

VITALITY® ALL-MAN

PROFESSIONAL INFORMATION

Complementary Medicine: Health Supplement/Western Herbal Medicine

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

VITALITY® ALL-MAN, Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Vitality® All-Man tablet contains:

<i>Eleutherococcus senticosus</i> (Rupr. & Maxim.) Maxim. (Siberian Ginseng) [root, 10:1 extract providing 400 mg of dried herb equivalent]	40 mg
<i>Serenoa repens</i> (W. Bartram) Small (Saw Palmetto) [fruit, 8:1 extract standardised to fatty acids 25 % providing 20 mg of dried herb equivalent]	2,5 mg
Calcium phosphate dihydrate	194,50 mg
providing Calcium	45,32 mg
Phosphorus	35,01 mg
Ascorbic acid (Vitamin C)	60 mg
Ferrous fumarate	30,40 mg
providing Iron	10 mg
Calcium carbonate	24,97 mg
providing Calcium	10 mg
Rutin	20 mg
Di-Potassium phosphate	17,82 mg
providing Potassium	8 mg
Phosphorus	3,17 mg
Magnesium oxide	16,60 mg
providing Magnesium	10,01 mg
Nicotinamide (Vitamin B3)	14,98 mg
Copper amino acid chelate	10 mg
providing Copper	1 mg
Manganese amino acid chelate	10 mg
providing Manganese	1 mg
Vitamin A acetate	8 mg
providing Vitamin A	4 000 IU
Riboflavin (Vitamin B2)	2,00 mg
Thiamine hydrochloride	2,00 mg
providing Vitamin B1	1,78 mg
Zinc oxide	1,24 mg
providing Zinc	1 mg
Pyridoxine hydrochloride	1 mg
providing Vitamin B6	0,82 mg
Cyanocobalamin (Vitamin B12)	0,001 mg
Vitamin D3	400 IU
Vitamin E (as D-alpha-tocopherol acetate)	14,9 IU
Sugar free	

For a full list of excipients, see Section 6.1

3. PHARMACEUTICAL FORM

Tablets.

Dark brown, oval film coated tablets

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Vitality® All-Man is a comprehensive multi-nutrient supplement that supports daily nutrition and boosts general health and well-being.

4.2 Posology and method of administration

Posology

Adult men over 18 years: Take one tablet daily with or after food, or as directed by a healthcare professional.

Method of administration

Oral administration only.

4.3 Contraindications

Vitality® All-Man is contraindicated in patients:

- who are hypersensitive (allergic) to the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Use cautiously in patients with diabetes or those using hypoglycaemic agents, based on the potential for blood sugar lowering or increase.

Use with caution in patients with hyperlipidaemia or those taking antilipemics, as an increase or decrease in lipid levels may occur.

Use cautiously in patients with cardiovascular conditions as chest pain, changes in blood pressure and heart rhythm may occur.

Use with caution in patients with bleeding disorders or in those taking anticoagulants.

Use with caution in patients with renal impairment or liver disease.

4.5 Interaction with other medicines and other forms of interaction

Vitality® All-Man may:

- reduce the effects of levodopa, but this does not occur if a dopa decarboxylase inhibitor is given.
- reduce the activity of altretamine, phenobarbital and phenytoin.
- reduce the absorption of fluoroquinolones, penicillamine, tetracyclines, aminoglycosides, cefdinir, bisphosphonates, entacapone, methylidopa, mycophenolate mofetil.
- reduce the efficacy of levothyroxine.
- reduce the activity of antacids.
- increase the risk of bleeding when taken with anticoagulants and antiplatelet medicines.
- affect blood glucose levels, therefore requiring possible dose adjustment of antidiabetic medicines

4.7 Effects on ability to drive and use machines

No data is available but no effect is expected on your ability to drive and use machines.

4.8 Undesirable effects

The following side effects may occur:

MedDRA System Organ Class	Frequency	Adverse reaction
Vascular disorders	Less frequent	Flushing
Gastrointestinal disorders	Frequent	Nausea, vomiting, abdominal pain, diarrhoea
Skin and subcutaneous tissue disorders	Less frequent	Itching, rash, sweating

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 medicinal product. 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

An overdose may intensify the listed side effects and include nausea and vomiting. Discontinue use and treat symptomatically.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

D33.7 Complementary Medicines: Discipline-Specific Traditional Claims – Combination Product

Vitality® All-Man provides a source of essential vitamins and minerals to support daily nutrition. It also contains ginseng, rutin and saw palmetto.

5.2 Pharmacokinetic properties

No data is available for the proposed formulation.

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Castor oil
- Magnesium stearate
- Maize starch
- Microcrystalline cellulose
- Polyvinylpyrrolidone K-29/32
- Shellac-Blonded
- Silicon dioxide

Film Coating:

- Black oxide
- Polyvinylalcohol-polyethylene glycol graft copolymer
- Red oxide
- Talc
- Titanium dioxide

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store at or below 25 °C in a cool, dry place.

Protect from light.

Keep in the original container.

6.5 Nature and contents of container

Clear round polyethylene terephthalate (PET) 125 ml bottle with a white plastic 53 mm screw cap containing 30 tablets, contained in an outer carton.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

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2 Old Main Road,
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8. REGISTRATION NUMBER

To be allocated

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be allocated

10. DATE OF REVISION OF THE TEXT

Not applicable