

MENTAL LIFT

PROFESSIONAL INFORMATION

D 33.6 Western Herbal Medicine. 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: **SD**1. NAME OF THE MEDICINE
BIOGEN MENTAL LIFT™

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains	%NRV*
Bacopa Monnieri (L.) Wettst. (Bacopa) [Whole herb, 8:1 - 12:1 extract standardised to 20 % Bacosides]	150.00 mg
N-acetyl-L-carnitine	125.00 mg
N-acetyl-L-tyrosine	125.00 mg
Cytidine 5'-diphosphatecholine (CDP-choline) [Cognizin® Citicoline]	50.00 mg
Rhodiola rosea L. (Arctic root) [Root, extract standardised to 3 % Salidroside]	50.00 mg
L-Theanine	50.00 mg
Ginkgo biloba L. (Ginkgo Biloba) [Leaf, extract standardised to 24 % ginkgo flavones and 6 % lactones]	40.00 mg
Panax ginseng C.A. (Panax Ginseng) [Root, 5:1 extract providing 125.00 mg DHE]	25.00 mg
Phosphatidylserine	25.00 mg
Pyridoxine (Vitamin B ₆) (from pyridoxine hydrochloride)	5.00 mg
Vitamin B ₁₂ (Cyanocobalamin)	12.50 µg
	521 %

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

Sugar Free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Vegetable Capsules

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

BIOGEN MENTAL LIFT™, a combination of vitamins, minerals and herbs that contributes to the reduction of exhaustion and fatigue and enhance cognitive function and memory. With adaptogens to help increase energy and resistance to stress.

4.2 Posology and method of administration

Adults:

Take 2 (two) capsules daily with breakfast, or as recommended by your healthcare provider.

The safety and efficacy of BIOGEN MENTAL LIFT™ in children has not yet been established. Not allowed in children under 18 years.

4.3 Contraindications

- If you have a hypersensitivity to Bacopa, N-acetyl-L-carnitine, N-acetyl-L-tyrosine, CDP-Choline, Rhodiola, L-Theanine, Ginkgo Biloba, Panax Ginseng, Phosphatidylserine, Vitamin B₆, and Vitamin B₁₂ or any of the excipients listed in 6.1.
- Not recommended in patients that are taking blood coagulation supplements as this may increase the risk of spontaneous bleeding.
- Acetyl-L-carnitine might interfere with the activity of thyroid hormone in the body, avoid use in patients with hypothyroidism.
- Not recommended during pregnancy and lactation.

4.4 Special warnings and precautions for use

Special care should be taken with BIOGEN MENTAL LIFT™. If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine. Please take note of the following:

- Bacopa extract is does not have enough reliable information about the safety.
- Consult a health care provider prior to use if you have liver disease, kidney disease and/or a seizure disorder.
- The use of Ginkgo Biloba in patients with a pathologically increased bleeding tendency (haemorrhagic diathesis) should discuss dosage recommendations with your relevant healthcare provider.
- Ginkgo Biloba might increase susceptibility to bleeding, and should be discontinued as a precaution prior to scheduled surgeries.
- It is advised to discuss Vitamin B₁₂ or folic acid deficiency with your healthcare provider as administration of > 10 µg daily may produce a haematological response in patients.
- Patients who have early Leber's disease (hereditary optic nerve atrophy) have been found to suffer severe and swift optic atrophy when Vitamin B₁₂ is administered.
- Treatment of severe Vitamin B₁₂ megaloblastic anaemia may result in severe hypokalemia.
- Consult a healthcare provider prior to use if you are pregnant or breastfeeding.
- BIOGEN MENTAL LIFT™ is not recommended for use in children under the age of 18 years.

