PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0.
Category D: Complementary medicine.
Discipline: Discipline specific
33.7 Combination Product

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

CONCENTRATED ULTRA PROSTAGEN™, 60 Capsules

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

- **CONCENTRATED ULTRA PROSTAGEN™ is** available without a doctor's prescription.
- Nevertheless, you still need to use **CONCENTRATED ULTRA PROSTAGEN™** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **CONCENTRATED ULTRA PROSTAGEN™** with any other person.
- Ask your pharmacist or healthcare professional if you need more information or advice.

WHAT IS IN THIS LEAFLET

WHAT CONCENTRATED ULTRA PROSTAGEN™ CONTAINS

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

Saw Palmetto (*Serenoa repens*) [Berry Extract standardized 320 mg to 45 % (144 mg) fatty acids and sterols]	320 mg
Stinging Nettle (*Urtica dioica*) [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)

WHAT CONCENTRATED ULTRA PROSTAGEN™ IS AND WHAT IT IS USED FOR CONCENTRATED ULTRA PROSTAGEN™ supports healthy prostate and urinary function while maintaining overall good health.

BEFORE YOU TAKE CONCENTRATED ULTRA PROSTAGEN™

If you are taking any chronic medication, do not use this product without consulting your healthcare provider. 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.
This medicine has not been evaluated by the SAHPRA for quality, safety, or intended use.

PREGNANCY AND BREASTFEEDING

Safety during pregnancy and breastfeeding has not been established, consult with your healthcare professional before use. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult with your healthcare professional before taking this supplement.

DRIVING AND USING MACHINES

It is not always possible to predict to what extent **CONCENTRATED ULTRA PROSTAGEN™** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in activities relating to requiring mental alertness, judgement and/or sound co-ordination and vision e.g. driving, riding, flying, sailing, operating machines/equipment, until they are aware of the measure to which **CONCENTRATED ULTRA PROSTAGEN™** may affect you.

TAKING OTHER MEDICINES WITH CONCENTRATED ULTRA PROSTAGEN™

Complementary medicine products contain ingredients which may interact with some medication. If you are taking any chronic medication, do not use this product without consulting your medical practitioner

HOW TO TAKE CONCENTRATED ULTRA PROSTAGEN™

Do not share medicines prescribed for you with any other person. Always take **CONCENTRATED ULTRA PROSTAGEN™** exactly as described in this leaflet, or as your doctor, healthcare provider has instructed you. You should check with your doctor, pharmacist or healthcare provider if you are unsure.

Directions for use:

Adults Take one (1) capsule daily or as advised by your healthcare practitioner. **Do no take more than the recommended dose.**

IF YOU TAKE MORE CONCENTRATED ULTRA PROSTAGEN™ THAN YOU SHOULD

In the event of overdosage, consult your doctor, pharmacist. Should none of these be available, contact the nearest hospital or poison control centre.

IF YOU FORGET TO TAKE CONCENTRATED ULTRA PROSTAGEN™

Do not take a double dose to make up for a missed dose.

POSSIBLE SIDE EFFECTS

CONCENTRATED ULTRA PROSTAGEN™ may have side effects.
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, metalic taste in the mouth.

Not all side effects and interactions reported for **CONCENTRATED ULTRA PROSTAGEN™** are included in this leaflet.
Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice. If you notice any side effects not mentioned in this leaflet, please inform your doctor, pharmacist or healthcare professional.

REPORTING OF SIDE EFFECTS

If you experience side effects, talk to your doctor, pharmacist or other healthcare professional. You can also report side effects to SAHPRA via "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 **CONCENTRATED ULTRA PROSTAGEN™.**

STORAGE AND DISPOSING OF CONCENTRATED ULTRA PROSTAGEN™

Store all medicines out of the reach of children.
Store in a cool, dark place, below 25 °C.
Protect from direct sunlight and heat.
Store in the original packaging.
Do not use after the expiry date stated on the bottle.
Do not use **CONCENTRATED ULTRA PROSTAGEN™** if you notice visible signs of deterioration.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF CONCENTRATED ULTRA PROSTAGEN™

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

IDENTIFICATION OF CONCENTRATED ULTRA PROSTAGEN™

Clear, vegetable capsule, with a tan fill.

REGISTRATION NUMBER

To be allocated by SAHPRA upon registration.

