

PROFESSIONAL INFORMATION

- Vigro® BIO CAPSULES**
- Complementary Medicine,
 - D.34.12 Complementary Medicines: Health Supplements – Multiple Substance formulation.
 - This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS
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1. NAME OF THE MEDICINE
Vigro® BIO CAPSULES (capsules)
2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each capsule contains:

Active ingredients	Per capsule	Per maximum daily dose (2 capsules)	% NRV* per 2 capsules (maximum daily dose)
Nicotinamide (Vitamin B3)	25 mg	50 mg	313 %
Calcium D-pantothenate (Vitamin B5)	100 mg 92 mg	200 mg 184 mg	3 680 %
Folic acid (Vitamin B9)	400 µg	800 µg	200 %
Cyanocobalamin (Vitamin B12)	5 µg	10 µg	417 %
Copper II sulphate pentahydrate providing copper (elemental)	200 µg 50,9 µg	400 µg 101,8 µg	11 %
Ferrous gluconate providing iron (elemental)	18 mg 2,2 mg	36 mg 4,3 mg	24 %
Manganese glycerolphosphate providing manganese (elemental)	5 mg 0,6 mg	10 mg 1,3 mg	54 %
Zinc gluconate providing zinc (elemental)	15 mg 2,2 mg	30 mg 4,3 mg	39 %
Choline bitartrate (Choline)	125 mg 51,4 mg	250 mg 102,8 mg	19 %
Inositol	125 mg	250 mg	*
Para-aminobenzoic acid (PABA)	30 mg	60 mg	*

* Nutrient reference values for adults and children older than 4 years. * NRV not established. **Amino Acid Chelate. Vigro® Bio Capsules are sugar and preservative free. For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Capsule, hard gelatine.
Vigro® Bio Capsules are white / blue hard gelatine capsules.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
Vigro® Bio Capsules is a health supplement containing nutrients in quantities targeted for promoting healthy hair and normal hair growth. Vigro® Bio Capsules also promotes the health of skin and nails. Vigro® Bio 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: One (1) capsule per day, after a meal, with a glass of water.
• Acute dosage: Two (2) capsules per day, after a meal, with a glass of water.
Children:
This product is not indicated for children.
Advise the patient to not take dosage at the same time as other medications (see 4.5).

4.3 Contraindications
• Must not be given to patients with known hypersensitivity or allergy towards any of the ingredients of Vigro® Bio 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 suffering from liver disease or have peptic ulcer disease as Vigro® Bio Capsules contain nicotinamide and manganese.
• Must not be given to patients known to have cobalamin or cobalt hypersensitivity as Vigro® Bio Capsules contain vitamin B12.
4.4 Special warnings and precautions for use
• Patients who are pregnant or breastfeeding or taking sulphonamides (see 4.5) should use this product with caution as it contains PABA, consult a relevant healthcare provider prior to use.
• 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 medicinal products and other forms of interactions
No interaction studies have been performed on Vigro® Bio Capsules, see below interactions with individual ingredients.

Active ingredient	Medicine	Description
Vitamin B3	Blood thinners (anticoagulant- or anti-platelet medication) e.g. Warfarin.	May have a blood thinning effect increasing the risk of bleeding and bruising.
Para-aminobenzoic acid (PABA) and minerals (zinc, iron and manganese).	Antibiotics.	May reduce the absorption of antibiotics. Oral antibiotics should be taken at least two (2) hours before, or four (4) hours after Vigro® Bio Capsules or similar supplements.
Para-aminobenzoic acid (PABA).	Sulfones (decreases swelling and stops the growth of bacteria).	May inhibit the antibacterial effects. Avoid concurrent use.

4.6 Fertility, pregnancy and lactation
Pregnancy
Safety of some of the ingredients for use during pregnancy has not been established (see section 4.4), therefore this product should not be used in patients who are pregnant.
Breastfeeding
Safety of some of the ingredients for use during lactation has not been established (see section 4.4), therefore this product should not be used if patients are lactating.

