

Rehmannia (Rehmannia glutinosa) [Root 4:1 extract]	290 mg
Schisandra (Schisandra chinensis) [Fruit 4:1 extract]	120 mg
Jujube (Ziziphus spinosa) [Fruit 4:1 extract]	120 mg
Chinese Asparagus (Asparagus cochinchinensis) [Root 4:1 extract]	70 mg
Dong Quai (Angelica sinensis) [Root 4:1 extract]	70 mg
Ophiopogon (Ophiopogon japonicus) [Root 4:1 extract]	70 mg
Scrophularia (Scrophularia ningpoensis) [Root 4:1 extract]	70 mg
Asian Ginseng (Panax ginseng) [Root 4:1 extract]	40 mg
Chinese Salvia (Salvia miltiorrhiza) [Root 4:1 extract]	40 mg
Poria Fungus (Wolfiporia cocos) [Whole 4:1 extract]	40 mg
Polygala (Polygala tenuifolia) [Root 4:1 extract]	40 mg
Platycodon (Platycodon grandiflorum) [Root 4:1 extract]	30 mg

**Inactive Ingredients:** Microcrystalline cellulose, croscarmellose sodium, cellulose, stearic acid (vegetable), silica, magnesium stearate (vegetable), and coating (hypromellose, medium-chain triglycerides, and hydroxypropylcellulose).

**This product is suitable for Vegetarians, is non-GMO, gluten and dairy free.**

(Sugar free)

#### PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

#### INDICATION & PHARMACOLOGICAL ACTION

SERENAGEN® offers a unique combination of adaptogenic herbs traditionally used to support organs and systems involved in the stress response.

Formulated for individuals who are stressed and tense.



#### WARNING AND SPECIAL PRECAUTIONS

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: Diabetes, high blood pressure, Bleeding disorders, Hormone-sensitive conditions such as breast cancer, uterine cancer, ovarian cancer, endometriosis, or uterine fibroids. If you are taking the following medication, please consult with your healthcare professional before taking: diabetes (Antidiabetes drugs), high blood pressure (Antihypertensive drugs), Bleeding disorders, slow blood clotting (Anticoagulant / Antiplatelet drugs). If any of the following happens, stop using SERENAGEN® and tell your doctor or go to the casualty department at your nearest hospital:

- Allergic reactions— rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing; These are all very serious effects. If you have them, you may have had a serious reaction to SERENAGEN®. You may need urgent medical attention or hospitalisation.

Side effects that usually do not require medical attention (report to your healthcare professional if they continue):

- nausea/vomiting, constipation, loss of appetite, increased thirst, increased urination, mental/mood changes, unusual tiredness.

These are all very serious effects. If you have them, you may have had a serious reaction to SERENAGEN®. You may need urgent medical attention or hospitalisation.

Seek advice from a healthcare professional if you have any medical condition. Discontinue use immediately should any adverse reaction occur.

Read this leaflet carefully because it contains important information for you. This product is available without a doctor's prescription.

- Keep this leaflet. You may need to read it again.
- Do not share medication with any other person.
- Ask your pharmacist if you need more information or advice.
- You must consult a doctor should your condition worsen or does not improve.

**DO NOT USE THIS PRODUCT:**

- If you are hypersensitive (allergic) to any of the ingredients listed.
- Do not accept this package if seals are broken.

#### INTERACTIONS

Always tell your healthcare professional if you are taking any other medicine. It is possible that exposure of certain supplement ingredients may interfere with certain medications. (See **Warnings & Special precautions**)

**Surgery:** SERENAGEN® might affect blood sugar levels. This might interfere with blood sugar control during and after surgery. Stop using SERENAGEN® at least 2 weeks before a scheduled surgery. **Latex allergy:** People who are allergic to latex might also be allergic to SERENAGEN®.

#### DOSAGE AND DIRECTIONS FOR USE

**Adults:** Take two (2) tablets daily or as directed by your healthcare practitioner.

**Do not take more than the recommended dose.**

#### SIDE EFFECTS

Should your general health worsen, or if you experience any untoward effects while being exposed to this product, please consult your doctor, pharmacist or other healthcare professional for advice.

#### KNOWN SYMPTOMS OF OVER DOSAGE AND PARTICULARS OF ITS TREATMENT

See side-effects.

#### Treatment:

Discontinue use and consult your doctor, pharmacist or other healthcare professional for advice.

#### STORAGE INSTRUCTION

Store in a cool, dark place, below 25 °C.

Protect from direct sunlight and heat.

Store in the original bottle.

Keep the bottle tightly closed.

Replace the protective cap after each use.

Do not use after the expiry date stated on the bottle.

Do not use SERENAGEN® if you notice visible signs of deterioration.

