

PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline: Discipline specific

33.7 Combination Product

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

CONCENTRATED ULTRA PROSTAGEN™,

60 Capsules

COMPOSITION

Each one (1) capsule of CONCENTRATED ULTRA PROSTAGEN™ contains the following actives:

Saw Palmetto (<i>Serenoa repens</i>) [Berry Extract standardized 320 mg to 45 % (144 mg) fatty acids and sterols]	320 mg
Stinging Nettle (<i>Urtica dioica</i>) [Root 10:1 Extract]	100 mg
Glycine	50 mg
L-Alanine	50 mg
L-Glutamic Acid	50 mg
Vitamin B6 (as pyridoxine HCl)	10 mg
Zinc (as zinc citrate)	7.5 mg
Lycopene	2 mg
Vitamin D (as Cholecalciferol)	5 µg (200 I.U.)

Inactive Ingredients: Capsule (hydroxypropylmethylcellulose), dicalcium phosphate, magnesium stearate (vegetable), microcrystalline cellulose.

This product is dairy and gluten free and non-GMO. (Sugar free)

PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

INDICATION & PHARMACOLOGICAL ACTION

CONCENTRATED ULTRA PROSTAGEN™ supports healthy prostate and urinary function while maintaining overall good health.

Ingredient	Uses for Ingredients
Saw Palmetto (<i>Serenoa repens</i>)	Supports prostate health, alleviates symptoms of benign prostatic hyperplasia (BPH), and promotes urinary health.
Stinging Nettle (<i>Urtica dioica</i>)	Helps manage urinary symptoms associated with BPH and provides support for inflammatory conditions.
Glycine	Enhances collagen production, supports muscle recovery, and promotes healthy sleep patterns.
L-Alanine	Supports energy production and aids in muscle recovery during physical activity.
L-Glutamic Acid	Plays a role in protein synthesis, supports gut health, and acts as a neurotransmitter precursor for the brain.
Vitamin B6 (as pyridoxine HCl)	Supports energy metabolism, aids in the production of neurotransmitters, and helps regulate hormonal activity.
Zinc (as zinc citrate)	Promotes immune function, supports wound healing, and aids in skin health and reproductive health.
Lycopene	Provides antioxidant support, promotes cardiovascular health, and may protect against oxidative stress.
Vitamin D (as Cholecalciferol)	Supports bone health, aids in calcium absorption, and promotes a healthy immune system.

CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take CONCENTRATED ULTRA PROSTAGEN™ 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. **SURGERY: CONCENTRATED ULTRA PROSTAGEN™** should be discontinued at least 2 weeks prior to reduce bleeding risks.

LABORATORY TESTS: Monitor potential interference with PSA levels, glucose tests, and liver/metabolic tests. Advise your healthcare professional that you are taking CONCENTRATED ULTRA PROSTAGEN™ before having any laboratory tests. **ANTIBIOTICS: CONCENTRATED ULTRA PROSTAGEN™** may reduce the efficacy of antibiotics like fluoroquinolones and tetracyclines if taken together. Take CONCENTRATED ULTRA PROSTAGEN™ two hours before or after any antibiotic medication.

WARNING AND SPECIAL PRECAUTIONS

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: Hormone-sensitive conditions (e.g., prostate or breast cancer), Bleeding disorders (mild anticoagulant effects), Hypoglycemia or diabetes (may lower blood sugar levels), Kidney disease (diuretic effects may worsen symptoms), Wilson's disease or copper deficiency (zinc competes with copper for absorption), Hypercalcemia or hyperparathyroidism, Kidney disease (risk of calcium-phosphate deposition). If you are taking the following medication, please consult with your healthcare practitioner before taking: Increases bleeding risk when combined with anticoagulants (e.g., warfarin, aspirin). Can affect PSA levels, interfering with prostate cancer diagnostics. May enhance the effects of diuretics, leading to electrolyte imbalances. Can potentiate hypoglycemic medications (e.g., insulin, metformin). May enhance the sedative effects of CNS depressants (e.g., benzodiazepines, barbiturates). Reduces effectiveness of isoniazid, hydralazine, and penicillamine by competing for metabolism. Reduces absorption of antibiotics (e.g., fluoroquinolones, tetracyclines). May interact with anticoagulants, increases risk of hypercalcemia when combined with calcium supplements or thiazide diuretics. If any of the following happens, stop using CONCENTRATED ULTRA PROSTAGEN™ 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 CONCENTRATED ULTRA PROSTAGEN™. 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):

- Gastrointestinal discomfort, headaches, metallic taste in the mouth.

