

PROFESSIONAL INFORMATION

COMPLEMENTARY MEDICINE: MULTIPLE SUBSTANCE FORMULATION

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

Health supplements are intended only to complement the health or supplement the diet.

SCHEDULING STATUS

S0

1. NAME OF THE MEDICINE

REBOUND NUTRITION RECOVER LEMON-LIME (powder)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains:	
VITAMIN AND MINERAL COMPLEX	
Ascorbic Acid (Vitamin C)	250,00 mg
Zinc (from 18,86 mg Zinc Oxide)	15,00 mg
Vitamin B6 (from 1,24 mg Pyridoxine Hydrochloride)	1,00 mg
Vitamin A (from 5,99 mg Vitamin A Palmitate)	450,00 µg RAE (1500,00 IU)
Cholecalciferol (Vitamin D3)	12,00 µg (480,00 IU)
ESSENTIAL AMINO ACID COMPLEX	
L-Leucine	5073,00 mg
L-Glutamine	5000,00 mg
L-Arginine (from 3682,79 mg L-Arginine Hydrochloride and 1440,00 mg L-Arginine Alpha-Ketoglutarate)	4440,00 mg
L-Isoleucine	771,00 mg
L-Valine	760,00 mg
L-Lysine (from 368,53 mg L-Lysine Monohydrochloride 98,50 %)	363,00 mg
L-Phenylalanine	135,00 mg
L-Methionine	97,00 mg
L-Histidine (from 101,55 mg L-Histidine Hydrochloride)	81,00 mg
L-Tryptophan	13,60 mg
CIRCULATORY SUPPORT COMPLEX	
L-Citrulline (from 5295,68 mg L-Citrulline Malate)	3000,00 mg
Creatine Monohydrate	2200,00 mg
Calcium Hydroxymethylbutyrate (Ca-HMB) (providing 258,40 mg elemental Calcium)	1900,00 mg
L-Cysteine (from 1024,89 mg L-Cysteine Hydrochloride Monohydrate)	700,00 mg
L-Theanine	230,00 mg
Calcium (from 978,21 mg Tricalcium Citrate Anhydrous)	202,00 mg
Boron (from 60,00 mg Boron Glycinate 5 %)	3,00 mg

Contains sweetener: 20,00 mg sucralose and 20,00 mg steviol glycosides per sachet.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder.

Lemon-Lime: Off-white to yellow fine, dry powder. Dissolves into a cloudy yellow/off-white liquid with a citrus flavour and odour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

REBOUND NUTRITION RECOVER is a health supplement that provides a combination of essential amino acids, key vitamins and minerals, and a circulatory support complex to support protein synthesis, muscle recovery, wound healing and tissue repair. It also supports the function of the immune system, particularly during and after intense physical stress.

4.2 Posology and method of administration

Posology

Adults 18 years and older:

Add the contents of one sachet to 250 – 300 ml of cold water. Stir well until dissolved and drink immediately. Take one (1) sachet daily, or as recommended by a healthcare provider.

Take a few hours before or after other medications or supplements.

Consult a healthcare provider prior to use for individuals below the age of 18 years.

Method of administration

For oral use.

4.3 Contraindications

- Hypersensitivity to any of the active ingredients listed in section 2 or to any of the excipients listed in section 6.1.
- Patients who are pregnant, breastfeeding, or who are trying to conceive.

4.4 Special warnings and precautions for use

- Consult a healthcare provider prior to use if you have a kidney disease, liver disease, severe protein malnutrition, arteriosclerosis, histoplasmosis, hypercalcaemia, hyperparathyroidism, lymphoma, sarcoidosis, tuberculosis, Amyotrophic Lateral Sclerosis (ALS, Lou Gehrig's Disease), branched-chain ketoaciduria, diabetes, bipolar disorder, monosodium glutamate (MSG) hypersensitivity, seizure disorder, Guanidinoacetate Methyltransferase Deficiency (GAMT), heart disease or history of myocardial infarction, Lysinuric Protein Intolerance, Phenylketonuria (PKU), schizophrenia, acidosis, atherosclerosis, cirrhosis,

Methylenetetrahydrofolate Reductase (MTHFR) Deficiency, folic acid deficiency, or a hormone sensitive cancer or condition.