#### IDENTIFICATION

Brown, speckled, coated oval tablet.

#### PRESENTATION

**60 TABLETS** - A white 175 ml HDPE bottle with a white cap, induction seal, tamper shrink seal, wadding and silica gel sachet.

**120 TABLETS** - A white 250 ml HDPE bottle with a white cap, induction seal, tamper shrink seal, wadding and silica gel sachet.

#### REGISTRATION NUMBER

To be allocated by SAHPRA upon registration.

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

#### NAME AND BUSINESS ADDRESS OF APPLICANT

Distributed by:

Amipro Advanced Development Products (Pty) Ltd  
Unit 3, Eastgate Business Park, 1 South Road, Eastgate Extension,  
Sandton, 2146

Tel: 011-802-8101

#### DATE OF PUBLICATION

To be allocated by the regulatory authority.

Ingredients	Uses for ingredient
Rehmannia (Rehmannia glutinosa)	Some chemicals in rehmannia might affect the immune system and nervous system. Rehmannia might also reduce pain and swelling.
Schisandra (Schisandra chinensis)	Some people use schisandra for improving vision and muscular activity, protecting against radiation, preventing motion sickness, preventing infection, boosting energy at the cellular level, and improving the health of the adrenal glands.
Jujube (Ziziphus spinosa)	Jujubes are widely used in alternative medicine to improve sleep quality and brain function. Emerging research suggests their unique antioxidants may be responsible for these effects.
Dong Quai (Angelica sinensis)	Dong Quai is a powerful adaptogen that may help protect the body from stress and disease, boost the immune system, and create balance in the body.
Chinese Asparagus (Asparagus cochinchinensis)	Asparagus can increase urine production and is also a good source of dietary fiber, folic acid, vitamin C, vitamin E, vitamin B6, and several minerals.
Ophiopogon (Ophiopogon japonicus)	Ophiopogon japonicus is used to treat colitis and other intestinal barrier abnormalities.
Scrophularia (Scrophularia ningpoensis)	S. ningpoensis is a valuable Chinese medicinal herb with many pharmacological uses in the treatment of cardiovascular, diabetic, and liver diseases.
Asian Ginseng (Panax ginseng)	Panax ginseng contains many active chemicals. The most important are called ginsenosides or panaxosides. Panax ginseng is taken by mouth for memory and thinking skills.
Chinese Salvia (Salvia miltiorrhiza)	Miltiorrhiza is characterized as a common drug for promoting blood circulation and removing blood stasis.
Poria Fungus (Wolfiporia cocos)	Poria mushroom contains chemicals that might reduce swelling and change immune function. Poria mushroom has been used for memory, anxiety, fatigue, and many other conditions.
Polygala (Polygala tenuifolia)	It is thought to relax the mind, calm emotions and help with sleeping.
Platycodon (Platycodon grandiflorum)	Platycodon grandiflorus (PG) has been shown to be beneficial in relieving cough and asthma and to have anti-tumor, anti-inflammatory, anti-diabetic activities.

#### CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take SERENAGEN® if you are hypersensitive (allergic) to any of the ingredients. If you have allergies, be sure to check with your healthcare professional before taking this supplement.

# PROFESIONELE INLIGTINGSBLAD

SKEDULERINGSSTATUS: 50

Kategorie D: Komplementêre medisyne.

Dissipline: Dissipline Spesifiek

33.4 Tradisionele Chinese medisyne

HANDELSNAAM EN DOSEERVORM,

## SERENAGEN®, 60 & 120 tablette

### SAMESTELING

**Elke twee (2) tablette SERENAGEN® bevat die volgende aktiewe stowwe:**

Rehmannia (Rehmannia glutinosa) [Wortel 4:1 uittreksel]	290 mg
Schisandra (Schisandra chinensis) [Vrug 4:1 uittreksel]	120 mg
Jujube (Ziziphus spinosa) [Vrug 4:1 uittreksel]	120 mg
Chinese Asperge (Asparagus cochinchinensis) [Wortel 4:1 uittreksel]	70 mg
Dong Quai (Angelica sinensis) [Wortel 4:1 uittreksel]	70 mg
Ophiopogon (Ophiopogon japonicus) [Wortel 4:1 uittreksel]	70 mg
Scrophularia (Scrophularia ningpoensis) [Wortel 4:1 uittreksel]	70 mg
Asiatiese Ginseng (Panax ginseng) [Wortel 4:1 uittreksel]	40 mg
Chinese Salvia (Salvia miltiorrhiza) [Wortel 4:1 uittreksel]	40 mg
Poria Fungus (Wolfiporia cocos) [Hele 4:1 uittreksel]	40 mg
Polygala (Polygala tenuifolia) [Wortel 4:1 uittreksel]	40 mg
Platycodon (Platycodon grandiflorum) [Wortel 4:1 uittreksel]	30 mg

**Onaktiewe bestanddele:** Mikrokristallyne sellulose, kroskarmellose-natrium, sellulose, steariensuur (plant), silika, magnesiumstearaat (plant), en bedekking (hipromellose, mediumketting triglyseriede, en hidrokispiroellose).

