

RE I NU MEN'S HAIR & BEARD GROWTH

PROFESSIONAL INFORMATION

D 33.7 Combination product. Complementary Medicine.

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use. Health supplements are intended only to complement health or supplement the diet.

SCHEDULING STATUS: SO

1. NAME OF THE MEDICINE REINU MEN HAIR & BEARD GROWTH

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per capsule: 160,00 mg %NRV Serenoa repens (Saw Palmetto)
[Fruit, extract standardized to 25 % fatty acids (40 mg fatty acids) 50 % Choline (as Choline bitartrate) 125,00 mg 23 % L-Theanine 125,00 mg Zinc sulphate heptahydrate (providing 12.50 mg elemental zinc) 54.97 ma 114 % Silicon (as Silicon dioxide)
Pantothenic Acid (Vitamin B₅) 50,00mg 50,00 mg 1 000 % 10.00 mg Niacinamide (Vitamin B₃) 63 % 667 % 50 % Biotin (as D-Biotin) 200,00 μg Folic acid 200,00 µg 2,50 μg (100 IU) Cholecalciferol (Vitamin D_3) / Kolekalsiferol (Vitamien D_3)

*%Nutrient Reference Values (NRVs) for individuals 4 years and older (2010)

Sugar free

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM Bovine gelatine capsule.

4. CLINICAL PARTICULARS

4.1 Therapeutic indication

REINU MEN HAIR & BEARD GROWTH, supports optimal hair follicle health.

4.2 Posology and method of administration

Adults 18 years and older: Take 2 (two) capsules daily, or as recommended by your healthcare provider

Elderly: No specific studies have been performed in older patients, but according to clinical experience dosage adjustment is not required when treating otherwise healthy, older patients.

Patient with impaired renal and/or liver function: In patients with impaired renal and/or liver function no dose recommendations can be given, since no studies have been performed (see also section 4.4).

Children and adolescents: Not recommended in children and adolescents below the age of 18 years (see section 4.4).

- If you have a hypersensitivity to Saw palmetto, Choline, L-theanine, Zinc, Silicon, Vitamin B5, Vitamin B3, Folic acid and Vitamin D3 or any of the excipients listed in 6.1.
 Contraindicated in patients with Hepatic disease.
- Not recommended in patients that are taking blood coagulation supplements as this may increase the risk of spontaneous bleeding.
 Do not use this product if you have hypotension or liver deficiency.
- Contraindicated in patients with prostate cancer.

4.4 Special warnings and precautions for use

Special care should be taken with REINU MEN HAIR & BEARD GROWTH. If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine. Please take note of the following:

Consult a healthcare provider prior to use if you are pregnant or breastfeeding
 Not recommended for use in children under the age of 18 years.

- Not recommended in patients that are taking blood coagulation supplements as this may increase the risk of spontaneous bleeding.
- Consult a healthcare provider if symptoms persist or worsen.

If you are taking medication for an enlarged prostate talk to your doctor before taking this product. It may not be suitable for you.
 Nutritional supplementation should not replace a balanced diet. Do not exceed the recommended dose without consulting a healthcare provider.

4.5 Interaction with other medicines and other forms of interactions
No specific drug interaction studies have been performed on REINIU MEN HAIR & BEARD GROWTH, however, the known interactions of Saw palmetto, Choline, L-theanine, Zinc, Silicon, Vitamin B5, Vitamin B3, Folic acid and Vitamin D3 have been summarized.

Saw Palmetto may interact with warfarin causing increased INR-values, caution is advised. Theanine might lower blood pressure, potentiating the effects of antihypertensive drugs. Concomitant use of theanine and antihypertensive drugs might potentiate the antihypertensive activity.

- Zinc and Amiloride can modestly reduce zinc excretion and increase zinc levels, decrease cephalexin levels by chelating with cephalexin in the gut and preventing its absorption.
 Zinc might interfere with the therapeutic effects of cisplatin, and taking zinc along with integrase inhibitors might decrease the levels and clinical effects of these medicines.

- Clinc interferes with penicillamine absorption and activity. Zinc supplements reduce the efficacy of low-dose penicillamine (0.5-1 gram/day), but do not seem to affect higher doses (1-2.75 gram/day), provided dosing times are separated. Patients are advised to take zinc and penicillamine at least 2 hours apart.

