PROFESSIONAL INFORMATION
ViGRO® MEN CAPSULES

- Complementary Medicine.
- D.33.7 Complementary Medicines: Discipline Specific Traditional Claims – Combination Product.
- This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS
S0

1. NAME OF THE MEDICINE
ViGRO® MEN CAPSULES (capsules)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients	Per capsule	Per min daily dose (2 capsules)	Per max daily dose (4 capsules)	% NRV# per maximum daily dose (4 caps)
Calcium D-pantothenate (Vitamin B5)	1,25 mg	2,5 mg	5 mg	100 %
Folic acid (Vitamin B9)	100 µg	200 µg	400 µg	100 %
Cyanocobalamin (Vitamin B12)	0,6 µg	1,2 µg	2,4 µg	100 %
Ascorbic acid (Vitamin C)	25 mg	50 mg	100 mg	100 %
Cholecalciferol (Vitamin D3)	150 IU (3,8 µg)	300 IU (7,5 µg)	600 IU (15 µg)	100 %
Tocopheryl acetate (Vitamin E)	5,6 IU (3,8 mg a-TE**)	11,2 IU (7,5 mg a-TE**)	22,4 IU (15,0 mg a-TE**)	100 %
D-Biotin (Biotin)	7,5 µg	15 µg	30 µg	100 %
Copper AAC*** Providing Copper (elemental)	1,13 mg 112,5 µg	2,26 mg 225 µg	4,52 mg 450 µg	500 %
Magnesium oxide Providing Magnesium (elemental)	87,5 mg 52,77 mg	175 mg 105,54 mg	350 mg 211,08 mg	50 %
Selenium AAC*** Providing Selenium (elemental)	7 mg 14 µg	14 mg 28 µg	28 mg 56 µg	102 %
Zinc AAC*** Providing Zinc (elemental)	27,5 mg 2,8 mg	55 mg 5,5 mg	110 mg 11 mg	100 %
Serenoa repens (W. Bartram) Small (Saw palmetto) [fruit, extract standardised to 25 % fatty acids]	100 mg	200 mg	400 mg	*
Phytosterols (Beta-sitosterol)	26,3 mg (18,4 mg)	52,6 mg (36,8 mg)	105,3 mg (73,7 mg)	*
Lycopene	3,25 mg	6,5 mg	13 mg	*
Panax ginseng C.A. Meyer (Chinese ginseng) [root, extract standardised to 7,5 % ginsenosides]	26,67 mg	53,34 mg	106,68 mg	*

#Nutrient reference values for adults and children older than 4 years. *NRV not established. **D-alpha-Tocopherol Equivalents. ***Amino Acid Chelate.
ViGRO® MEN CAPSULES are sugar and preservative free. For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Capsule, hard gelatine. ViGRO® MEN CAPSULES are blue hard gelatine capsules.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
ViGRO® MEN CAPSULES is a health supplement containing nutrients in quantities targeted for promoting healthy hair and normal hair growth. ViGRO® MEN CAPSULES also promotes the health of skin and nails. ViGRO® MEN CAPSULES contains antioxidants which can assist in prevention of cellular oxidative damage.
4.2 Posology and method of administration
The recommended daily dosage is
Adults 18 years and older:
- Maintenance dosage: Two (2) capsules per day, after a meal, with a glass of water.
- Acute dosage: Four (4) capsules per day, after a meal, with a glass of water.

Advise the patient to not take dosage at the same time as other medications (see **4.5**). Advise patients to take with food to minimize gastric disturbance. Advise patients to consult with a medical practitioner if symptoms persist or worsen beyond 3 months.
4.3 Contraindications
- Must not be given to patients with known hypersensitivity or allergy towards any of the ingredients of ViGRO® MEN CAPSULES (see section 6.1 List of excipients). Patients should be advised to consult their medical practitioner if in doubt.
- Must not be given to patients with hepatic disease.
- Must not be given to patients known to have cobalamin or cobalt hypersensitivity as this product contains vitamin B12.

