

VITALITY® ALL-WOMAN

PROFESSIONAL INFORMATION

Complementary Medicine: Health Supplement

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-WOMAN, Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each **Vitality® All-Woman** tablet contains:

Calcium carbonate 50 mg providing Calcium	20 mg
Flaxseed oil	50 mg
Ascorbic acid/Vitamin C (Ascorbic acid)	30 mg
Ferrous fumarate 21 mg providing Iron	7 mg
Magnesium oxide 21 mg providing Magnesium	12,5 mg
Vitamin B3 (Nicotinamide)	20 mg
Pyridoxine hydrochloride 12,5 mg providing Vitamin B6	10,25 mg
Zinc oxide 9 mg providing Zinc	7 mg
Thiamine hydrochloride 5 mg providing Vitamin B1	4,45 mg
Riboflavin/Vitamin B2 (Riboflavin)	5 mg
Vitamin A acetate 4 mg providing Vitamin A	2 000 IU
Folic Acid	0,4 mg
Biotin	0,2 mg
Vitamin B12 (Cyanocobalamin)	0,013 mg
Vitamin D3	120 IU
Vitamin E (as D-alpha-tocopherol acetate)	22 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-Woman 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 women: 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-Woman is contraindicated in patients:

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

4.4 Special warnings and precautions for use

As a health supplement in the recommended dose, **Vitality® All-Woman** is generally considered safe but caution is advised:

- in patients with hepatic or renal dysfunction and liver disease.
- in patients with bleeding disorders or those taking anticoagulant or antiplatelet medication.

4.5 Interaction with other medicines and other forms of interaction

As a health supplement in the recommended dose, interactions with **Vitality® All-Woman** is unlikely to occur.

Vitality® All-Woman may:

- reduce the effects of anticoagulants and antiplatelets.

4.6 Fertility, pregnancy and lactation

The safety of **Vitality® All-Woman** in pregnancy and lactation has not been established.

No fertility data available.

4.7 Effects on ability to drive and use machines

No effect is expected on your ability to drive and use machines.

4.8 Undesirable effects

The following side effects may occur:

Immune system disorders

Frequency unknown: Hypersensitivity reactions

Gastrointestinal disorders

Frequency unknown: Gastrointestinal irritation or discomfort, nausea, vomiting, abdominal pain, flatulence, diarrhoea or constipation.

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

D34.12 Complementary Medicines: Health Supplements – Multiple substance formulation

Vitality® All-Woman provides a source of essential vitamins and minerals, and flaxseed, as a source of omega-3 fatty acids, to support daily nutrition.

5.2 Pharmacokinetic properties

No data is available for the formulation of **Vitality® All-Woman** tablets.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Castor oil, croscarmellose sodium, Flexicoat Dark Brown, magnesium stearate, maize starch, microcrystalline cellulose, polyvinylpyrrolidone, Shellac-Blonded, silicon 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.

Keep in the original container.

Protect from light.

6.5 Nature and contents of container

Clear 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 <and other handling>

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

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Tel: 0860 104 061
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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.