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 interaction

Interactions with Medicines

- Because bacopa could increase thyroid hormone levels, people taking thyroid hormone drugs should avoid taking bacopa.
- Taking both bacopa and fluoxetine, an antidepressant, could cause such symptoms as confusion, agitation, and changes in blood pressure or temperature.
- Bacopa might boost levels of certain chemicals in the brain, heart, and other parts of the body. Some drugs, such as those used to treat Alzheimer disease and glaucoma, including pilocarpine, donepezil, and tacrine, might also affect these chemicals.
- Bacopa could also increase levels of other drugs, such as the blood thinner warfarin, diabetes drugs such as metformin, sulfonylureas, or biguanides, some chemotherapy drugs, such as etoposide, vinorelbine, or vincristine.
- Bacopa might inhibit acetylcholinesterase and might increase acetylcholine levels, which could counteract the effects of anticholinergic drugs. Similarly, anticholinergic drugs might counteract the cholinergic effects of bacopa.
- If Ginkgo Biloba is taken concomitantly with antiplatelet agents (e.g. pravaspirin and warfarin) or platelet aggregation inhibitors (e.g. clopidogrel, aspirin and other non-steroidal anti-inflammatory drugs), their effect may be influenced.
- Available studies indicate no interaction between warfarin and Ginkgo biloba products. Adequate monitoring is however advised when starting, changing or ending Ginkgo biloba intake or if changing product.
- An interaction study with talinolol indicates that Ginkgo biloba may inhibit P-glycoprotein at the intestinal level. This may give rise to increased exposure of drugs mainly affected by P-glycoprotein in the intestine such as dabigatran etexilate. Caution is advised if combining and dabigatran etexilate.
- One interaction study has indicated that the Crmax of nifedipine may be increased by Ginkgo biloba. In some individuals, increases by up to 100% were observed resulting in dizziness and increased severity of hot flushes.
- Concomitant use of Ginkgo biloba and efavirenz is not recommended. Plasma concentrations of efavirenz may be decreased because of induction of CYP3A4 (see section 4.4).
- Acetyl-L-carnitine might increase the risk of mania in patients with bipolar disorder; use with caution in patients with bipolar disorder.
- Acetyl-L-carnitine in patients undergoing taxane-based chemotherapy may increase symptoms of neuropathy; avoid use for the prevention of chemotherapy-induced peripheral neuropathy.
- Acetyl-L-carnitine might interfere with the activity of thyroid hormone in the body, avoid use in patients with hypothyroidism.
- Acetyl-L-carnitine might increase the risk for seizures in patients with seizure disorders, avoid use in patients with a history of seizures.
- Tyrosine and levodopa compete for absorption in the proximal duodenum by the large neutral amino acid (LNAA) transport system. Patients are advised to separate doses of tyrosine and levodopa by at least 2 hours.
- Tyrosine is a precursor to thyroxine and might increase levels of thyroid hormones.
- Concomitant use of Rhodiola with antibiotic drugs might increase the risk of hypoglycemia, Rhodiola extract can decrease blood glucose levels due to alpha-glucosidase activity.
- Rhodiola extract inhibits angiotensin-converting enzyme (ACE) and might lower blood pressure, taking Rhodiola with antihypertensive drugs might decrease the risk of hypertension.
- Rhodiola has immunomodulatory effects, and might interfere with immunosuppressive therapy, and might increase the levels and adverse effects of losartan.
- Rhodiola inhibits P-glycoprotein, and might increase levels of P-glycoprotein substrates.
- Theanine might lower blood pressure, potentiating the effects of antihypertensive drugs. Concomitant use of theanine and antihypertensive drugs might potentiate the antihypertensive activity.
- Taking Panax ginseng with antidiabetics drugs might increase the risk of hypoglycemia, Panax ginseng might decrease blood glucose levels and it is advised that blood glucose levels are monitored closely.
- Caution is advised when taking Panax ginseng with caffeine, concomitant use might increase the risk of stimulant effects.
- Panax ginseng might decrease levels of drugs metabolized by CYP1A1, increase levels of drugs metabolized by CYP2D6 and increase or decrease levels of drugs metabolized by CYP3A4.
- Concomitant use of large amounts of Panax ginseng might interfere with hormone replacement therapy, decrease blood levels of oral fexofenadine, reduce effects of furosemide, increase the effects and adverse effects of imatinib, and interfere with immunosuppressive therapy.
- Panax ginseng in combination with insulin might increase the risk of hypoglycemia.
- Phosphatidylserine might decrease the effectiveness of anticholinergic drugs and might have additive effects with cholinergic drugs.
- Vitamin B₆ might increase the photosensitivity caused by amiodarone, have additive effects when used with antihypertensive drugs, may increase the metabolism of levodopa when taken alone, but not when taken in conjunction with carbidopa. Vitamin B₆ may reduce the levels and clinical effects of phenobarbital and phenytoin.
- Vitamin B₁₂ is not a substitute for folic acid and since it might improve folic acid deficient megaloblastic anemia, its selective use of vitamin B₁₂ could mask the true diagnosis.
- Antibiotics (used to treat infections) and antimetabolites (used to treat some cancers) can affect the blood tests to determine Vitamin B₁₂.
- Colchicine, aminoglycosides, certain anticonvulsants (e.g., phenytoin, Phenobarbital, primidone), para-aminosalicylic acid or excessive alcohol intake for longer than 2 weeks may impair the absorption of Vitamin C. Vitamin C may destroy Vitamin B₁₂. Patients are advised to avoid ingesting large amounts of Vitamin C within 1 hour of oral Vitamin B₁₂ administration.