4.4 Special warnings and precautions for use
- Patients diagnosed or suspected to suffer from prostate cancer should consult a relevant healthcare provider prior to use. This product contains saw palmetto which may decrease Prostate-Specific Antigen (PSA) levels. This product is not intended to support prostate health or treat disease.
- Use with caution in patients with a history of non-melanoma skin cancer as this product contains selenium.
- Use with caution in patients with diabetes as this product contains *Panax ginseng*.
- Use with caution in patients taking antidepressant medication, blood thinners or digoxin (see section **4.5**).
- Patients taking any chronic medication should not use this product without consulting their medical practitioner.
- Do not exceed the daily recommended dose.
- Do not use after the date of expiry.

Porphyria
Safety has not been established.
4.5 Interaction with other medicines and other forms of interaction
No interaction studies have been performed on ViGRO® MEN CAPSULES, see below interactions with individual ingredients.

Active ingredient	Medicine	Description
Saw palmetto, vitamin E and selenium.	Blood thinners (anticoagulant or antiplatelet medication) e.g. warfarin	May have a blood thinning effect increasing the risk of bleeding and bruising.
Panax ginseng	Antidiabetic medication	*Panax ginseng* might increase the risk of hypoglycemia. Monitor blood glucose levels closely.
Panax ginseng	Digoxin	*Panax ginseng* might increase the effects of digoxin. It may also interfere with laboratory tests due to the structural similarities between ginsenosides to cardiac glycosides. Ginsenosides may falsely elevate serum digoxin concentrations when the Abbott Digoxin II assay or fluorescence polarization immunoassay (FPIA) are used. Ginsenosides may falsely lower digoxin concentrations when microparticle enzyme immunoassay (MEIA).
Magnesium and zinc	Antibiotics	May reduce the absorption of antibiotics. Oral antibiotics should be taken at least two (2) hours before, or four (4) hours after this product or similar supplements.
Magnesium	Levodopa / carbidopa	Magnesium may reduce bioavailability of levodopa / carbidopa. Take at least two (2) hours before, or four (4) hours after this product or similar supplements.

4.6 Fertility, pregnancy and lactation
Pregnancy
This product is formulated for men only. Saw palmetto is specifically contraindicated, therefore this product should not be used in patients who are pregnant.
Breastfeeding
This product is formulated for men only. Saw palmetto is specifically contraindicated, therefore this product should not be used if patients are lactating (breastfeeding).
Fertility
There are no known effects of ViGRO® MEN CAPSULES on fertility.
4.7 Effects on the ability to drive and use machines
Based on the side effect profile, ViGRO® MEN CAPSULES is not expected to affect the ability to drive or operate machinery. It is not always possible to predict to what extent this supplement may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which this supplement affects them.
4.8 Undesirable effects
ViGRO® MEN CAPSULES is generally well tolerated with the occurrence of adverse events unknown. Patients experiencing any side effects or sensitivity to any of the ingredients, should discontinue use. Adverse reactions reported in the literature are listed below, by system organ class and frequency. Frequencies are defined as:
- very common (≥1/10)
- common (≥1/100 to <1/10)
- uncommon (≥1/1,000 to <1/100)
- rare (≥1/10,000 to 1</,000)
- very rare (<1/10,000)
- not known (cannot be estimated from the available data)

Adverse events table		
System Organ Class	**Frequency**	**Adverse Event**
Immune system disorders	Not known	Hypersensitivity reactions or anaphylaxis, symptoms include: difficulty breathing or swallowing, angioedema, itchy throat, urticaria, itching.
Nervous system disorders	Not known	Insomnia, anxiety or headaches.
Gastrointestinal disorders	Not known	Abdominal discomfort or pain, constipation, diarrhoea, heartburn, nausea, vomiting.
Hepato-biliary disorders	Not known	Acute hepatitis.
Skin and subcutaneous tissue disorders	Not known	Hypersensitivity reaction (rash, pruritus, erythema, oedema and urticaria).