 Quinolones form complexes with zinc in the gastrointestinal tract, reducing absorption of both the quinolone and zinc if taken at the same time. Patients are advised to take these drugs at least 2 hours before, or 4-6 hours after, zinc supplements.

Interactions with Diseases / Impairments

- If you are taking medication for an enlarged prostate talk to your doctor before taking this product. It may not be suitable for you.
- Saw Palmetto might increase the risk of bleeding with anticoagulant or antiplatelet drugs
- Saw Palmetto might reduce the effectiveness of contraceptive drugs and estrogens.
- Administering choline one hour before administering atropine can attenuate atropine-induced decreases in brain levels of acetylcholine. Concomitant use of choline and atropine may decrease the effects of atropine.
 Patients are advised to discontinue REINU MEN HAIR & BEARD GROWTH at least 2 weeks before elective surgical procedures (see section 4.4).
- REINU MEN HAIR & BEARD GROWTH and use in Haemophiliacs and patients scheduled for surgery are advised to discontinue use at least 2 weeks before elective surgical procedures (see section 4.4).
 Low dietary zinc intake is associated with a greater chance of developing chronic kidney disease.
- B vitamins might increase the rate of restenosis after bare metal stent placement. Bariatric surgery reduces zinc absorption and can cause zinc insufficiency despite zinc supplementation.
- Interactions with Foods Vitamins, minerals and nutrients obtained from other sources should be taken into account when prescribing / suggesting REINU MEN HAIR & BEARD GROWTH.

Fertility, pregnancy and lactation
• The safety and efficacy of REINIU MEN HAIR & BEARD GROWTH in pregnancy and lactation has not been established. 4.6 Effects on ability to drive and use machines

Patients should exercise caution before driving or operating machinery until they are reasonably certain that REINU MEN HAIR & BEARD GROWTH does not affect their performance. 4.7 Undesirable effects

No clinical data are available on the effects of REINU MEN HAIR & BEARD GROWTH. Orally, Saw palmetto, Choline, L-theanine, Zinc, Silicon, Vitamin B5, Vitamin B3, Folic acid and Vitamin D3 is well-tolerated when used in recommended dosage instructions but may have side effects **Summary of reactions**

Immune system disorders: Frequency unknown: Allergic reactions including fever and skin rash.

Psychiatric disorders: Frequency unknown: hypermania.

Nervous system disorders:
Frequency unknown: fatigue, headache, insomnia, sleepiness, vertigo, tremors, agitation, dizziness, vivid dreams, anxiety, lethargy, neuropathy, paresthesia, disorientation, inability to concentrate.

Frequency unknown: Rash, itching, sweating, hives, flushing, edema. Frequency rare: skin sensitivity, eczema

Cardiac disorders: Frequency unknown: Chest pain, angina, flushing.

Pulmonary/Respirator

Gastrointestinal disorders:

Trequency unknown: nausea, vomiting, esophagitis, heartburn, abdominal cramps, gastrointestinal obstruction, diarrhea, increased salivation, bloating, flatulence, bowel symptoms, constipation, hunger, thirst, anorexia, blood in the stool, dry mouth, anorexia, dyspepsia, fever, indigestion, epigastric pain, gastrointestinal irritation, loss of appetite, gastric upset, intolerance to taste.

Renal and urinary disorders:
Frequency unknown: Increased urinary frequency.

Other:

Trequency unknown: : Choline intake may cause a fishy body odor due to intestinal metabolism of choline to trimethylamine.

Description of selected adverse reactions

No clinical data are available on the effects of REINU MEN HAIR & BEARD GROWTH on other special populations.

REINU MEN HAIR & BEARD GROWTH is not recommended for use by children under 18 years, as insufficient data are available concerning its safety and efficacy.

Other special populations

No clinical data are available on the effects of REINU MEN HAIR & BEARD GROWTH on other special populations. Reporting of suspected adverse reactions Reporting of suspected adverse reactions. Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine, Health care 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

In the event of overdose, treatment should be symptomatic and supportive

5. PHARMACOLOGICAL PROPERTIES

Mechanism of actions

Saw Palmetto, inhibit 5α -reductase, which is an enzyme responsible for conversion of testosterone to dihydrotestosterone. Inhibition of such conversion maintains prostate health. Choline, produced in the liver via the methylation of phosphatidylethanolamine. S-adenosylmethionine is the methyl donor for this reaction.

