

PATIENT INFORMATION LEAFLET

Scheduling status:

[S0]

ViGRO® BIO CAPSULES PLUS capsule

Choline (choline bitartrate); Inositol; Lycopene; Para-aminobenzoic acid (PABA); Vitamin B3 (nicotinamide); Vitamin B9 (folic acid); Vitamin B12 (cyanocobalamin); Vitamin B5 (calcium d-pantothenate); Copper (Copper (II) sulphate pentahydrate); Iron (ferrous gluconate); Manganese (manganese glycerophosphate); Selenium (selenium amino acid chelate); Zinc (zinc gluconate).

Sugar and preservative free.

- D.34.12 Complementary Medicines: Health Supplements – Multiple Substance formulation.
- A varied diet is the most effective and safe way to achieve good nutrition, health, body composition as well as mental and physical performance. This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

Read all of this leaflet carefully because it contains important information for you.

Vigro® Bio Capsules Plus is available without a doctor's prescription. Nevertheless, you still need to use Vigro® Bio Capsules Plus carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Vigro® Bio Capsules Plus with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

WHAT IS IN THIS LEAFLET

1. What Vigro® Bio Capsules Plus is and what it is used for
2. What you need to know before you take Vigro® Bio Capsules Plus
3. How to take Vigro® Bio Capsules Plus
4. Possible side effects
5. How to store Vigro® Bio Capsules Plus
6. Contents of the pack and other information

1. What Vigro® Bio Capsules Plus is and what it is used for

Vigro® Bio Capsules Plus is a health supplement containing nutrients in quantities targeted for promoting healthy hair and normal hair growth. Vigro® Bio Capsules Plus also promotes the health of skin and nails. Vigro® Bio Capsules Plus contains antioxidants which can assist in prevention of cellular oxidative damage.

2. What you need to know before you take Vigro® Bio Capsules Plus

Do not take Vigro® Bio Capsules Plus:

- If you are hypersensitive (allergic) to any of the ingredients of Vigro® Bio Capsules Plus (listed in section 6 **Contents of pack and other information**).
- If you suffer from liver disease or have a stomach ulcer (peptic ulcer disease) as Vigro® Bio Capsules Plus contains nicotinamide and manganese.
- If you have cobalamin or cobalt hypersensitivity as Vigro® Bio Capsules Plus capsules contains vitamin B12.

Warnings and precautions

- Consult a healthcare provider before use if you have a history of non-melanoma skin cancer as Vigro® Bio Capsules Plus contain selenium.
- The Vigro® Bio Capsules Plus is not intended to support prostate health or treat disease. Consult a healthcare provider before use if you have been diagnosed or suspected to suffer from prostate cancer.
- Special care should be taken if you are pregnant or breastfeeding or taking antibiotics (sulfonamides), as Vigro® Bio Capsules Plus contains PABA.
- If you are taking any chronic medication, do not use without consulting your medical practitioner.
- Do not exceed the daily recommended dose (see **3. How to take Vigro® Bio Capsules Plus capsules**)
- Do not use after the date of expiry.

Porphyria: Safety has not been established.

Tell your doctor if you are not sure about any of the above.

Other medicines and Vigro® Bio Capsules Plus

Always tell your healthcare provider if you are taking any other medicine (including complementary or traditional medicines).

Consult your doctor, pharmacist or healthcare provider before use if you are taking:

- Blood thinners (anticoagulant or anti-platelet medication e.g. Warfarin) as vitamin B3 and selenium may have a blood thinning effect increasing the risk of bleeding and bruising; or
- antibiotics (used to treat infections), as the minerals and Para-aminobenzoic acid (PABA) in Vigro® Bio Capsules Plus may reduce their absorption. You should take all oral antibiotics at least two (2) hours before, or four (4) hours after Vigro® Bio Capsules Plus or similar supplements; or
- sulfones (decreases swelling and stops the growth of bacteria) as PABA may inhibit the antibacterial effects, avoid concurrent/ simultaneous use.

Taking Vigro® Bio Capsules Plus with food and drink and alcohol

You should take Vigro® Bio Capsules Plus capsules after a meal with a glass of water a few hours before or after taking other medications or health products.

Pregnancy and Breastfeeding

It is not advisable to take Vigro® Bio Capsules Plus while you are pregnant or breastfeeding as it contains Para-aminobenzoic acid (PABA) which is specifically contraindicated. If you are pregnant or breastfeeding, think you might be pregnant or are planning to have a baby, please consult your doctor or pharmacist or other healthcare provider for advice before taking this medication.

Driving and using machines

Vigro® Bio Capsules Plus should not affect your ability to drive or use machinery. However, if you think you are affected you should not drive or operate machinery until you feel better.

3. How to take Vigro® Bio Capsules Plus

Do not share medicines with any other person.

Always take Vigro® Bio Capsules Plus exactly as described in this leaflet or as your healthcare provider has instructed you. You should check with your doctor, pharmacist or nurse if you are unsure.

The usual dose for 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.

Take a few hours before or after taking other medications (see **Other medicines with Vigro® Bio Capsules Plus**)

If you take more Vigro® Bio Capsules Plus than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take Vigro® Bio Capsules Plus

Take your missed dose when you remember. Do not take a double dose to make up for forgotten individual doses.

If you stop taking Vigro® Bio Capsules Plus

If you are taking the dose as indicated, it is unlikely that there should be withdrawal effects when you stop using this medication.

4. Possible side effects

Vigro® Bio Capsules Plus can have side effects

Not all side effects reported for Vigro® Bio Capsules Plus are included in this leaflet. Should your general health worsen while or if you experience any untoward effects while taking this medicine, please consult your healthcare provider for advice.

If any of the following or other side effects occur, stop taking this product and consult your doctor or pharmacist or go to the casualty department at your nearest hospital:

Allergic reactions such as: skin inflammation or rash, difficulty breathing or swallowing, swelling beneath the skin (angioedema), itchy throat, urticaria (hives) and itching.

Tell your doctor or pharmacist if you notice any of the following:

Frequency unknown:

- Abdominal complaints (such as; Stomach discomfort, pain, cramps and fullness, constipation, diarrhoea, indigestion, heartburn, nausea, vomiting, bad breath and dry mouth).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the **“6.04 Adverse Drug Reaction Reporting Form”**, found online under SAHPRA's publications: <https://www.sah-pra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of Vigro® Bio Capsules Plus.

5. How to store Vigro® Bio Capsules Plus

- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Store in a dry place at or below 25 °C.
- Protect from light and moisture.
- Keep in original packing until required for use.
- Do not refrigerate.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label and carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of pack and other information

What Vigro® Bio Capsules Plus 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)	312,5 µg 79,5 µg	625 µg 159 µg	18 %
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 %
Selenium AAC** providing selenium (elemental)	2,5 mg 50 µg	5 mg 100 µg	182 %
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	*
Lycopene	1 mg	2 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.

The other ingredients are: Gelatine capsule (capsule constituents: bovine gelatine, colourants), magnesium stearate, maize starch and talc.

Vigro® Bio Capsules Plus are sugar and preservative free.

What Vigro® Bio Capsules Plus looks like and contents of the pack

Vigro® Bio Capsules Plus capsules are maroon, available in white plastic container with a white flip-top cap. It contains 60 capsules and includes a patient information leaflet in a printed unit carton.

Holder of Certificate of Registration

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This leaflet was last revised in

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Date of registration

To be allocated

Registration number

To be allocated

Professional Information

The Vigro® Bio Capsules Plus Professional Information may be obtained from the Nativa website (www.nativa.co.za).