- Consult a healthcare provider prior to use if you are taking any other medications or health products, as REBOUND NUTRITION RECOVER may alter their effectiveness.
- Discontinue use and consult a healthcare provider if symptoms persist or worsen, or if you develop any new symptoms.
- Discontinue use at least two weeks prior to elective surgical procedures.
- Larger amounts of vitamin C can increase the risk of oxalate kidney stones, use with caution in those who are prone to oxalate kidney stone formation.

4.5 Interaction with other medicines and other forms of interaction

Not all possible interactions are listed in this leaflet. Always tell your healthcare provider if you are taking any other medicine (this includes all complementary or traditional medicines).

Ascorbic Acid

- **Alkylating agents:** theoretically, the antioxidant effects of vitamin C might reduce the effectiveness of alkylating agents.
- **Antitumour antibiotics:** theoretically, the antioxidant effects of vitamin C might reduce the effectiveness of antitumour antibiotics.
- **Fluphenazine:** theoretically, vitamin C might decrease levels of fluphenazine.
- **Indinavir:** vitamin C can modestly reduce indinavir levels.
- **Levothyroxine:** vitamin C can increase levothyroxine absorption.
- **Oestrogen:** vitamin C may increase blood levels of oestrogen.
- **Warfarin:** high doses of vitamin C may reduce the levels and effectiveness of warfarin.

Zinc

- **Antiretroviral medication:** zinc may decrease levels of antiretroviral medication through chelation.
- **Cephalexin:** zinc may decrease cephalexin levels through chelation in the gut and preventing its absorption.
- **Cisplatin:** theoretically, zinc may interfere with the therapeutic effects of cisplatin.
- **Integrase inhibitors:** theoretically, taking zinc concomitantly with integrase inhibitors may decrease the levels and clinical effects of these medications.
- **Penicillamine:** zinc may reduce the levels and clinical effects of penicillamine.
- **Quinolone antibiotics:** zinc can decrease the levels and clinical effects of quinolone antibiotics.
- **Tetracycline antibiotics:** zinc may reduce the levels of tetracycline antibiotics.

Vitamin B6

- **Amiodarone:** vitamin B6 may increase the photosensitivity caused by amiodarone.
- **Antihypertensive medication:** vitamin B6 may have additive effects when used concomitantly.
- **Phenobarbital:** high doses of vitamin B6 may reduce the levels and clinical effects of phenobarbital.
- **Phenytoin:** high doses of vitamin B6 may reduce the levels and clinical effects of phenytoin.

Vitamin A

- **Hepatotoxic medication:** concomitant use of vitamin A with hepatotoxic medication may increase the risk of liver disease.

- **Retinoids:** concomitant use may produce supratherapeutic vitamin A levels.
- **Tetracycline antibiotics:** concomitant use may increase the risk of pseudotumor cerebri.
- **Warfarin:** high doses of vitamin A may increase the risk of bleeding with warfarin.

Vitamin D

- **Aluminium:** vitamin D may increase aluminium absorption and toxicity in patients with renal failure.
- **Atorvastatin:** vitamin D may reduce absorption of atorvastatin.
- **Calcipotriene:** taking calcipotriene with vitamin D increases the risk for hypercalcaemia.
- **Digoxin:** theoretically, hypercalcaemia induced by high-dose vitamin D can increase the risk of arrhythmia from digoxin.
- **Diltiazem:** theoretically, hypercalcaemia induced by high-dose vitamin D can reduce the therapeutic effects of diltiazem for arrhythmia.
- **Thiazide diuretics:** theoretically, taking thiazide diuretics and high-dose vitamin D can increase the risk of hypercalcaemia.
- **Verapamil:** hypercalcaemia induced by high-dose vitamin D can reduce the therapeutic effects of verapamil for arrhythmia.

Branched-Chain Amino Acids (Leucine, Isoleucine, Valine)

- **Antidiabetes medication:** BCAA's may alter the effects of antidiabetes medications.
- **Levodopa:** BCAA's in large doses can reduce the effects of levodopa.

L-Glutamine

- **Anticonvulsants:** glutamine may antagonise the effects of anticonvulsant medication.

L-Arginine

- **ACE inhibitors:** concomitant use may increase the risk of hypotension and hyperkalaemia.
- **Angiotensin receptor blockers:** concomitant use may increase the risk of hypotension and hyperkalaemia.
- **Anticoagulant/antiplatelet medication:** concomitant use may increase the risk of bleeding.
- **Antidiabetes medication:** concomitant use may have additive effects.
- **Antihypertensive medication:** concomitant use may increase the risk of hypotension.
- **Isoproterenol:** concomitant use may increase the risk of hypotension.
- **Potassium-sparing diuretics:** concomitant use may increase the risk of hyperkalaemia.
- **Sildenafil:** concomitant use may increase the risk of hypotension.

