

**SCHEDULING STATUS:**

Unscheduled

**PROPRIETARY NAME AND DOSAGE FORM:**

Rejuvenesse® Vitalex Libido, capsules

**COMPOSITION:**

Each Rejuvenesse® Vitalex Libido capsule contains:	
Maca Extract	250 mg
Epimedium Extract (Horny Goat Weed)	100 mg
Panax Ginseng Extract	50 mg
Ginkgo Biloba Extract	25 mg
Guarana Extract	25 mg
Nicotinamide (Vitamin B3)	10 mg
Calcium D-Pantothenate (Vitamin B5)	5 mg
Pyridoxine (Vitamin B6)	5 mg
Cyanocobalamin (Vitamin B12)	2.5 µg
Vitamin E	5 IU

Other ingredients: Silicon dioxide, maize starch, magnesium stearate. Capsule contains: Bovine gelatine. Sugar free.

**CATEGORY AND CLASS:**

Complementary medicines: Health Supplements. Category D. 34.12 Multiple substance formulation.

**PHARMACOLOGICAL ACTION:****Maca Extract**

Two polyunsaturated fatty acids, macaene and macamide, are used as marker compounds for maca. Lipid extracts of macaene and macamide seem to increase sexual activity and correct erectile dysfunction in experimental animals. The mechanism for this activity is unknown.

**Epimedium Extract (Horny Goat Weed)**

The glycosides in horny goat weed might have hormonal effects. Animal research suggests that horny goat weed promotes semen secretion and stimulates growth of prostate, testes, and anus rector muscles. Some researchers think it might increase testosterone secretion. Horny goat weed exhibits estrogenic activity in vitro. It is a strong activator of oestrogen receptor-alpha and oestrogen receptor-beta; however, it does not seem to affect androgen receptors.

**Panax Ginseng**

Ginseng is widely used as a general tonic or "adaptogen" for fighting stress. There is some evidence that it might work against stress by affecting the hypothalamic-pituitary-adrenal (HPA) axis. Panax ginseng saponins seem to increase serum cortisol concentrations. Panax ginseng might also increase dehydroepiandrosterone sulphate (DHEA-S) levels in women.

**Ginkgo Biloba**

Ginkgo leaf products might benefit vascular conditions by improving circulation. Ginkgo leaf seems to improve blood flow to capillaries throughout the body. Ginkgo leaf likely improves circulation by both decreasing blood viscosity and affecting vascular smooth muscle. Ginkgo leaf seems to restore the balance between prostacyclin and thromboxane A2, resulting in improved vasoregulation. Therefore, ginkgo leaf relaxes spasmodic contracting vasculature and contracts abnormally dilated vessels. It is not clear exactly how ginkgo causes vascular contraction and improves venous tone, but these effects might be due to phosphodiesterase inhibition, resulting in increased cAMP levels and release of catecholamines. Some ginkgo constituents may also have a potent relaxing effect on vascular smooth muscle and improve blood flow to the corpus cavernosum; which is thought to be helpful for erectile dysfunction. Overall, ginkgo leaf seems to increase cerebral and peripheral blood flow microcirculation, and reduce vascular permeability.

**Guarana extract**

Caffeine is responsible for the pharmacologic effects of guarana. Caffeine stimulates the central nervous system (CNS), heart, muscles, and possibly the pressor centres that control blood pressure.

**Nicotinamide (Vitamin B3)**

Nicotinamide is a precursor of nicotinamide adenine dinucleotide (NAD) and nicotinamide adenine dinucleotide phosphate (NADP), which are essential for oxidation-reduction reactions, ATP synthesis, and ADP-ribose transfer reactions.

**Calcium D-Pantothenate (Vitamin B5)**

Calcium D-Pantothenate is required for intermediary metabolism of carbohydrates, proteins, and lipids. Calcium D-Pantothenate is a precursor of coenzyme A, which is 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 compound.

#### **Pyridoxine (Vitamin B6)**

Pyridoxine is required for amino acid, carbohydrate and lipid metabolism. In the body, pyridoxine is converted to coenzymes pyridoxal phosphate and pyridoxamine phosphate, in a wide variety of metabolic reactions.

Pyridoxine has some antioxidant and free radical scavenging activities.

#### **Cyanocobalamin (Vitamin B12)**

Cyanocobalamin is required for nucleoprotein and myelin synthesis, cell reproduction, normal growth, and normal erythropoiesis. Cyanocobalamin is involved in maintaining sulfhydryl groups in the reduced form required by enzymes involved in fat and carbohydrate metabolism and protein synthesis.

#### **Vitamin E**

The major function of vitamin E is that of a chain-breaking antioxidant that prevents the formation of free radicals.

### **INDICATIONS:**

Rejuvenesse® Vitalex Libido is a health supplement for optimum performance and vitality.

### **CONTRA-INDICATIONS:**

**Allergy or sensitivity:** Avoid in people with known allergy or sensitivity to any of the ingredients.

**Caffeine sensitivity:** Guarana extract contains caffeine and can induce cardiac arrhythmias in sensitive individuals. Avoid guarana in individuals with known sensitivity to caffeine.