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**)

DOSAGE AND DIRECTIONS FOR USE

Adults Take one (1) capsule daily or as advised 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 CONCENTRATED ULTRA PROSTAGEN™ if you notice visible signs of deterioration.

IDENTIFICATION

Clear, vegetable capsule, with a tan fill.

PRESENTATION

A white 175 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.

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PROFESIONELE INLIGTINGSBLAD

SKEDULERINGSSTATUS: **S0**

Kategorie D: Komplementêre medisyne.

Dissipline: Dissipline spesifiek

33.7 Kombinasie produk

HANDELSNAAM EN DOSEERVORM,

CONCENTRATED ULTRA PROSTAGEN™,

60 Kapsules

SAMESTELING

Elke (1) kapsule **CONCENTRATED ULTRA PROSTAGEN™** bevat die volgende aktiewe stowwe:

Saw Palmetto (<i>Serenoa repens</i>) [Berry Extract gestandaardiseer 320 mg tot 45% (144 mg) vetsure en steroïe]	320 mg
Brandnetel (<i>Urtica dioica</i>) [Wortel 10:1 Uittreksel]	100 mg
Glisien	50 mg
L-alanien	50 mg
L-glutamiensuur	50 mg
Vitamiën B6 (as piridoksien HCl)	10 mg
Sink (as sinkstraat)	7,5 mg
Likopeen	2 mg
Vitamiën D (as Cholecalciferol)	5 µg (200 IE)

Onaktiewe bestanddele: : Kapsule (hydroxypropylmethylcellulose), dicalciumfosfaat, magnesiumstearaat (groente), mikrokristallyne sellulose.

Hierdie produk is suiwel- en glutenry en nie-GGO. (Suikervry)

FARMAKOLOGIESE KLASSIFIKASIE

Komplementêre medisyne

AANDUIDING EN FARMAKOLOGIESE WERKING

CONCENTRATED ULTRA PROSTAGEN™ is 'n dubbelaksieformule wat gewig ondersteun bestuur, en gesonde glukosemetabolisme, terwyl dit ondersteun gesonde cholesterolvlakke.

Bestanddeel	Gebruik vir bestanddele
Saw Palmetto (<i>Serenoa repens</i>)	Ondersteun prostaatgesondheid, verlig simptome van goedaardige prostaathiperplasie (BPH) en bevorder urinêre gesondheid.
Brandnetel (<i>Urtica dioica</i>)	Help om urinêre simptome wat met BPH geassosieer word, te bestuur en bied ondersteuning vir inflammatiese toestande.
Glisien	Verhoog kollageenproduksie, ondersteun spierherstel en bevorder gesonde slaappatrone.
L-alanien	Ondersteun energieproduksie en help met spierherstel tydens fisieke aktiwiteit.
L-glutamiensuur	Speel 'n rol in proteïensintese, ondersteun dermisgesondheid en dien as 'n neurotransmitter-voorloper vir die brein.
Vitamiën B6 (as piridoksien HCl)	Ondersteun energiemetabolisme, help met die produksie van neurotransmitters en help om hormonale aktiwiteit te reguleer.
Sink (as sinkstraat)	Bevorder immuunfunksie, ondersteun wondgenesing en help met velgesondheid en reprodktiewe gesondheid.
Likopeen	Bied antioksidantondersteuning, bevorder kardiovaskulêre gesondheid en kan beskerm teen oksidatiewe stres.
Vitamiën D (as Cholecalciferol)	Ondersteun beengesondheid, help met kalsiumabsorpsie en bevorder 'n gesonde immuunstelsel.