L-Lysine

- **5-HT4 agonists:** lysine may reduce the effects of 5-HT4 agonists.

L-Phenylalanine

- **Baclofen:** concomitant intake may reduce intestinal absorption of baclofen.
- **Levodopa:** phenylalanine may reduce the effectiveness of levodopa.
- **Monoamine oxidase inhibitors:** concomitant use may increase the risk of hypertensive crisis.

L-Methionine

None known.

L-Histidine

None known.

Tryptophan

- **CNS depressants:** concomitant use may cause additive sedative effects.
- **Serotonergic medications:** concomitant use may cause additive serotonergic effects.

L-Citrulline

- **Antihypertensive medication:** concomitant use may increase the risk of hypotension.
- **Phosphodiesterase-5 inhibitors:** concomitant use may result in additive vasodilation.

Creatine

None known.

L-Cysteine

- **Antidiabetes medication:** concomitant use may increase the risk of hypoglycaemia.

L-Theanine

- **Antihypertensive medication:** theanine may lower blood pressure, potentiating the effects of antihypertensive medication.

Calcium

- **Antiretroviral medication:** calcium may decrease levels of antiretroviral medication through chelation.
- **Bisphosphonates:** calcium reduces the absorption of bisphosphonates.
- **Calcipotriene:** taking calcium with calcipotriene may increase the risk for hypercalcaemia.
- **Diltiazem:** calcium may reduce the therapeutic effects of diltiazem.
- **Levothyroxine:** calcium may reduce the absorption and effectiveness of levothyroxine.
- **Lithium:** concomitant use of calcium and lithium may increase the risk of hypercalcaemia.
- **Quinolone antibiotics:** calcium may reduce the absorption of quinolone antibiotics.
- **Sotalol:** calcium appears to reduce the absorption of sotalol.
- **Tetracycline antibiotics:** calcium appears to reduce the absorption of tetracycline antibiotics.
- **Thiazide diuretics:** concomitant use may increase the risk of hypercalcaemia and renal failure.
- **Verapamil:** calcium may reduce the therapeutic effects of verapamil.

Boron

None known.

4.6 Fertility, pregnancy and lactation

Do not use if pregnant, breastfeeding, or trying to conceive.

4.7 Effects on ability to drive and use machines

REBOUND NUTRITION RECOVER may cause drowsiness. Patients should take caution when driving a vehicle or operating machinery requiring their attention within 2 hours of consumption.

4.8 Undesirable effects

REBOUND NUTRITION RECOVER is generally well tolerated when taken at the recommended dose.

Cardiac disorders

Frequency unknown: hypotension, oedema.

Eye disorders

Frequency unknown: visual blurring.

Gastrointestinal disorders

Frequency unknown: nausea, vomiting, oesophagitis, heartburn, abdominal cramps, gastrointestinal obstruction, diarrhoea, metallic taste in the mouth, indigestion, dry mouth, mouth irritation, loss of appetite, abdominal pain, bloating, belching, constipation.

Musculoskeletal disorders

Frequency unknown: asthenia, increased body mass, muscle cramping.

Nervous system disorders

Frequency unknown: fatigue, headache, insomnia, sleepiness, paraesthesia, somnolence, loss of motor coordination, dizziness, vertigo, irritability, light-headedness, ataxia, thirst, syncope, increased duration of sleep, increased dream activity.

Psychiatric disorders

Frequency unknown: anxiety, hypomania, sedation, depression, aggression, nervousness.

Renal and urinary disorders

Frequency unknown: precipitation of urate, oxalate or cysteine kidney stones in the urinary tract, gout, increased urinary calcium excretion, renal dysfunction.

Reproductive system disorders

Frequency unknown: breast soreness or enlargement, delayed menstruation.

Skin and subcutaneous tissue disorders

Frequency unknown: worsened acne, skin sensitivity, eczema, seborrheic dermatitis, photosensitivity, flushing, rash, hives.

Other disorders

Frequency unknown: night sweats, heat intolerance.

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. Healthcare providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website.