ACCESS TO THE CORRESPONDING PROFESSIONAL INFORMATION

Scan QR code.

THIS LEAFLET WAS LAST REVISED ON

06 January 2025

NAME AND ADDRESS OF REGISTRATION HOLDER

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Unit 3, Eastgate Business Park, 1 South Road, Eastgate Extension, Sandton, 2146
Tel: 011-802-8101

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PASIËNT INLIGTINGSBLAD

SKEDULERINGSTATUS: S0
Kategorie D: Komplementêre medisyne.
Dissipline: Dissipline spesifiek
33.7 Kombinasie produk

HANDELSNAAM EN DOSEERVORM**,**

CONCENTRATED ULTRA PROSTAGEN™,

60 Kapsules

LEES HIERDIE INLIGTINGSBLAD NOUKEURIG, WANT DIT BEVAT BELANGRIKE INLIGTING VIR U

- **CONCENTRATED ULTRA PROSTAGEN™** is beskikbaar sonder doktersvoorskrif**.**
- U moet steeds **CONCENTRATED ULTRA PROSTAGEN™** versigtig gebruik om die beste resultate daaruit te kry.
- Hou hierdie inligtingsblad. Miskien moet u dit weer lees.
- Moenie **CONCENTRATED ULTRA PROSTAGEN™** met enige ander persoon deel nie**.**
- Vra jou apteker of gesondheidsorgpraktisyn of jy meer inligting of advies benodig.

WAT IS IN HIERDIE INLIGTINGSBLAD

- Wat **CONCENTRATED ULTRA PROSTAGEN™** is en waarvoor dit gebruik word.
- Wat jy moet weet voordat jy **CONCENTRATED ULTRA PROSTAGEN™** neem**.**
- Hoe om **CONCENTRATED ULTRA PROSTAGEN™** te neem.
- Moontlike newe-effekte.
- Hoe om **CONCENTRATED ULTRA PROSTAGEN™** te bêre.
- Inhoud van die pak en ander inligting

WAT CONCENTRATED ULTRA PROSTAGEN™ BEVAT
Elke een (1) kapsule CONCENTRATED ULTRA PROSTAGEN™ bevat die volgende aktiewe:

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

Onaktiewe bestanddele: Kapsule (hydroxypropylmethylcellulose), dicalciumfosfaat, magnesiumstearaat (groente), mikrokristallyne sellulose.
Hierdie produk is suiwel- en glutenvry en nie-GGO. (Suikervry)

WAT IS CONCENTRATED ULTRA PROSTAGEN™ KAPSULES EN WAARVOOR WORD DIT GEBRUIK
CONCENTRATED ULTRA PROSTAGEN™ ondersteun gesond prostaat- en urinêre funksie terwyl die algehele gehandhaaf word goeie gesondheid.

VOORDAT JY CONCENTRATED ULTRA PROSTAGEN™ NEEM
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 potensiële inmenging met PSA-vlakke, glukosetoetse 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.
Hierdie medisyne is nie deur SAHPRA geëvalueer vir kwaliteit, veiligheid of beoogde gebruik nie.

SWANGERSKAP EN BORSVOEDING
Veiligheid tydens swangerskap en borsvoeding is nie vasgestel nie, raadpleeg u gesondheidsorgpraktisyn voor gebruik. As u swanger is of borsvoed, dink dat u swanger is of beplan om 'n baba te hê, raadpleeg u gesondheidsorgpraktisyn voordat u hierdie aanvulling neem.

BESTUUR EN GEBRUIK VAN MASJIENE
Dit is nie altyd moontlik om te voorspel in watter mate **CONCENTRATED ULTRA PROSTAGEN™** die daaglikse aktiwiteite van 'n pasiënt kan belemmer nie. Pasiënte moet seker maak dat hulle nie betrokke raak by aktiwiteite wat verband hou met die vereiste van verstandelike waaksaamheid, oordeel en/of gesonde koördinasie en visie nie, byvoorbeeld bestuur, ry, vlieg, seil, bedryfsmasjiene/toerusting, totdat hulle bewus is van die mate waartoe **CONCENTRATED ULTRA PROSTAGEN™** jou beïnvloed.