Fertility
There are no known effects of Vigro® Bio Capsules on fertility.
4.7 Effects on the ability to drive and use machines
Based on the side effect profile, Vigro® Bio 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® Bio 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 <1/1,000)
• 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.
Gastrointestinal disorders	Not known	Abdominal discomfort, pain, cramps and fullness, constipation, diarrhoea, dyspepsia, heartburn, nausea, vomiting, halitosis, dry mouth.
Skin and subcutaneous tissue disorders	Not known	Hypersensitivity reaction (rash, pruritus, erythema, 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.34.12 Complementary Medicines: Health Supplements – Multiple Substance formulation.
• **Pharmacotherapeutic classification:** Vitamins and other combinations
ATC code: A11JC
Choline
Choline is required for the structure of cell membranes, lipid metabolism and transport, as well as for the formation of compounds involved in neurotransmission and platelet function.
Choline has anti-inflammatory effects as it selectively activates alpha-7 nicotinic acetylcholine receptors found in both the central and peripheral nervous system and on immune cells. Activation leads to decreased production of inflammatory cytokines including tumour necrosis factor (TNF).
Inositol
Inositol is a sugar alcohol, endogenous inositol is an essential component of cell membrane phospholipids. Inositol is a component of the intracellular phosphatidyl inositol second messenger system, which is linked to numerous neurotransmitters including alpha 1 noradrenergic, norepinephrine, dopamine, serotonin, glutamate and cholinergic receptors.
Para-aminobenzoic acid (PABA)
PABA is a part of the folic acid molecule. Endogenous PABA seems to be involved in a number of biologic processes. PABA appears to affect melanin metabolism as clinically it has been observed to increase hair pigmentation.
Vitamin B3
Nicotinamide acts as an antioxidant by preventing adenine dinucleotide (NAD) depletion during DNA repair when inhibiting poly (ADP-ribose) polymerase (PARP). It also decreases inflammation by modulating interleukin-1-exposed chondrocytes.
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 sulphydryl 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.
Iron
Iron is an essential component of every cell present in the body. Although best known for its crucial role in the transport and storage of oxygen (in haemoglobin and myoglobin, respectively), within a large variety of enzymes iron also acts as a catalyst for oxygenation, a carrier for electrons, hydroxylation, and is necessary for cellular growth and proliferation. Iron plays an important role in melanogenesis through modulation of tyrosinase.
Manganese
Manganese is an essential nutrient involved in glucose regulation, normal cell growth, generation of the immune response, and metabolism of carbohydrates, lipids, and proteins. It acts as a cofactor in several enzymatic and metabolic pathways.
Zinc
Zinc is a co-factor in many biological processes. Zinc plays a role in immune function as it is important for neutrophil, natural killer cell and T-lymphocyte function.

5.2 Pharmacokinetic properties
Choline
Absorption: Choline displays one-compartment modelling with slow oral absorption.
Distribution: Choline concentrates as a component of cell membranes in nervous tissue.
Elimination: The elimination half-life of oral choline has been reported to extend up to 56 hours.
Inositol
Absorption: Orally, inositol is transported across the intestinal mucosa and absorbed nearly completely.
Metabolism: Inositol is metabolized by myo-inositol oxidase, located at the renal cortex.
Excretion: Information on the excretion of inositol is limited.
Para-aminobenzoic acid (PABA)
Absorption: It has been shown that PABA is passively absorbed from the small intestine and then enters the portal circulation with the bioavailability possibly declining with age.
Metabolism: PABA becomes acetylated after absorption and conjugated in the liver to glycine. Its major metabolites are para-aminohippuric acid (PAHA), para-acetamidohippuric acid (PAAHA), and para-acetoamidobenzoic acid (PAAABA).
Excretion: PABA is excreted primarily in the urine, with small amounts found in the milk, faeces, bile, and other secretions.
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
Gelatine capsule (capsule constituents: bovine gelatine, colourants)
Magnesium stearate
Maize starch
Talc
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.
• Keep in original packaging until required for use.
6.5 Nature and contents of container
Vigro® Bio Capsules are available in a white high density polyethylene plastic securitainer with a white flip-top cap. It contains 30 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
December 2022