If symptoms persist, or if any adverse reactions occur, advise the patient to consult a healthcare provider.
Reporting of suspected adverse reactions
Reporting of suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**," found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.
4.9 Overdose
Symptoms
See **4.8 Undesirable effects**
In overdose, side effects can be precipitated and/or be increased. There is no evidence that this product can lead to an overdose when used as recommended. Due allowance should always be made for intake of the vitamins from other sources.
Treatment
If an accidental overdose occurs, treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Category and class: D.33.7 Complementary Medicines: Discipline Specific Traditional Claims – Combination Product.
Pharmacotherapeutic classification: Vitamins and other combinations
ATC code: V06DX
D-Biotin
In mammals, biotin containing enzymes are involved in gluconeogenesis, fatty acid synthesis, propionate metabolism, and catabolism of leucine. *In vivo* evidence suggests biotin may improve brittle nails and hair growth. This may be through inducing epidermal differentiation.
Panax ginseng
Some evidence proposes that *Panax ginseng* might work against stress by affecting the hypothalamic-pituitary-adrenal axis. *Panax ginseng* saponins seem to increase serum cortisol concentrations in animal studies.
Phytosterols (beta-sitosterol)
Phytosterols (plant sterols) are plant-derived fatty compounds representing the largest portion of unsaponifiable matter in plant lipids. Sterols in this group include beta-sitosterol, campesterol, and stigmasterol. It is theorized that beta-sitosterol may reduce the undesirable impact of dihydrotestosterone (DHT) on hair follicles' growth phase and size. Animal research suggests that beta-sitosterol may inhibit 5-alpha reductase activity, thereby preventing conversion of testosterone to dihydrotestosterone (DHT). Alternatively, as phytosterols reduce cholesterol bioavailability this may also reduce biosynthesis of testosterone and DHT.
Magnesium
Magnesium is a component of many compounds and is known to be essential for all ATPase activity.
Serenoa repens (saw palmetto)
The lipid fraction of saw palmetto contains volatile oils and fatty oils. Saw palmetto has antiandrogenic, antiproliferative, and anti-inflammatory properties. *In vitro*, saw palmetto appears to noncompetitively inhibit 5-alpha-reductase (types 1 and 2) in addition to preventing the conversion of testosterone to DHT. This enzyme inhibition and prevention of conversion of testosterone to DHT, is theorised to reduce the undesirable impact of DHT on hair follicles' growth phase and size.
Vitamin C
Vitamin C is involved in multiple of metabolic processes including oxidation-reduction reactions and cellular respiration, carbohydrate metabolism, lipids and protein synthesis, cholesterol to bile acid catabolism, conversion of folic acid to folinic acid, iron metabolism and collagen synthesis. Vitamin C in the skin plays a key role in neutralizing free radicals and reducing UV induced skin damage.
Vitamin D3
Vitamin D is important for calcium homeostasis. Both calcium and vitamin D's active metabolite (1,25(OH)2D) play a role in regulating the skin differentiation process. The receptor (VDR) and 1,25(OH)2D itself regulate processing of long chain glycosylceramides. These are critical for the skin barrier formation and skin defense. VDR appears to promote the progression of the hair cycle. *In vitro*, the expression of VDR, correlation with the stages of the hair cycle.
Vitamin E
Vitamin E aids in the prevention of free radical damage to cells caused by reactive oxygen species. It is used for photo-aged skin and to prevent damage related to ultraviolet (UV) radiation.
Lycopene
Lycopene is a carotenoid without provitamin A activity. It aids in the prevention of free radical damage to cells caused by reactive oxygen species. Lycopene has been examined in the prevention of UV light-induced skin and integument system damage through its antioxidant action and absorption of UVA and UVB wavelengths. Though this process, the lycopene molecule is changed, resulting in reduced skin lycopene levels.
Vitamin B5