NEEM VAN ANDER MEDISYNE SAAM MET CONCENTRATED ULTRA PROSTAGEN™
Komplementêre medisyne produkte bevat bestanddele wat met sommige medisyne 'n interaksie kan hê. As jy enige chroniese medisyne gebruik, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie.
HOE OM CONCENTRATED ULTRA PROSTAGEN™ TE NEEM
Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie. Neem altyd **CONCENTRATED ULTRA PROSTAGEN™** presies soos beskryf in hierdie inligtingsblad, of soos u dokter, gesondheidsorgpraktisyn voorgeskryf het. Raadpleeg jou dokter, apteker of gesondheidsorgpraktisyn as jy onseker is.

Aanwysings vir gebruik:
Volwassenes Neem daagliks een (1) kapsule of soos aanbeveel deur jou gesondheidspraktisyn.
Moenie meer as die aanbevole dosis neem nie.
AS JY MEER CONCENTRATED ULTRA PROSTAGEN™ NEEM AS WAT JY MOET
In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een hiervan beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.
AS JY VERGEET OM CONCENTRATED ULTRA PROSTAGEN™ TE NEEM
Moenie 'n dubbele dosis neem om op te maak vir 'n dosis wat oorgeslaan is nie.
MOONTLIKE NEWE-EFFEKTE
CONCENTRATED ULTRA PROSTAGEN™ kan newe-effekte hê.
Indien jy enige van die volgende gediagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Hormoonsensitiewe toestande (bv. prostaat- of borskanker), Bloedversteurings (ligte antikoagulante 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 antikoagulante (bv. warfarien, aspirien), Kan PSA-vlakke beïnvloed, inmeng 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 antikoagulante hê, Verhoog die risiko van hiperkalsemie wanneer dit gekombineer word met kalsiumaanvullings of tiasiedduretika. As enige van die volgende gebeur, hou op om **CONCENTRATED ULTRA PROSTAGEN™** te gebruik en vertel jou dokter of gaan na die ongevalle-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 mag dalk dringende mediese hulp of hospitalisasie nodig hê.
Newe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteer aan u gesondheidsorgpraktisyn as dit voortduur):

- Gastro-intestinale ongemak, hoofpyn, metaalsmaak in die mond.

Nie alle newe-effekte en interaksies wat vir **CONCENTRATED ULTRA PROSTAGEN™** gerapporteer word, is by hierdie inligtingsblad ingesluit nie. 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 newe-effekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteker of gesondheidsorgpraktisyn in kennis.
AANMELDING VAN NEWE-EFFEKTE
As jy newe-effekte ervaar, praat met jou dokter, apteker of ander gesondheidsorgpraktisyn. U kan ook newe-effekte aan SAHPRA rapporteer via "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind word onder SAHPRA se publikasies:
https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van **CONCENTRATED ULTRA PROSTAGEN™.**
HOE OM CONCENTRATED ULTRA PROSTAGEN™ TE BERÊ
Bêre alle medisyne buite bereik van kinders.
Bêre in 'n koel, donker plek, onder 25 °C.
Beskerm teen direkte sonlig en hitte.
Bêre in die oorspronklike verpakking.
Moet nie gebruik word na die vervaldatum wat op die bottel aangedui word nie.
Moenie **CONCENTRATED ULTRA PROSTAGEN™** gebruik as u sigbare tekens van agteruitgang opmerk nie.
Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.
AANBIEDING VAN CONCENTRATED ULTRA PROSTAGEN™
'n Wit 175 ml HDPE-bottel met 'n wit dop, induksieseël, peuterkrimpseël, spons en silikagelsakkie.
IDENTIFIKASIE VAN CONCENTRATED ULTRA PROSTAGEN™
Duidelike, groentekapsule, met 'n bruin vulsel.
REGISTRATION NOMMER - Om deur SAHPRA toegeken te word by registrasie.
TOEGANG TOT DIE OOREENSTEMMENDE PROFESSIONELE INLIGTING
Skandeer QR-kode.
HIERDIE INLIGTINGSBLAD IS LAAS HERSIEN OP
06 Januarie 2025

NAAM EN ADRES VAN REGISTRASIEHOUER
Versprei deur:
Amipro Advanced Development Products (Pty) Ltd
Unit 3, Eastgate Business Park, 1 South Road, Eastgate Extension,
Sandton, 2146
Tel: 011-802-8101