**Hierdie produk is geskik vir vegetariërs, is nie-GGO, gluten en suiwelvr.**

### FARMAKOLOGIESE KLASSIFIKASIE

Komplementêre medisyne

### AANDUIDING EN FARMAKOLOGIESE WERKING

**SERENAGEN®** bied 'n unieke kombinasie van adaptogene kruie wat tradisioneel gebruik word om die organe en stelsels te ondersteun wat betrokke is by die liggaam se stresreaksie. Dit is geformuleer vir individue wat gestres en gespanne is.

**KONTRA-INDIKASIES:** As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **SERENAGEN®** neem as jy hipersensitief (allergies) is vir enige van die bestanddele nie. As jy allergieë het, maak seker dat jy met jou gesondheidsorgpraktisyn gaan voordat jy hierdie aanvulling neem.

Bestanddele	Gebruik vir bestanddeel
Rehmannia (Rehmannia glutinosa)	Sommige chemikalieë in rehmannia kan die immuunstelsel en senuweestelsel beïnvloed. Rehmannia kan ook pyn en swelling verminder.
Schisandra (Schisandra chinensis)	Sommige mense gebruik skisandra vir die verbetering van visie en spieraktiwiteit, beskerming teen bestraling, voorkoming van bewegingsiekte, voorkoming van infeksie, die bevordering van energie op sellulêre vlak en die verbetering van die gesondheid van die biniere.
Jujube (Ziziphus spinosa)	Jujubes word wyd gebruik in alternatiewe medisyne om slaapkwiliteit en breinfunksie te verbeter. Opkomende navorsing dui daarop dat hul unieke antioksidante verantwoordelik kan wees vir harte-afsette.
Dong Quai (Angelica sinensis)	Dong Quai is 'n kragtige adaptogeen wat kan help om die liggaam teen stres en siektes te beskerm, die immuunstelsel 'n hupstoot te gee en balans in die liggaam te skep.
Chinese asperies (Asparagus cochinchinensis)	Asperies kan urineproduksie verhoog en is ook 'n goeie bron van dieetvesel, foliensuur, vitamien C, vitamien E, vitamien B6 en verskeie minerale.
Ophiopogon (Ophiopogon japonicus)	Ophiopogon japonicus word gebruik om kolitis en ander dermsverperringsafwykings te behandel.
Scrophularia (Scrophularia ningpoensis)	S. ningpoensis is 'n waardevolle Chinese medisinale kruie met baie farmakologiese gebruike in die behandeling van kardiovaskulêre, diabetiese en lewersiektes.
Asiatiese ginseng (Panax ginseng)	Panax ginseng bevat baie aktiewe chemikalieë. Die belangrikste word ginsenosides of panaxosides genoem. Panax ginseng word deur die mond geneem vir geheue en denkvaardighede.
Chinese Salvia (Salvia miltiorrhiza)	Salvia miltiorrhiza word gekenmerk as 'n algemene middel vir die bevordering van bloedsirkulasie en die verwydering van bloedstase.
Poria swam (Wolfiporia cocos)	Poria-sampioen bevat chemikalieë wat swelling kan verminder en immuunfunksie kan verander. Poria sampioen is gebruik vir geheue, angst, moegheid en baie ander toestande.
Polygala (Polygala tenuifolia)	Daar word vermoed dat dit die gees ontspan, emosies kalmeer en help met slaap.
Platycodon (Platycodon grandiflorum)	Daar is getoon dat Platycodon grandifloras (PG) voordelig is om hoë en asma te verlig en dat dit anti-tumor, anti-inflammatoriese, anti-diabetiese aktiwiteite het.

### WAARSKUWING EN SPESIALE VOORSORGMATREËLS

Indien jy enige van die volgende gedagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik Diabetes, hoë bloeddruk, bloedingsversteurings, hormoonsensitiewe toestande soos borskanker, baarmoederkanker, eierstokkanker, endometriose of baarmoederfibroïede. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisyn voordat jy neem: diabetes (Antidiabetes dwelms), hoë bloeddruk (Antihypertensiewe middels), Bloedingsversteurings, stadige bloedstolling (Antikoagulant / Antiplaatjie middels). As enige van die volgende gebeur, hou onse SERENAGEN® te gebruik en vertel jou dokter of gaan na die ongevallende afdeling by jou naaste hospitaal:

- Allergiese reaksies- uitslag, jeuk / swelling (veral van die gesig / tong / keel), erge duiseligheid, probleme met asemhaling.; Dit is alles baie ernstige gevolge. As jy dit het, het jy dalk 'n ernstige reaksie op **SERENAGEN®** gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig hê.