L-theanine, breaks down to glutamic acid and ethylamine. Within the cell, cysteine and glutamic acid are combined with glycine to form the antioxidant glutathione (GSH).

Zinc, plays an important role in the metabolism of proteins, carbohydrates, lipids and nucleic acids. It is a cofactor in a range of biochemical processes, including the synthesis of DNA, RNA and protein. Zinc is also required for the hepatic synthesis of retinol-binding protein, the protein involved in transporting vitamin A. Silicon, is involved in collagen synthesis or stabilization and/or extracellular matrix mineralization.

Vitamin B5, required in the acetylation reactions in gluconeogenesis; in the release of energy from carbohydrates; in the synthesis and degradation of fatty acids; and in the synthesis of sterols, steroid hormones, porphyrins, acetylcholine, and other compounds.

Vitamin B3, Niacin is a precursor of nicotinamide adenine dinucleotide (NAD) and nicotinamide adenine dinucleotide phosphate (NADP). These coenzymes are essential for oxidation-reduction reactions, ATP synthesis, and ADP-ribose transfer reactions.

Folic acid, Folic acid reduces damage to DNA and prevents replication errors. Folic acid deficiency disturbs cell cycling, induces cell apoptosis, and increases the rate of cell death Vitamin D3.

Pharmacodynamic effects:

Saw Palmetto, Inhibits 5-alpha-reductase conversion of testosterone to dihydrotestosterone. Anti-inflammatory inhibition of cycloxygenase, lipoxygenase pathways.

Choline, is produced in the liver via the methylation of phosphatidylethanolamine. S-adenosylmethionine is the methyl donor for this reaction.

L-theanine, It is thought that this combination reduces blood levels of interleukin (IL)-6 following surgery by preventing decreases in glutathione levels.

Zinc, is required for the catalytic activity of more than 200 enzymes, and it plays a role in immune function wound healing, protein synthesis, DNA synthesis, and cell division.

Silicon, Silicon stimulates synthesis of collagen and other molecules associated with extracellular matrix production.

Vitamin B5, required for intermediary metabolism of carbohydrates, proteins, and lipids. Dexpanthenol is converted in the body to pantothenic acid.

Vitamin B3, Niacin is converted to niacinamide when ingested in amounts that do not exceed physiological

Folic acid, tetrahydrofolate-based coenzymes play a major role in intracellular metabolism. Tetrahydrofolate plays an indirect role in the rate-limiting step of DNA synthesis.

Vitamin D3, Cholecalciferol is synthesized in the skin via 7-dehydrocholesterol, a cholesterol precursor. Both ergocalciferol and cholecalciferol are biologically inert and require hydroxylation in the body to form the active metabolite, calcitriol.

Absorption: In one pharmacokinetic study, the peak plasma level after taking saw palmetto extract 320 mg was 2.6 mg/L (Cmax) at 1.5 hours (Tmax).

Pharmacokinetic properties:

Absorption/ Distribution/ Metabolism/ Extretion:

Elimination: In one pharmacokinetic study, the half-life of saw palmetto was 19 hours. Choline

Absorption: Choline displays one-compartment pharmacokinetics with very slow oral absorption. Distribution: Choline concentrates in nervous tissue as a component of cell membranes.

Metabolism: Choline that is not absorbed is metabolized by intestinal bacteria to trimethylamine.

Elimination: The elimination half-life of oral choline has been reported to extend up to 56 hours. Absorption: Theanine is absorbed through the intestines. The peak concentration of L-theanine in the plasma occurs at about 50 minutes after oral intake.

Distribution: Following absorption, L-theanine is distributed to the plasma and erythrocytes. L-theanine can cross the blood brain barrier and appears to do so in a dose-dependent manner. Metabolism: L-theanine is hydrolyzed in the intestines to ethylamine and glutamic acid. The elimination half-life of L-theanine from plasma ranges from 0.8-1.2 hours .