Pantothenic acid is required for the metabolism of carbohydrates, proteins and lipids. Pantothenic acid also appears to play a role in regulating of hair follicle growth. *In vitro* data suggests this may be through up-regulation of inhibitor of DNA binding 3 ID3.
Vitamin B9
Folic acid reduces damage to DNA, prevents replication errors and is involved in the metabolism of homocysteine. In population studies and clinical trials on the integument system positive outcomes are linked to higher folate intake.
Vitamin B12
Vitamin B12 is required for myelin and nucleoprotein synthesis, normal erythropoiesis, normal growth, and cell reproduction. Vitamin B12 is involved in conserving sulfhydryl groups in the reduced form required by enzymes involved in carbohydrate and fat metabolism and protein synthesis.
Copper
Copper acts as a cofactor for several enzymes involved in connective tissue synthesis, energy production, iron metabolism, neuropeptide activation and neurotransmitter synthesis. Furthermore, copper is involved in many physiologic processes. Defence against oxidative damage depends mainly on the copper-containing superoxide dismutases. Copper is required for tyrosinase activity, hence play an important role in melanogenesis.
Selenium
Selenium is a major component of the glutathione peroxidase enzyme system. This system protects intracellular structures from oxidative damage.
Zinc
Zinc is a co-factor in many biological processes. Zinc is present in more than 300 enzymes and plays a role in reproduction, immune function, wound healing, blood clotting, thyroid hormone function and insulin action. Zinc supplementation has shown to reduce inflammatory markers, including C-reactive protein, high-sensitivity C-reactive protein, tumour necrosis factor alpha, interleukin 6, malondialdehyde and neutrophils.
Sub-optimum levels of zinc, copper, magnesium, selenium, vitamins B12, B5, B9, E and D are associated with poor hair growth.
5.2 Pharmacokinetic properties
Panax ginseng
Absorption: In humans and animal models, ginsenosides seem to have a low oral bioavailability. However, intestinal microflora seem to improve absorption through transformation of ginsenosides by deglycosylation.
Elimination: In humans, a single oral dose of *Panax ginseng* extract results in ginsenoside (specifically, ginsenoside compound K) half-life of 10,2 hours. In rats, orally administered ginsenosides are primarily eliminated by first-pass biliary excretion.
Phytosterols (beta-sitosterol)
Insufficient information available.
Serenoa repens (saw palmetto)
Insufficient information available.
Lycopene
Absorption: Lycopene is fat soluble and is incorporated into micelles containing bile salts, cholesterol, and fatty acids in the intestine.
Distribution: Average plasma lycopene levels are reported to be 0,22 to 1,06 mcM/L. Lycopene is found in high concentrations in the adrenal glands, testes, liver, and prostate, and in lower concentrations in the kidneys, lungs, and ovaries.
Vitamins and minerals
A sufficient intake of vitamins and minerals is necessary to maintain normal energy metabolism, and physiological function. Unbalanced diet and insufficient dietary intake of vitamins and minerals can result in subnormal health.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Colloidal silicon dioxide
Gelatine capsule (capsule constituents: bovine gelatine, colourants)
Dicalcium phosphate
Magnesium stearate
6.2 Incompatibilities
None known
6.3 Shelf life
24 months
6.4 Special precautions for storage
- Store in a dry place at or below 25 °C.
- Protect from light and moisture.
- Do not use after the expiry date printed on the carton.

6.5 Nature and contents of container
ViGRO® MEN CAPSULES are available in a black high density polyethylene plastic container with a black flip-top cap. It contains 60 capsules and includes a patient information leaflet in a printed unit carton.
6.6 Special precautions for disposal and other handling
No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION
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8. REGISTRATION NUMBER(S)
To be allocated

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
To be allocated

10. DATE OF REVISION OF THE TEXT
February 2023