**Pregnancy and lactation:** Avoid using if pregnant or lactating as safety and efficacy have not been established.

**Hormone sensitive conditions:** Panax ginseng, maca and horny goat weed might have estrogenic effects.

Women with hormone sensitive conditions should avoid panax ginseng, maca and. horny goat weed. Some of these conditions include breast cancer, uterine cancer, ovarian cancer, endometriosis, and uterine fibroids.

**Autoimmune conditions:** Panax ginseng seems to stimulate immune function and might exacerbate autoimmune diseases by stimulating disease activity. Avoid use in patients with autoimmune diseases such as multiple sclerosis (MS), systemic lupus erythematosus (SLE) and rheumatoid arthritis (RA).

**Leber's disease:** Cyanocobalamin is contraindicated in early Leber's disease, which is hereditary optic nerve atrophy. Cyanocobalamin can cause severe and swift optic atrophy.

**QT Interval-prolonging drugs:** Horny goat weed may prolong the QT interval on electrocardiogram in healthy men. Prolonged QT interval is a risk factor for sudden cardiac death. Theoretically, horny goat weed could have an additive effect when combined with drugs that prolong the QT interval and potentially increase the risk of ventricular arrhythmias.

**Organ transplant:** Panax ginseng might have immune system stimulating properties; avoid concurrent use with immunosuppressive therapy.

**Bleeding disorders:** Panax ginseng, ginkgo leaf extract, epimedium extract and the caffeine in guarana can inhibit platelet aggregation and are contraindicated in cases of bleeding disorders.

**Infertility:** Ginkgo extract might inhibit oocyte fertilization and should be avoided in couples attempting to conceive.

**Surgery:** Nicotinamide, panax ginseng, ginkgo leaf extract, horny goat weed and the caffeine in guarana have antiplatelet effects and can cause excessive bleeding if used prior to surgery. Discontinue Rejuvenesse® Vitalex Libido at least 2 weeks before elective surgical procedures.

### **WARNINGS AND SPECIAL PRECAUTIONS:**

**Hypotension:** Horny goat weed might have hypotensive effects and may exacerbate hypotension in people with existing low blood pressure.

**Insomnia:** High doses of ginseng have been associated with insomnia. Use in patients with insomnia might worsen the condition.

**Diabetes:** Ginkgo leaf extract, nicotinamide and the caffeine in guarana may affect blood glucose levels and may interfere with the management of diabetes. A dosing adjustment of antidiabetic medication may be necessary. Monitor blood glucose levels closely.

**Anxiety disorders:** The caffeine in guarana might aggravate anxiety disorders.

**Glaucoma:** Consuming guarana increases intraocular pressure due to its caffeine content.

**Hypertension:** The caffeine in guarana might increase blood pressure in people with high blood pressure.

**Irritable Bowel Syndrome (IBS):** The caffeine in guarana, especially when taken in large amounts, can exacerbate diarrhoea and may worsen the symptoms of Irritable Bowel Syndrome (IBS).

**Allergies:** Nicotinamide may exacerbate allergies by causing histamine release.

**Gallbladder disease:** Nicotinamide may exacerbate gallbladder disease.

**Dependence:** Guarana contains a significant amount of caffeine. Chronic use, especially in large amounts, can produce tolerance, habituation and psychological dependence.

### **INTERACTIONS:**

**Anticoagulant / Antiplatelet drugs:** Nicotinamide, ginkgo biloba, horny goat weed, panax ginseng and the caffeine in guarana might decrease platelet aggregation and might potentiate the effects of anticoagulant and antiplatelet drugs and possibly increase the risk of bleeding. Use cautiously in patients taking anticoagulant or antiplatelet drugs.

**Antihypertensive drugs:** Horny goat weed and pyridoxine might have hypotensive effects. Concomitant use with antihypertensive drugs might have additive effects on blood pressure and increase the risk of hypotension.

**Oestrogen therapy:** Horny goat weed and panax ginseng may have oestrogenic activity and may increase blood levels of oestrogen in some women. Concomitant use with oestrogens might increase therapeutic and adverse effects.

**QT Interval-prolonging drugs:** Horny goat weed and panax ginseng may prolong the QT interval on electrocardiogram in and could have an additive effect when combined with drugs that prolong the QT interval and potentially increase the risk of ventricular arrhythmias.

**Antidiabetic drugs:** Concomitant use of guarana, ginseng panax and ginkgo leaf extract with antidiabetic drugs might affect blood glucose levels and might alter the response to antidiabetic drugs. Monitor blood glucose levels closely and adjust dosages of antidiabetic drugs if required.

**CNS stimulant drugs:** Caffeine and stimulant drugs might have an additive effect on the stimulant effects of ginseng panax and guarana extract.

**Immunosuppressant therapy:** Ginseng panax might have immune system stimulating properties. Concurrent use with immunosuppressants might interfere with immunosuppressive therapy.