Neuwe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteer aan jou gesondheidsorgpraktisyn as hulle voortduur):

- naarheid / braking, hardlywigheid, verlies aan eetlus, verhoogde dors, verhoogde urinering, geestelike / gemoedsveranderinge, ongewone moegheid.

Dit is alles baie ernstige gevolge. As u dit het, het u moontlik 'n ernstige reaksie op **SERENAGEN®** gehad. Miskien het u dringende mediese hulp of hospitalisasie nodig.

Raadpleeg 'n gesondheidsorgpraktisyn as u enige mediese toestand het. Staak baie onmiddellik indien enige nadelige reaksie plaasvind. Lees hierdie inligtingsblad aandagtig deur, want dit bevat belangrike inligting vir u. Hierdie produk is beskikbaar sonder doktersvoorskrif.

- Hou hierdie inligtingsblad. Miskien moet u dit weer lees.
- Moenie medisyne met enige ander persoon deel nie.
- Vra jou apteker of jy meer inligting of advies benodig.
- Jy moet 'n dokter raadpleeg indien jou toestand vererger of nie verbeter nie.

### MOENIE HIERDIE PRODUK GEBRUIK NIE:

- As jy hipersensitief (allergies) is vir enige van die bestanddele wat gehels word.
- Jy moet nie hierdie produk aanvaar as seëls gebreek word nie.

### INTERAKSIES

Vertel altyd jou gesondheidsorgpraktisyn as jy enige ander medisyne gebruik. Dit is moontlik dat blootstelling van sekere aanvullingsbestanddele met sekere medisyne 'n interaksie mak hê. (Sien **Waarskuwings en Spesiale voorsorgmatreëls**)

**Chirurgie:** **SERENAGEN®** kan bloedsuikervlakke beïnvloed. Dit kan inmeng met bloedsuikerbeheer tydens en na die operasie. Hou op om **SERENAGEN®** ten minste 2 weke voor 'n geskeduleerde operasie te gebruik. **Latexallergie:** Mense wat allergies is vir latex kan ook allergies wees vir **SERENAGEN®**.

### DOSES EN AANWYSINGS VIR GEBRUIK

**Volwasse:** Neem twee (2) tablette daagliks of soos voorgeskryf deur jou gesondheidspraktisyn.

**Moenie meer as die aanbevole dosis neem nie.**

### NEWE-EFFEKTE

Indien jou algemene gesondheid vererger of as jy enige nadelige effekte ervaar tydens die gebruik van hierdie medisyne, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgpraktisyn vir raad. As jy enige nuwe-effekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteker of gesondheidsorgpraktisyn in kennis.

### BEKENDE SIMPTOME VAN OORDOESING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN

Sien nuwe-effekte.

### Behandeling:

Staak gebruik en raadpleeg jou dokter, apteker of ander gesondheidsorgpraktisyn vir advies.

### BERGING INSTRUKSIE

Bêre in 'n koel, donker plek, onder 25 °C.

Beskerk teen direkte sonlig en hitte.

Bêre n die oorspronklike bottel.

Hou die bottel styf toe.

Vervang die beskermende dop na elke gebruik.

Moet nie gebruik word na die vervaldatum wat op die bottel aangedui word nie.

Moenie **SERENAGEN®** gebruik as u sigarete tekens van agteruitgang opmerk nie.

### IDENTIFIKASIE

Bruin, gesjikkelde, bedekte ovaal tablet.

### AANBEDIING

**60 TABLETTE** - 'n Wit 175 ml HDPE-bottel met 'n wit dop, induksieseel, peuterkrimpseel, spons en silikagelsakkie.

**120 TABLETTE** - 'n Wit 250 ml HDPE-bottel met 'n wit dop, induksieseel, peuterkrimpseel, spons en silikagelsakkie.

### REGISTRASIE NOMMER

Om by registrasie deur SAHPRA toegeken te word.

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

### NAAM EN BESIGHEIDSADRES VAN APPLIKANT

**Versprei deur:** Amipro Advanced Development Products (Pty) Ltd

Unit 3, Eastgate Business Park, 1 South Road,

Eastgate Extension,

Sandton, 2146,

Tel: 011- 802-8101

### DATUM VAN PUBLIKASIE

Om deur die regulerende owerheid toegeken te word.