Interactions with Diseases/Impairments

- Bacopa may inhibit acetylcholinesterase, which might produce cholinergic effects and this could therefore worsen bradyarrhythmia and exacerbate gastrointestinal obstruction and peptic ulcer disease; use with caution.
- Bacopa may inhibit acetylcholinesterase, which might produce cholinergic effects, such as increasing secretions in the respiratory tract. This could exacerbate pulmonary conditions such as asthma and chronic obstructive pulmonary disease; use with caution.
- Bacopa may increase thyroxine (T4) levels and might exacerbate hyperthyroidism. Bacopa should be used cautiously in patients with thyroid disorder.
- Ginkgo biloba has been associated with increased bleeding tendency (haemorrhagic diathesis), patients should monitor blood coagulation levels (see section 4.4).
- Ginkgo biloba may worsen an onset of further seizures in patients with epilepsy.
- Patients with Diabetes should monitor blood sugar levels. Concomitant use of Ginkgo biloba and diabetes medications might have an impact on the efficacy of the patients' diabetes medication.
- Acetyl-L-carnitine might increase the risk of mania in patients with bipolar disorder; use with caution in patients with bipolar disorder.
- Acetyl-L-carnitine in patients undergoing taxane-based chemotherapy may increase symptoms of neuropathy; avoid use for the prevention of chemotherapy-induced peripheral neuropathy.
- Acetyl-L-carnitine might interfere with the activity of thyroid hormone in the body, avoid use in patients with hypothyroidism.
- Acetyl-L-carnitine might increase the risk for seizures in patients with seizure disorders, avoid use in patients with a history of seizures.
- Tyrosine, a precursor for thyroxine, might boost thyroid hormone levels. This might exacerbate hyperthyroidism and Graves' disease, or alter the treatment of hypothyroidism, patients with thyroid disorders should avoid taking tyrosine supplements.
- Rhodiola and Panax ginseng might exacerbate certain autoimmune diseases by stimulating disease activity; avoid use or use with caution in patients with autoimmune diseases such as multiple sclerosis (MS), systemic lupus erythematosus (SLE), rheumatoid arthritis (RA), or others. Rhodiola might have immunostimulatory effects. Panax ginseng may stimulate immune function.
- Panax ginseng might increase bleeding; patients are advised to avoid use in cases of hemorrhage or thrombosis. Panax ginseng has been reported to decrease blood coagulation.
- Panax ginseng might increase adverse cardiovascular effects; caution is advised in patients with cardiac conditions.
- Panax ginseng might increase the development of hormone-sensitive tumors; avoid in patients with hormone-sensitive conditions such as breast cancer, uterine cancer, ovarian cancer, endometriosis, and uterine fibroids.
- Panax ginseng might interfere with immunosuppressive therapy; avoid use. Panax ginseng might have immune system stimulating properties.
- Panax ginseng might worsen some symptoms; use with caution. High doses of ginseng have been associated with insomnia and agitation in people with schizophrenia.
- B vitamins might increase the rate of restenosis after bare metal stent placement.
- Supplemental vitamin B₆ at levels above the dietary reference intakes (DRI) should not be recommended following bariatric surgery.
- Hypokalemia and thrombocytopenia could occur upon conversion of severe megaloblastic to normal erythropoiesis with Vitamin B₁₂ therapy. Therefore, serum potassium levels and the platelet count should be monitored carefully during oral administration.
- Vitamin B₁₂ deficiency may suppress the signs of polycythemia vera.

Interactions with Foods

- Vitamins, minerals and nutrients obtained from other sources should be taken into account when prescribing / suggesting BIOGEN MENTAL LIFT™.
- Alcohol intake for longer than 2 weeks may impair the absorption of Vitamin B₁₂.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established and is contraindicated in pregnancy (see section 4.3).

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive or use machinery have been performed. Patients should exercise caution before driving or use of machinery until they are reasonably certain BIOGEN MENTAL LIFT™ does not adversely affect their performance.

4.8 Undesirable effects

Orally, Bacopa, N-acetyl-L-carnitine, N-acetyl-L-tyrosine, CDP-Choline, Rhodiola, L-Theanine, Ginkgo Biloba, Panax Ginseng, Phosphatidylserine, Vitamin B₆, and Vitamin B₁₂ is well-tolerated.

Summary of adverse reactions

Gastrointestinal disorders:

Frequent: Dry mouth, diarrhea, vomiting, decreased appetite, nausea, flatulence, bloating and abdominal pain or discomfort. Acetyl-L-carnitine may cause nausea, vomiting, hiccups, abdominal distension and gastrointestinal upset or pain. Acetyl-L-carnitine may also cause dry mouth and anorexia. The combined use of acetyl-L-carnitine and alpha-lipoic acid may cause diarrhea, constipation, and dyspepsia. Citicoline may cause abdominal pain, constipation, diarrhea, and nausea in some patients. Rhodiola extract may cause dry mouth or excessive saliva production. Panax ginseng can cause decreased appetite, diarrhea, abdominal pain, and nausea. Phosphatidylserine can cause gastrointestinal upset such as flatulence or nausea. Gastrointestinal upset can occur at doses of 200-300 mg/day. Vitamin B₆ (pyridoxine) can cause nausea, vomiting, heartburn, abdominal pain, mild diarrhea, and loss of appetite.