4.9 Overdose

In the event of an overdose, undesirable effects as listed in 4.8 can be precipitated or be of increased severity.

Treatment of overdose is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Class and category: Category D 34.12 Multiple Substance Formulation. Complementary Medicine: Health Supplement.

REBOUND NUTRITION RECOVER is a health supplement that provides a combination of essential amino acids, key vitamins and minerals, and a circulatory support complex to support protein synthesis, muscle recovery, wound healing and tissue repair. It also supports the function of the immune system, particularly during and after intense physical stress.

5.2 Pharmacokinetic properties

Pharmacokinetic studies have not been conducted on REBOUND NUTRITION RECOVER.

Ascorbic Acid:

Vitamin C is well absorbed orally at lower doses, but absorption decreases as the dose increases. Approximately 87% of a 30 mg oral dose is absorbed, 80% of a 100 mg dose is absorbed, 63 % of a 500 mg dose is absorbed, and less than 50% of a 1250 mg dose is absorbed. Most vitamin C that is absorbed is excreted in the urine.

Zinc:

Zinc is mostly absorbed in the small intestine, particularly the jejunum. Most zinc is excreted in the faeces, with a small amount eliminated in the urine.

Vitamin B6:

Vitamin B6 is absorbed passively in the upper gastrointestinal tract. Vitamin B6 metabolites are excreted in the urine.

Vitamin A:

In the plasma, vitamin A is bound to retinol-binding protein. Dietary retinyl esters are hydrolysed by pancreatic and intestinal enzymes. Unesterified retinol is directly absorbed in to intestinal cells, mostly by active transport at lower concentrations and by diffusion at higher concentrations. The majority of vitamin A is excreted in the urine. Lesser amounts are lost through the breath and faeces, as inactive metabolites. In vitamin A excess, biliary excretion increases.

Vitamin D:

The two forms of vitamin D, cholecalciferol and ergocalciferol, are well absorbed.

Branched-Chain Amino Acids (Leucine, Isoleucine, Valine)

BCAA's cross the blood-brain barrier rapidly.

L-Glutamine:

Glutamine is absorbed in the jejunum. Glutamine is eliminated in the urine but is almost fully reabsorbed by the renal tubules.

L-Arginine:

L-arginine has an oral bioavailability of 68 %.

L-Lysine:

Lysine is excreted in the faeces and urine.

L-Phenylalanine:

Absorption occurs within 60 minutes of ingestion. Oral doses of D-phenylalanine or DL-phenylalanine is excreted in the urine in healthy adults.

L-Methionine:

There is insufficient reliable information available about the pharmacokinetics of methionine.

L-Histidine:

There is insufficient reliable information available about the pharmacokinetics of histidine.

L-Tryptophan:

The body absorbs L-tryptophan from dietary protein sources. Both L-tryptophan and its metabolite 5-HTP can penetrate the blood-brain barrier. Following consumption of L-tryptophan, nicotinamide and its break down products, as well as L-tryptophan and its metabolites in the L-tryptophan to nicotinamide pathway are excreted in the urine.

L-Citrulline:

Less than 5% of oral doses of L-citrulline is excreted unchanged in the urine.

Creatine:

Intestinal absorption of creatine is nearly 100%. Creatine is excreted renally, with 40% excreted within 10 hours of administration and excretion increased from 1.1 to 1.2 grams per 24 hours.

L-Cysteine:

There is insufficient reliable information available about the pharmacokinetics of L-cysteine.

L-Theanine:

Theanine is absorbed through the intestines. Most L-theanine and its metabolites are excreted in the urine 3-24 hours after oral intake.

Calcium:

Calcium absorption and excretion is affected by several factors. It varies based on age, environmental and dietary conditions, and race. Calcium is excreted in the urine and faeces.

Boron:

Boron is well-absorbed from foods and dietary beverages. When taken orally, boron is excreted unchanged in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lemon-Lime:

Flavouring
Sucralose
Malic Acid
Citric Acid
Steviol Glycosides

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

24 months from date of manufacturing.

6.4 Special precautions for storage

Store at or below 25 °C.
Store in a dry place away from direct sunlight and moisture.
Store in the original package until required for use.

6.5 Nature and contents of container

Laminated foil sachets containing 32 g powder in each. 21 sachets are packed into an outer carton.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Manufactured for:
Machin Holdings (Pty) Ltd
KwaZulu-Natal
South Africa
info@reboundnutrition.co.za

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.