PROFESSIONAL INFORMATION

COMPLEMENTARY MEDICINE: COMBINATION PRODUCT

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

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1. NAME OF THE MEDICINE

REBOUND NUTRITION RESTORE (capsules)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:	
Glucosamine Sulphate (Shellfish)	750,00 mg
Methylsulfonylmethane (MSM)	400,00 mg
Vitamin C (as Ascorbic Acid)	300,00 mg
Chondroitin Sulphate (Bovine)	250,00 mg
Humulus lupulus L. (Hops) [flower, as 200,00 mg of a 5:1 extract providing 1000,00 mg dried herb equivalent]	200,00 mg
Avocado Soybean Unsaponifiables [*Persea americana* and *Glycine max*, fruit and seeds, as 200,00 mg of an extract standardised to 35 % (70,00 mg) phytosterols and 10 % (20,00 mg) tocopherols]	200,00 mg
Carica papaya L. (Papaya) [papain, standardised to 100,00 TU/mg]	126,00 mg
Curcuma longa (Turmeric) [rhizome, as 100,00 mg of a 64:1 extract standardised to 95 % (95,00 mg) curcuminoids]	100,00 mg
Piper nigrum (Black Pepper) [fruit, as 10,00 mg of a 50:1 extract standardised to 95 % (9,50 mg) piperine]	10,00 mg
Vitamin D3 (as Cholecalciferol)	25,00 µg (1000,00 IU)

Sugar free.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsules.
Size 00, white, vegetarian capsules.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

REBOUND NUTRITION RESTORE is a complementary medicine that provides anti-inflammatory support for the relief of joint pain, supports collagen formation for the healthy function of bones and cartilage, and helps promote the development of strong bones and the maintenance of muscle function.

4.2 Posology and method of administration

Posology

Adults 18 years and older:

Take four (4) capsules daily, or as recommended by a healthcare provider. Do not exceed the recommended daily dose.

Do not take immediately before bedtime.

Swallow the capsule whole with a glass of water.

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 hypersensitive (allergic) to shellfish or soy.

4.4 Special warnings and precautions for use

- Consult a healthcare provider prior to use if you have a liver or biliary disorder, hormone-sensitive condition (e.g. breast, uterine or ovarian cancer, endometriosis, uterine fibroids), gastrointestinal lesions or ulcers, gallstones or gallbladder disease, kidney disease, hypercalcaemia, histoplasmosis, hyperparathyroidism, lymphoma, sarcoidosis, tuberculosis, arteriosclerosis, a fertility disorder, bleeding disorder, glaucoma, or asthma.
- Consult a healthcare provider prior to use if you have prostate cancer or a history thereof.
- Consult a healthcare provider prior to use if you have an allergy to latex or fruits (e.g. avocado, banana, chestnut, passion fruit, fig, melon, mango, kiwi, pineapple, peach, or tomato).
- Consult a healthcare provider prior to use if you are taking any other medications or health products, as REBOUND NUTRITION RESTORE 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).

Glucosamine

- Topoisomerase II Inhibitors: glucosamine may induce resistance to topoisomerase II inhibitors.
- Warfarin: glucosamine may increase the anticoagulant effects of warfarin and increase the risk of bruising and bleeding.

Methylsulfonylmethane (MSM)

None reported.

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.

Chondroitin Sulphate

- Warfarin: taking chondroitin in combination with glucosamine may increase the anticoagulant effects of warfarin.

Humulus lupulus L. (Hops)

- CNS depressants: theoretically, concomitant use of hops with sedatives may cause additive sedation.
- Oestrogen: theoretically, concomitant use of hops might interfere with hormone replacement therapy due to competition for oestrogen receptors.

Avocado Soybean Unsaponifiables

None reported.

Papain

- Warfarin: theoretically, papain may increase the effects and side effects of warfarin.

Turmeric/Curcumin

- Alkylating agents: theoretically, the antioxidant effects of turmeric may reduce the effectiveness of alkylating agents.
- Amlodipine: taking turmeric with amlodipine may increase the levels of amlodipine.

- Anticoagulant/antiplatelet medication: turmeric may have antiplatelet effects and may increase the risk of bleeding if used concomitantly with anticoagulant or antiplatelet medications.
- Antidiabetic medication: theoretically, concomitant use may increase the risk of hypoglycaemia.
- Antitumor antibiotics: theoretically, the antioxidant effects of turmeric may reduce the effectiveness of antitumor antibiotics.
- Hepatotoxic medication: theoretically, turmeric may increase the risk of liver damage when used with hepatotoxic medication.
- Organic Anion-Transporting Polypeptide Substrates (OATP): theoretically, turmeric might increase the blood levels of OATP4C1 substrates.
- Sulfasalazine: turmeric might increase the effects and adverse effects of sulfasalazine.
- Tacrolimus: turmeric might increase the effects and adverse effects of tacrolimus.
- Talinolol: turmeric may reduce the absorption of talinolol in some situations.
- Tamoxifen: theoretically, turmeric might reduce the levels and clinical effects of tamoxifen.
- Topoisomerase I Inhibitors: theoretically, the antioxidant effects of turmeric may reduce the effectiveness of topoisomerase I inhibitors.
- Tramadol: theoretically, turmeric might increase or decrease levels of tramadol.
- Warfarin: turmeric might increase the risk of bleeding when used concomitantly with warfarin.