**Antidepressants:** Ginkgo may increase synaptosomal reuptake of serotonin and may decrease the efficacy of serotonergic antidepressants. Ginkgo in combination with fluoxetine (Prozac), St. John's wort, melatonin, and buspirone might cause hypomania in patients with depression. Use of ginkgo leaf extract with trazodone has been associated with coma.

**Non-nucleoside reverse transcriptase inhibitors (NNRTIs):** There are reports of decreased efavirenz concentrations and increased viral load in patients taking ginkgo. Use caution if taking ginkgo with efavirenz and other non-nucleoside reverse transcriptase inhibitors (NNRTIs) that are metabolized by CYP3A4.

**Beta-agonists:** Concomitant use of large amounts of guarana might increase cardiac inotropic effects of beta-agonists, due to guarana's caffeine content.

**Riluzole:** The caffeine in guarana may increase serum riluzole concentrations and the risk of adverse effects.

**Pentobarbital:** The caffeine in guarana might negate the hypnotic effects of pentobarbital.

**Theophylline:** The caffeine in guarana may increase serum theophylline concentrations and the risk of adverse effects.

## **HUMAN REPRODUCTION:**

Safety and efficacy have not been established. Avoid using if pregnant or lactating.

## **DOSAGE AND DIRECTIONS FOR USE:**

Take 2 capsules daily with water, as required or as recommended by your healthcare professional. Do not exceed the recommended dosage.

## **SIDE EFFECTS:**

### **Maca extract**

Maca is well tolerated by most people.

### **Epimedium Extract (Horny Goat Weed)**

Long-term use of horny goat weed has been associated with reports of dizziness, vomiting, dry mouth, thirst, and nosebleed. Large doses of horny goat weed may cause respiratory arrest and exaggeration of tendon reflexes to the point of spasm.

### **Panax Ginseng**

Panax ginseng is usually well tolerated, but some patients can experience side effects. The most common side effect is insomnia. Less commonly patients can experience mastalgia, vaginal bleeding, amenorrhea, tachycardia and palpitations, hypertension, hypotension, oedema, decreased appetite, diarrhoea, hyperpyrexia, pruritus, rose spots, headache, vertigo, euphoria, and mania. Uncommon side effects can include cerebral arteritis, Stevens-Johnson syndrome, cholestatic hepatitis, and anaphylaxis.

### **Ginkgo Biloba**

Ginkgo leaf extract is well tolerated. It can cause mild gastrointestinal (GI) upset, headache, dizziness, palpitations, constipation, and allergic skin reactions. Large doses can cause restlessness, diarrhoea, nausea, vomiting, lack of muscle tone, and weakness. Spontaneous bleeding is one of the most concerning potential side effects associated with ginkgo. Ginkgo leaf extract can cause allergic skin reactions in some patients.

### **Guarana extract**

Guarana can cause side effects related to the caffeine content. Caffeine can cause insomnia, nervousness, restlessness, gastric irritation, nausea, vomiting, tachycardia, quickened respiration, tremors, delirium, convulsions, and diuresis. Other symptoms include headache, anxiety, and agitation, ringing in the ears, hypokalemia, respiratory alkalosis, chest pain, premature heartbeat, and arrhythmia.

**Nicotinamide (Vitamin B3)**

Nicotinamide is well tolerated but might cause minor adverse effects such as gastrointestinal upset, flatulence, dizziness, rash and itching.

**Calcium D-Pantothenate (Vitamin B5)**

Calcium D-Pantothenate is well tolerated. Large amounts can cause diarrhoea.

**Pyridoxine (Vitamin B6)**

Pyridoxine can cause nausea, vomiting, abdominal pain, loss of appetite, headache, paraesthesia, somnolence, and decreased serum folic acid concentrations.

**Cyanocobalamin (Vitamin B12)**

Cyanocobalamin does not usually cause adverse effects. In some people, cyanocobalamin can cause diarrhoea, peripheral vascular thrombosis, itching, transitory exanthema, and urticaria.

**Vitamin E**

Vitamin E is well tolerated. In uncommon cases, vitamin E can cause nausea, diarrhoea, intestinal cramps, fatigue, weakness, headache, blurred vision, rash, gonadal dysfunction, and creatinuria.

**KNOWN SYMPTOMS OF OVERDOSAGE AND THE PARTICULARS OF ITS TREATMENT:**

Refer to side-effects. Treatment is symptomatic and supportive.

**IDENTIFICATION:**

A sky blue capsule.

**PRESENTATION:**

A white plastic bottle with a screw on cap that contains a white sponge, a white silica gel sachet and 60 capsules, packed in a unit carton together with a white paper printed Patient Information Leaflet (PIL).

**STORAGE INSTRUCTIONS:**

Store at or below 25 °C. Store out of reach of children.

**REGISTRATION NUMBER:**

To be allocated by Council upon registration.

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:**

Manufactured and packed under pharmaceutical control for Rejuvenesse® by:

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