Nervous system disorders:

Frequent: Drowsiness, dizziness, insomnia, vivid dreams and headaches. Acetyl-L-carnitine may cause agitation (restlessness and motor over activity). Rhodiola extract can cause dizziness. Panax ginseng may cause insomnia, headache and vertigo. Phosphatidylserine can cause insomnia. Insomnia is more likely to occur with a higher dose of 600 mg. Vitamin B₆ (pyridoxine) can cause headache, paresthesia, and somnolence.

Musculoskeletal:

Frequency unknown: Muscle fatigue. Vitamin B₆ (pyridoxine) can cause breast soreness or enlargement.

Dermatologic:

Less Frequent: The combined use of acetyl-L-carnitine and alpha-lipoic acid may cause rash. Citicoline may cause skin rash in some patients. Panax ginseng may cause itching or an allergic response consisting of systemic rash and pruritis.

Frequency unknown: Palpitations and chest tightness. Orally, citicoline may cause chest pain, palpitations, hypotension, bradycardia, tachycardia, and peripheral edema in some patients, although the incidence is likely similar to placebo. Panax ginseng may cause hypertension, hypotension, and edema when used orally in high doses, long-term.

Musculoskeletal:

Frequency unknown: Muscle fatigue. Vitamin B₆ (pyridoxine) can cause breast soreness or enlargement.

Dermatologic:

Less Frequent: The combined use of acetyl-L-carnitine and alpha-lipoic acid may cause rash. Citicoline may cause skin rash in some patients. Panax ginseng may cause itching or an allergic response consisting of systemic rash and pruritis.

Frequency unknown: Palpitations and chest tightness. Orally, citicoline may cause chest pain, palpitations, hypotension, bradycardia, tachycardia, and peripheral edema in some patients, although the incidence is likely similar to placebo. Panax ginseng may cause hypertension, hypotension, and edema when used orally in high doses, long-term.

Musculoskeletal:

Frequency unknown: Muscle fatigue. Vitamin B₆ (pyridoxine) can cause breast soreness or enlargement.

Dermatologic:

Less Frequent: The combined use of acetyl-L-carnitine and alpha-lipoic acid may cause rash. Citicoline may cause skin rash in some patients. Panax ginseng may cause itching or an allergic response consisting of systemic rash and pruritis.

Frequency unknown: Palpitations and chest tightness. Orally, citicoline may cause chest pain, palpitations, hypotension, bradycardia, tachycardia, and peripheral edema in some patients, although the incidence is likely similar to placebo. Panax ginseng may cause hypertension, hypotension, and edema when used orally in high doses, long-term.

Musculoskeletal:

Frequency unknown: Muscle fatigue. Vitamin B₆ (pyridoxine) can cause breast soreness or enlargement.

Dermatologic:

Less Frequent: The combined use of acetyl-L-carnitine and alpha-lipoic acid may cause rash. Citicoline may cause skin rash in some patients. Panax ginseng may cause itching or an allergic response consisting of systemic rash and pruritis.

Frequency unknown: Palpitations and chest tightness. Orally, citicoline may cause chest pain, palpitations, hypotension, bradycardia, tachycardia, and peripheral edema in some patients, although the incidence is likely similar to placebo. Panax ginseng may cause hypertension, hypotension, and edema when used orally in high doses, long-term.

Musculoskeletal:

Frequency unknown: Muscle fatigue. Vitamin B₆ (pyridoxine) can cause breast soreness or enlargement.

Dermatologic:

Less Frequent: The combined use of acetyl-L-carnitine and alpha-lipoic acid may cause rash. Citicoline may cause skin rash in some patients. Panax ginseng may cause itching or an allergic response consisting of systemic rash and pruritis.

Frequency unknown: Palpitations and chest tightness. Orally, citicoline may cause chest pain, palpitations, hypotension, bradycardia, tachycardia, and peripheral edema in some patients, although the incidence is likely similar to placebo. Panax ginseng may cause hypertension, hypotension, and edema when used orally in high doses, long-term.

Musculoskeletal:

Frequency unknown: Muscle fatigue. Vitamin B₆ (pyridoxine) can cause breast soreness or enlargement.