KONTRA-INDIKASIES:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **CONCENTRATED ULTRA PROSTAGEN™** 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.

CHIRURGIE: CONCENTRATED ULTRA PROSTAGEN™ moet ten minste 2 weke voor chirurgie om die vermindering van bloedingsrisiko's gestaak word.

LABORATORIUMTOETSE: Monitor potensieël inmenging met PSA-vlakke, glukose-toetse en lewer-/metaboliese toetse. Vertel asseblief jou gesondheidswerker dat jy **CONCENTRATED ULTRA PROSTAGEN™** neem voordat jy enige laboratoriumtoetse ondergaan.

ANTIBIOTIKA: CONCENTRATED ULTRA PROSTAGEN™ kan die doeltreffendheid van antibiotika soos fluorokinolone en tetrasikliene verminder as dit saam geneem word. Neem **CONCENTRATED ULTRA PROSTAGEN™** twee ure voor of na enige antibiotiese medisyne.

WAARSKUWING EN SPESIALE VOORSORGMATREËLS

Indien jy enige van die volgende gediagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Hormoonsonstiewe toestande (bv. prostaat- of borskanker), Bloedversteurings (ligte antikoagulantiese effekte), Hipoglukemie of diabetes (kan bloedsuikervlakke verlaag), Niersiekte (diuretiese effekte kan simptome vererger), Wilson se siekte of kopertekort (sink kompeteer) met koper vir absorpsie), hiperkalsemie of hiperparatiroïedisme, niersiekte (risiko van kalsiumfosfaatafsetting). As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisyn voordat jy neem: Verhoog die risiko van bloeding wanneer dit gekombineer word met antikoagulant (bv. warfarin, aspirien), kan PSA-vlakke verhoog, innem met prostaatkankerdiagnostiek, Kan die effekte van diuretika versterk, wat lei tot elektrolietwanbalanse, Kan hipoglisemiese medikasie versterk (bv. insulien, metformien), Kan die kalmerende effekte van SSS-depressante (bv. bensodiasepiene, barbiturate), Verminder doeltreffendheid van isoniazied, hidralasien en penisillasien deur om metabolisme te kompeteer, Verminder absorpsie van antibiotika (bv. fluorokinolone, tetrasikliene), Kan interaksie met antikoagulant hê, Verhoog die risiko van hiperkalsemie wanneer dit gekombineer word met kalsiumaanvullings of tiasieddiuretika.

As enige van die volgende gebeur, hou op om **CONCENTRATED ULTRA PROSTAGEN™** te gebruik en vertel jou dokter of gaan na die ongevallen-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 **CONCENTRATED ULTRA PROSTAGEN™** 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):
 - Gastro-intestinale ongemak, hoofpyn, metaalsmaak in die mond..

Dit is alles baie ernstige gevolge. As u dit het, het u moontlik 'n ernstige reaksie op **CONCENTRATED ULTRA PROSTAGEN™** gehad. Miskien het u dringende mediese hulp of hospitalisasie nodig. Raadpleeg 'n gesondheidsorgpraktisyn as u enige mediese toestand het. Staak gebruik 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 gelys 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 mag hê. (Sien **Waarskuwings en Spesiale voorsorgmaatreëls**)

DOSES EN AANWYSLINGS VIR GEBRUIK

Volwassenes Neem daaglik een (1) kapsule of soos aanbeveel 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.

BEKEMDE SIMPTOME VAN OORDOSEERING 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.

Beskermt teen direkte sonlig en hitte.

Bêre n die oorspronklike bottel.

Hou die bottel styf toe.

Vervang die beskermede dop na elke gebruik.

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

Moenie **CONCENTRATED ULTRA PROSTAGEN™** gebruik as jy sigbare tekens van agteruitgang opmerk nie.

IDENTIFIKASIE

Duidelike, groentekapsule, met 'n bruin vulsel.

AANBIEDING

'n Wit 175 ml HDPE-bottel met 'n wit dop, indusiesieël, peuterkrimpseël, 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: Ampiro 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.