Black Pepper

- Anticoagulant/antiplatelet medication: theoretically, black pepper might increase the risk of bleeding when taken concomitantly with anticoagulant or antiplatelet medication.
- Antidiabetic medication: theoretically, black pepper might increase the risk of hypoglycaemia when taken with antidiabetic medication.
- Atorvastatin: theoretically, black pepper might increase blood levels of atorvastatin.
- Cyclosporine: theoretically, black pepper might increase the effects and side effects of cyclosporine.
- Lithium: theoretically, black pepper might increase blood levels of lithium due to its diuretic effects. The dose of lithium might need to be reduced.
- Nevirapine: black pepper might increase blood levels of nevirapine.
- P-glycoprotein substrates: theoretically, black pepper might increase levels of P-glycoprotein substrates.
- Pentobarbital: black pepper might increase the sedative effects of pentobarbital.
- Phenytoin: black pepper might increase blood levels of phenytoin.
- Propranolol: black pepper might increase the blood levels of propranolol.
- Rifampin: black pepper might increase blood levels of rifampin.
- Theophylline: black pepper might increase blood levels of theophylline.

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.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

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

Blood and lymphatic system disorders

Frequency unknown: anticoagulant activity.

Eye disorders

Frequency unknown: ocular dryness, increased intraocular pressure.

Gastrointestinal disorders

Frequency unknown: epigastric and abdominal pain, abdominal cramps, heartburn, diarrhoea, nausea, dyspepsia, vomiting, constipation, flatulence, bloating, esophagitis, regurgitation, gastric ulcers, yellow and/or hard stools, loose stools, gastritis, distension, gastroesophageal reflux disease, abdominal fullness, burning aftertaste.

Hepatobiliary disorders

Frequency unknown: acute liver injury, increased aminotransferase levels.

Nervous system disorders

Frequency unknown: drowsiness, sedation, headache, migraine, fatigue, insomnia, difficulty concentrating, sleepiness, vertigo, giddiness.

Renal and urinary disorders

Frequency unknown: precipitation of urate, oxalate, or cysteine stones in the urinary tract.

Reproductive system disorders

Frequency unknown: postmenopausal bleeding.

Respiratory, thoracic and mediastinal disorders:

Frequency unknown: asthma exacerbations.

Skin and subcutaneous tissue disorders

Frequency unknown: itching, rash, erythema, fingernail and toenail toughening (with increased rate of growth), eyelid oedema, lower limb oedema, alopecia, water retention around eyes and scars, hives.

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 33.7 Combination Product. Complementary Medicine.

REBOUND NUTRITION RESTORE is a complementary medicine that provides anti-inflammatory support for the relief of joint pain, supports collagen formation for the healthy function of bones and cartilage, and helps promote the development of strong bones and the maintenance of muscle function.

5.2 Pharmacokinetic properties

Pharmacokinetic studies have not been conducted on REBOUND NUTRITION RESTORE.

Glucosamine:

Glucosamine is absorbed from the small intestine and is thought to be excreted mainly in the urine.

MSM (Methylsulphonylmethane):

MSM crosses the blood-brain barrier and is excreted in the urine.

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.

Chondroitin Sulphate:

Pharmacokinetic studies indicate that oral absorption of chondroitin sulphate is relatively fast, but oral bioavailability is moderate. Urinary excretion is the main route of elimination of chondroitin sulphate.

Humulus lupulus L. (Hops):

Absorption of hops constituents is described as “slow” and is affected by the demethylation of isoxanthohumol into 8-PN by intestinal microbiota in the distal colon.

Avocado Soybean Unsaponifiables:

There is insufficient reliable information available about the pharmacokinetics of Avocado Soybean Unsaponifiables.

Papain:

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

Turmeric/Curcumin:

In humans, the oral bioavailability of curcumin is low but appears to increase when taken with food or piperine, or when taken in a capsule. Curcumin is present in the faeces and some studies detected curcumin and its conjugates in the urine.

Black Pepper:

There is insufficient reliable information available about the pharmacokinetics of Black Pepper.

Vitamin D:

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule contents:

Corn starch
Magnesium stearate

Capsule shell:

Hypromellose
Titanium dioxide

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

120 capsules packed into a 250 ml amber glass bottle with a silver, aluminium cap and pressure seal, packed into an outer carton.
Pack sizes: 120 capsules.

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.