Dermatologic:

Less Frequent: The combined use of acetyl-L-carnitine and alpha-lipoic acid may cause rash. Citicoline may cause skin rash in some patients. Panax ginseng may cause itching or an allergic response consisting of systemic rash and pruritis.

Frequency unknown: Palpitations and chest tightness. Orally,

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: PRODUCT NAME
BIOGEN MENTAL LIFT™

Each vegetable capsule contains:

Bacopa, N-acetyl-L-carnitine, N-acetyl-L-tyrosine, CDP-Choline, Rhodiola, L-Theanine, Ginkgo Biloba, Panax Ginseng, Phosphatidylserine, Vitamin B₆, and Vitamin B₁₂.

Sugar free.

COMPLEMENTARY MEDICINE: D 33.6 Western Herbal Medicine

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

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

BIOGEN MENTAL LIFT™ is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to take BIOGEN MENTAL LIFT™ carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share BIOGEN MENTAL LIFT™ with any other person.
- Ask a healthcare provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What BIOGEN MENTAL LIFT™ is and what it is used for.
2. What you need to know before you take BIOGEN MENTAL LIFT™.
3. How to take BIOGEN MENTAL LIFT™.
4. Possible side effects.
5. How to store BIOGEN MENTAL LIFT™.
6. Contents of the pack and other information.

1. What BIOGEN MENTAL LIFT™ is and what it is used for

BIOGEN MENTAL LIFT™, a combination of vitamins, minerals and herbs that contributes to the reduction of exhaustion and fatigue and enhance cognitive function and memory. With adaptogens to help increase energy and resistance to stress.

2. What you need to know before you take BIOGEN MENTAL LIFT™

- Do not take BIOGEN MENTAL LIFT™:**
- If you have a hypersensitivity to Bacopa, N-acetyl-L-carnitine, N-acetyl-L-tyrosine, CDP-Choline, Rhodiola, L-Theanine, Ginkgo Biloba, Panax Ginseng, Phosphatidylserine, Vitamin B₆, and Vitamin B₁₂ or any of the other ingredients listed (see section 6).
 - Not recommended in patients that are taking blood coagulation supplements as this may increase the risk of spontaneous bleeding.
 - Acetyl-L-carnitine might interfere with the activity of thyroid hormone in the body, avoid use in patients with hypothyroidism.
 - Not recommended during pregnancy and lactation.

Warnings and precautions

Special care should be taken with BIOGEN MENTAL LIFT™.

If you are taking any prescribed medication, please check with your healthcare provider before taking this medicine. Please take note of the following:

- Bacopa extract is does not have enough reliable information about the safety.
- Consult a health care provider prior to use if you have liver disease, kidney disease and/or a seizure disorder.
- The use of Ginkgo Biloba in patients with a pathologically increased bleeding tendency (haemorrhagic diathesis) should discuss dosage recommendations with your relevant healthcare provider.
- Ginkgo Biloba might increase susceptibility to bleeding, and should be discontinued as a precaution prior to scheduled surgery.
- It is advised to discuss Vitamin B₁₂ or folic acid deficiency with your healthcare provider as administration of > 10 µg daily may produce a haematological response in patients.
- Patients who have early Leber's disease (hereditary optic nerve atrophy) have been found to suffer severe and swift optic atrophy when Vitamin B₁₂ is administered.
- Treatment of severe Vitamin B₁₂ megaloblastic anaemia may result in severe hypokalemia.
- Consult a healthcare provider prior to use if you are pregnant or breastfeeding.
- BIOGEN MENTAL LIFT™ is not recommended for use in children under the age of 18 years.

Nutritional supplementation should not replace a balanced diet. Do not exceed the recommended dose without consulting a healthcare provider.

Children and adolescents

BIOGEN MENTAL LIFT™ is not recommended for use in children under the age of 18 years.

Other medicines and BIOGEN MENTAL LIFT™

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

It is advised to consult your doctor if you want to take BIOGEN MENTAL LIFT™ combined with other medicines or treatments such as:

- Because bacopa could increase thyroid hormone levels, people taking thyroid hormone drugs should avoid taking bacopa.
- Taking both bacopa and fluoxetine, an antidepressant, could cause such symptoms as confusion, agitation, and changes in blood pressure or temperature.
- Bacopa might boost levels of certain chemicals in the brain, heart, and other parts of the body. Some drugs, such as those used to treat Alzheimer disease and glaucoma, including pilocarpine, donepezil, and tacrine, might also affect these chemicals.
- Bacopa could also increase levels of other drugs, such as the blood thinner warfarin, diabetes drugs such as glipizide, some blood pressure-lowering drugs, such as diltiazem or losartan, or some chemotherapy drugs, such as etoposide, vinblastine, or vincristine.
- Bacopa may inhibit acetylcholinesterase and might increase acetylcholine levels, which could counteract the effects of anticholinergic drugs. Similarly, anticholinergic drugs might counteract the cholinergic effects of bacopa.
- If Ginkgo biloba is taken concomitantly with anti-coagulants (e.g. phenprocoumon and warfarin) or platelet aggregation inhibitors (e.g. clopidogrel, aspirin and other non-steroidal anti-inflammatory drugs), their effect may be influenced.
- Available studies indicate no starting between warfarin and Ginkgo biloba products. Adequate monitoring is however advised when starting, changing or ending Ginkgo biloba intake or if changing product.
- An interaction study with talinolol indicates that Ginkgo biloba may inhibit P-glycoprotein at the intestinal level. This may give rise to increased exposure of drugs markedly affected by P-glycoprotein in the intestine such as dabigatran etexilate. Caution is advised if combining and dabigatran etexilate.
- One interaction study has indicated that the Cmax of nifedipine may be increased by Ginkgo biloba. In some individuals, increases by up to 100% were observed resulting in dizziness and increased severity of hot flushes.
- Concomitant use of Ginkgo biloba and efavirenz is not recommended; plasma concentrations of efavirenz may be decreased because of induction of CYP3A4 (see section 4.4).
- Acetyl-L-carnitine might increase the risk of mania in patients with bipolar disorder; use with caution in patients with bipolar disorder.
- Acetyl-L-carnitine in patients undergoing taxane-based chemotherapy may increase symptoms of neuropathy; avoid use for the prevention of chemotherapy-induced peripheral neuropathy.
- Acetyl-L-carnitine might interfere with the activity of thyroid hormone in the body, avoid use in patients with hypothyroidism.
- Acetyl-L-carnitine might increase the risk for seizures in patients with seizure disorders, avoid use in patients with a history of seizures.
- Tyrosine and levodopa compete for absorption in the proximal duodenum by the large neutral amino acid (LNAA) transport system. Patients are advised to separate doses of tyrosine and levodopa by at least 2 hours.
- Tyrosine is a precursor to thyroxine and might increase levels of thyroid hormones.
- Concomitant use of Rhoila with antidiabetic drugs might increase the risk of hypoglycemia, Rhoila extract can decrease blood glucose due to alpha-glucosidase activity.
- Rhoila extract inhibits angiotensin-converting enzyme (ACE) and might lower blood pressure, taking Rhoila with antihypertensive drugs might increase the risk of hypotension.
- Rhoila inhibits CYP1A2 and CYP2C9, and might increase levels of drug metabolized by CYP1A2 and CYP2C9.
- Rhoila has immunostimulatory effects, and might interfere with immunosuppressive therapy, and might increase the levels and adverse effects of losartan.
- Rhoila inhibits P-glycoprotein, and might increase levels of P-glycoprotein substrates.
- Theanine might lower blood pressure, potentially the effects of antihypertensive drugs. Concomitant use of theanine and antihypertensive drugs might potentiate the antihypertensive effects.
- Taking Panax ginseng with antidiabetes drugs might increase the risk of hypoglycemia, Panax ginseng might decrease blood glucose levels and it is advised that blood glucose levels are monitored closely.
- Caution is advised when taking Panax ginseng with caffeine, concomitant use might increase the risk of stimulant effects.
- Panax ginseng might decrease levels of drugs metabolized by CYP1A1, increase levels of drugs metabolized by CYP2D6 and increase or decrease levels of drugs metabolized by CYP3A4.
- Concomitant use of large amounts of Panax ginseng might interfere with hormone replacement therapy, decrease blood levels of oral furosemide, reduce effects of furosemide, increase the effects and adverse effects of imatinib, and interfere with immunosuppressive therapy.
- Panax ginseng in combination with insulin might increase the risk of hypoglycemia.
- Panax ginseng with stimulant drugs might increase the risk of adverse stimulant effects.
- Phosphatidylserine might decrease the effectiveness anticholinergic drugs and might have additive effects with cholinergic drugs.
- Vitamin B₆ might increase the photosensitivity caused by amiodarone, have additive effects when used with antihypertensive drugs, may increase the metabolism of levodopa when taken alone, but not when taken in conjunction with carbidopa. Vitamin B₆ may reduce the levels and clinical effects of phenobarbital and phenytoin.
- Vitamin B₁₂ is not a substitute for folic acid and since it might improve folate deficient megaloblastic anemia, unselective use of vitamin B₁₂ could mask the true diagnosis.
- Antibiotics (used to treat infections) and antimetabolites (used to treat some cancers) can affect the blood tests to measure Vitamin B₁₂.
- Colchicine, aminoglycosides, certain anticonvulsants (e.g., phenytoin, Phenobarbital, primidone), para-aminosalicylic acid or excessive alcohol intake for longer than 2 weeks may impair the absorption of Vitamin B₆. Vitamin C may destroy Vitamin B₆. Patients are advised to avoid ingesting large amounts of Vitamin C within 1 hour of oral Vitamin B₆ administration.