Excretion: A small amount of L-theanine is retained in erythrocytes, but most L-theanine and its metabolites are excreted in the urine 3-24 hours after oral intake.

Absorption: Silicon is rapidly absorbed in the proximal small intestine. Some absorption may also occur in the stomach; after total gastrectomy, plasma silicon levels can be reduced by as much as 26%. The absorption of silicon depends on the total amount present, as well as the forms in which it is present. After oral consumption, silicon is converted to silicic acid, which increases its absorption.

Distribution: The human body contains 1-2 grams of silicon. Silicic acid equilibrates freely across biological membranes, resulting in relatively constant intracellular concentrations of silicon. Metabolism: Preliminary research suggests that the pathways of silicon and iron metabolism may be directly linked. Excretion: About 50% of ingested silicon is excreted via the kidneys by glomerular filtration into the urine. The majority is excreted in less than eight hours following ingestion.

Absorption occurs throughout the length of the small intestine, mostly in the jejunum, both by a carrier-mediated process and by diffusion.

Inc is transported in association with albumin, amino acids and a 2-macroglobulin. Zinc is principally an intracellular ion and approximately 95% is found within the cells. Approximately 57% of the body pool is stored in skeletal muscle, 29% in bone and 6% in the skin, but zinc is found in all body tissues and fluids, including the liver, kidneys, pancreas, respective leady and resident and the skin. prostate gland and retina.

Zinc, absorption of zinc is enhanced by certain amino acids such as cysteine and histidine: meat, dairy produce and fish contain these amino acids and therefore their zinc is efficiently absorbed Zinc, Elimination of zinc is mainly in the faeces; smaller amounts are excreted in the urine and via the skin

Pantothenic acid is found in high levels in the brain when compared with the plasma, where it functions in normal biochemical pathways as the coenzyme, CoA. Acetyl-CoA, the precursor of acetylcholine, is derived from CoA. No clinical data are available for the metabolism and elimination of Vitamin B5. Pantothenic acid is excreted in the urine.

Vitamin B3,

Vitamin B5.

Absorption: Niacin is water-soluble and well-absorbed when taken orally.

Metabolism: Niacin is metabolized in the liver to nicotinamide adenine dinucleotide (NAD) and nicotinamide adenine dinucleotide phosphate (NADP), which are essential for oxidation-reduction reactions, ATP synthesis, and ADP-ribose transfer reactions.

Elimination: Urinary excretion of the metabolites has been shown following oral administration of niacin.

Absorption: The two forms of vitamin D, cholecalciferol and ergocalciferol, are well absorbed. However, cholecalciferol appears to be more efficient in raising 25-hydroxyvitamin D serum levels, which is the best measure of vitamin D status.

Distribution: transported primarily by chylomicron, which allows vitamin D to be distributed to peripheral tissues. If not taken up by peripheral tissue, vitamin D is transported to the liver, where it is converted to calcitriol.

Metabolism: Both ergocalciferol and cholecalciferol are biologically inert and require hydroxylation in the body to form the active metabolite, calcitriol.

Preclinical safety data

No clinical data are available on the effects of REINU MEN HAIR & BEARD GROWTH. 6. PHARMACEUTICAL PARTICULARS

Magnesium stearate and silicon dioxide.

6.1 List of excipients

6.2 Shelf life

6.3 Special precautions for storage Store in a cool, dry place at or below 25 °C. Do not use after expiry date.

Keep the container tightly closed. Protect from light.
KEEP OUT OF REACH OF CHILDREN.

6.4 Nature and contents of container The container is a 175 mL PET container. The cap is a plastic cap with a tamper evident seal. Packed in a unit carton.

No special requirements. 7. HOLDER OF CERTIFICATE OF REGISTRATION

23 Stag Rd

Glen Austin South Africa

8. REGISTRATION NUMBERWill be allocated by SAHPRA upon registration. **9. DATE OF FIRST AUTHORISATION**Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF THE TEXT

JOB: B RE|NU_ Mens Health_ Hair&Beard_60s **SIZE:** 210mm x 443mm **STOCK:** Foil Substrate: Clear Substrate: White Substrate: X Paper: Other: **COLOURS: FINISHING:** Available Available Slot Slot Slot Slot Spot UV Doming Embossing PLEASE CHECK CAREFULLY
Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.

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