Other Diseases / Impairments and BIOGEN MENTAL LIFT™

- Bacopa may inhibit acetylcholinesterase, which might produce cholinergic effects and this could therefore worsen bradycardia and exacerbate gastrointestinal obstruction and peptic ulcer disease; use with caution.
- Bacopa may inhibit acetylcholinesterase, which might produce cholinergic effects, such as increasing secretions in the respiratory tract. This could exacerbate pulmonary conditions such as asthma and chronic obstructive pulmonary disease; use with caution.
- Bacopa may increase thyroxine (T4) levels and might exacerbate hyperthyroidism. Bacopa should be used cautiously in patients with thyroid disorder.
- Ginkgo biloba has been associated with increased bleeding tendency (haemorrhagic diathesis), patients should monitor blood coagulation levels (see section 4.4).
- Ginkgo biloba may worsen an onset of further seizures in patients with epilepsy.
- Patients with Diabetes should monitor blood sugar levels. Concomitant use of Ginkgo biloba and diabetes medications might have an impact on the efficacy of the patients' diabetes medication.
- Acetyl-L-carnitine might increase the risk of mania in patients with bipolar disorder; use with caution in patients with bipolar disorder.
- Acetyl-L-carnitine in patients undergoing taxane-based chemotherapy may increase symptoms of neuropathy; avoid use for the prevention of chemotherapy-induced peripheral neuropathy.
- Acetyl-L-carnitine might interfere with the activity of thyroid hormone in the body, avoid use in patients with hypothyroidism.
- Acetyl-L-carnitine might increase the risk for seizures in patients with seizure disorders, avoid use in patients with a history of seizures.
- Tyrosine, a precursor for thyroxine, might boost thyroid hormone levels. This might exacerbate hyperthyroidism and Graves' disease, or alter the treatment of hypothyroidism, patients with thyroid disorders should avoid taking tyrosine supplements.
- Rhodiola and Panax ginseng might exacerbate certain autoimmune diseases by stimulating disease activity; avoid use or use with caution in patients with autoimmune diseases such as multiple sclerosis (MS), systemic lupus erythematosus (SLE), rheumatoid arthritis (RA), or others. Rhodiola might have immunostimulatory effects. Panax ginseng may stimulate immune function.
- Panax ginseng might increase bleeding; patients are advised to avoid in cases of hemorrhage or thrombosis. Panax ginseng has been reported to decrease blood coagulation.
- Panax ginseng might increase adverse cardiovascular effects; caution is advised in patients with cardiac conditions.
- Panax ginseng might increase the development of hormone-sensitive tumors; avoid in patients with hormone-sensitive conditions such as breast cancer, uterine cancer, ovarian cancer, endometriosis, and uterine fibroids.
- Panax ginseng might interfere with immunosuppressive therapy; avoid use. Panax ginseng might have immune system stimulating properties.
- Panax ginseng might worsen insomnia; use with caution. High doses of ginseng have been associated with insomnia.
- Panax ginseng might worsen some symptoms; use with caution. High doses of ginseng have been associated with insomnia and agitation in people with schizophrenia.
- B vitamins might increase the rate of restlessness after bare metal stent placement.
- Hypokalemia and thrombocytopenia could occur upon conversion of severe megaloblastic to normal erythropoiesis with Vitamin B₁₂ therapy. Therefore, serum potassium levels and the platelet count should be monitored carefully during oral administration.
- Vitamin B₁₂ deficiency may suppress the signs of polycythemia vera.

BIOGEN MENTAL LIFT™ with food and drink

- Vitamins, minerals and nutrients obtained from other sources should be taken into account when prescribing / suggesting BIOGEN MENTAL LIFT™.
- Alcohol intake for longer than 2 weeks may impair the absorption of Vitamin B₁₂.

Pregnancy, breastfeeding and fertility

Not recommended for use during pregnancy or lactation.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Driving and using machinery

No studies on the effects on the ability to drive or use machinery have been performed. Patients should exercise caution before driving or use of machinery until they are reasonably certain BIOGEN MENTAL LIFT™ does not adversely affect their performance.

3. How to take BIOGEN MENTAL LIFT™

Do not share your medicines with any other person.

Always take BIOGEN MENTAL LIFT™ exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults:

Take 2 (two) capsules daily with breakfast, or as recommended by your healthcare provider.

The safety and efficacy of BIOGEN MENTAL LIFT™ in children has not yet been established. Not allowed in children under 18 years.

If you take more BIOGEN MENTAL LIFT™ than you should

No known information. In the event of an overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Take this leaflet and the rest of the BIOGEN MENTAL LIFT™ oil with you so the doctor will know what you have taken.

If you forget to take BIOGEN MENTAL LIFT™

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

BIOGEN MENTAL LIFT™ can have side effects.

Not all side effects reported for BIOGEN MENTAL LIFT™ are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BIOGEN MENTAL LIFT™, please consult your healthcare provider for advice.

Side effects - mouth, diarrhoea, vomiting, decreased appetite, nausea, flatulence, bloating and abdominal pain or discomfort.

Acetyl-L-carnitine may also cause nausea, vomiting, hiccup, abdominal distension and gastrintestinal upset or pain. Rhodiola extract may cause dry mouth and anorexia. Citicoline may cause abdominal pain, constipation, diarrhea, and nausea in some patients. Rhodiola extract may cause dry mouth or excessive saliva production. Panax ginseng can cause decreased appetite, diarrhea, abdominal pain, and nausea. Phosphatidylserine can cause gastrintestinal upset such as flatulence or pain. Gastrointestinal upset can occur at doses of 200-300 mg/day. Vitamin B₆ (pyridoxine) can cause nausea, vomiting, heartburn, abdominal pain, mild diarrhea, and loss of appetite.Frequency unknown: Fatigue. Vitamin B₆ (pyridoxine) can cause breast soreness or enlargement.Less Frequent: Drowsiness, insomnia, vivid dreams and headaches. Acetyl-L-carnitine may cause agitation (restlessness and motor activity). Rhodiola extract can cause dizziness. Panax ginseng may cause insomnia, headache and vertigo. Phosphatidylserine can cause insomnia. Insomnia is more likely to occur with a higher dose of 600 mg. Vitamin B₆ (pyridoxine) can cause headache, paresthesia and somnolence.

Frequency unknown: Flu like symptoms and fatigue. One of the metabolites of acetyl-L-carnitine can cause the urine, breath and sweat to have a fishy odour. Also, foul smelling urine has been reported following use of a combination of acetyl-L-carnitine and alpha-lipoic acid. Citicoline may cause headache and insomnia in some patients. Rhodiola may cause may cause hypertension, hypotension, and edema when used orally in high doses, long-term.

Should you get general health worse or if you experience any untoward effects while BIOGEN MENTAL LIFT™, please consult your doctor, pharmacist or other healthcare practitioner for advice.

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

Reporting of side effects

If you experience side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: <http://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of BIOGEN MENTAL LIFT™.

5. How to store BIOGEN MENTAL LIFT™

- Store at below 25°C.
- Protect from light and moisture.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information What BIOGEN MENTAL LIFT™ contains

Active ingredients per capsule:

Bacopa monnieri (Bacopa) 150.00 mg, N-acetyl-L-carnitine 125.00 mg, N-acetyl-L-tyrosine 125.00 mg, CDP-choline (Cognizin® Citicoline) 50.00 mg, Rhodiola rosea 50.00 mg, L-Theanine 50.00 mg, Ginkgo biloba 40.00 mg, Panax ginseng 25.00 mg, Phosphatidylserine 25.00 mg, Pyridoxine (Vitamin B₆) 5.00 mg, Vitamin B₁₂ (Cyanocabalamin) 12.50 µg.

The other ingredients are magnesium stearate.

What BIOGEN MENTAL LIFT™ looks like and contents of the pack

BIOGEN MENTAL LIFT™ is a size 00 vegetable capsules.

BIOGEN MENTAL LIFT™ is a size 00 vegetable capsules.

BIOGEN MENTAL LIFT™ is a size 00 vegetable capsules.

BIOGEN MENTAL LIFT™ is a size 00 vegetable capsules.

BIOGEN MENTAL LIFT™ is a size 00 vegetable capsules.

BIOGEN MENTAL LIFT™ is a size 00 vegetable capsules.

BIOGEN MENTAL LIFT™ is a size 00 vegetable capsules.

BIOGEN MENTAL LIFT™ is a size 00 vegetable capsules.

BIOGEN MENTAL LIFT™ is a size 00 vegetable capsules.

BIOGEN MENTAL LIFT™ is a size 00 vegetable capsules.

BIOGEN MENTAL LIFT™ is a size 00 vegetable capsules.

BIOGEN MENTAL LIFT™ is a size 00 vegetable capsules.

BIOGEN MENTAL LIFT™ is a size 00 vegetable capsules.

BIOGEN MENTAL LIFT™ is a size 00 vegetable capsules.

BIOGEN MENTAL LIFT™ is a size 00 vegetable capsules.

BIOGEN MENTAL LIFT