



1. Generic Names

Alpha Lipoic acid

Ginkgo biloba

Chromium Picolinate

elemental chromium

Methylcobalamin

Methylcobalamin

Zinc sulphate

Vitamin B6

Vitamin C

Vitamin E

Elemental magnesium

2. Qualitative and Quantitative Composition

Alpha Lipoic acid	200 mg
Ginkgo biloba	120 mg
Chromium Picolinate equivalent to elemental chromium	1.66 mg
Methylcobalamin	1500 mcg
Zinc sulphate monohydrate equivalent to elemental zinc	12 mg
Vitamin B6	3 mg

Vitamin C	30 mg
Vitamin E	10 IU
Elemental magnesium	10 mg

3. Dosage form and strength

Otocap is available in form of Capsules for oral administration.

4. Clinical particulars

4.1 Therapeutic indication

- Sudden sensorineural hearing loss
- Senile (age related) sensorineural hearing loss
- Ototoxic drugs induced hearing loss (chemotherapeutic agents, such as cisplatin, and antibiotics, such as aminoglycosides)
- High intensity noise and vibration induced hearing loss
- Meniere's disease
- Vertigo and tinnitus

4.2 Posology and method of administration

Take one capsule daily with food or as directed by physician.

4.3 Contraindication

The use of Otocap is contraindicated in patients with hypersensitivity to any of the ingredients of the formulation.

4.4 Special warnings and precautions for use

Do not take this medication with milk, other dairy products, calcium supplements, or antacids that contain calcium. Calcium may make it harder for your body to absorb certain ingredients of the multivitamin.

4.5 Drug interactions

- Ginkgo can slow blood clotting. Ibuprofen, warfarin and anticoagulants can also slow blood clotting. Taking ginkgo with these drugs can slow blood clotting too much and increase the chance of bruising and bleeding.
- Warfarin: Increased hypoprothrombinemic effect occurs with high doses of vitamin E (>400 IU). Vitamin C can reduce the anticoagulant action of warfarin.
- Iron: Iron interferes with the absorption of vitamin E. Absorption of iron increases with co-administration of vitamin C.
- Vitamin C: Acidifies urine resulting in reabsorption of acidic drugs and an increase in the excretion of basic drugs from the renal tubules (unknown clinical relevance).
- Tetracycline and fluoroquinolones: Zinc decreases the absorption of tetracycline and fluoroquinolones.
- Magnesium can attach to tetracycline in the stomach. This decreases the amount of tetracycline that the body can absorb. Taking magnesium along with tetracycline might decrease the effectiveness of tetracycline.
- Some of these antibiotics that might interact with magnesium include ciprofloxacin, enoxacin, norfloxacin, sparfloxacin, trovafloxacin, and grepafloxacin.
- Magnesium might decrease blood pressure. Taking magnesium with medication for high blood pressure might cause your blood pressure to go too low.

4.6 Use in special population

- Pediatric: Safety and effectiveness of Otopac capsules in children have not been established.
- Geriatric: Safe.
- Liver impairment: Safe.
- Renal failure: Use with caution.
- Pregnancy and lactation: Doctor recommendation is advised.



4.7 Effects on ability to drive and use machine

No effect was observed.

4.8 Undesirable effects

- Vitamin C can cause nausea, abdominal cramps, fatigue, headaches, diarrhoea and kidney stones.
- Alpha lipoic acid can cause low blood sugar--headache, hunger, weakness, sweating, confusion, irritability, dizziness, fast heart rate, skin rash or feeling jittery
- Ginkgo biloba and Vitamin E can cause nausea, diarrhea, dizziness, headaches, stomach ache, restlessness, vomiting.

4.9 Overdose

There is limited experience of overdose with Otopap Capsules. Initiate general symptomatic and supportive measures in all cases of overdosages where necessary.

5. Pharmacological properties

5.1 Mechanism of action

Alpha-lipoic acid acts as a free radical scavenger and assists in repairing oxidative damage and regenerates endogenous antioxidants, including vitamins C and E and glutathione in the ear. This agent also promotes glutathione synthesis. In addition, alpha-lipoic acid exerts metal chelating capacities and functions as a cofactor in various mitochondrial enzyme complexes involved in the decarboxylation of alpha-keto acids.

The compounds found in ginkgo may have a protective role in different stages of the decline of intellectual function via several mechanisms of action: vasoregulating activity of arteries, capillaries, and veins (increased blood flow); platelet activating factor (PAF) antagonism; homeostasis of inflammation and oxidative stress; and prevention of cell membrane damage caused by free radicals; and neurotransmission modulation. The most important

substances are flavonoids (ginkgo flavone glycosides) and terpenoids (ginkgolides and bilobalide). The compounds in ginkgo act to varying degrees as scavengers for free radicals.

Rest all ingredients of Otopac capsule act as anti-oxidant.

5.2 Pharmacodynamic properties

NA.

5.3 Pharmacokinetic properties

NA.

6. Nonclinical properties

6.1 Animal Toxicology or Pharmacology

NA.

7. Description

Alpha-Lipoic Acid is a naturally occurring micronutrient, synthesized in small amounts by plants and animals (including humans), with antioxidant and potential chemo preventive activities. [27]



Class: Anti-oxidant

Chemical Name: 5-(dithiolan-3-yl)pentanoic acid

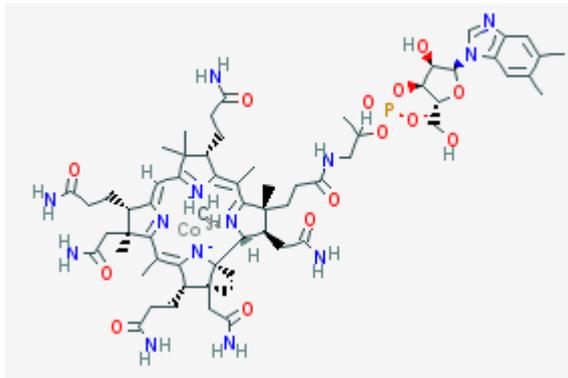
Empirical formula: $C_8H_{14}O_2S_2$

Molecular weight: 206.318 g/mol

Methylcobalamin, or vitamin B12, is a B-vitamin. It is found in a variety of foods such as fish, shellfish, meats, and dairy products.



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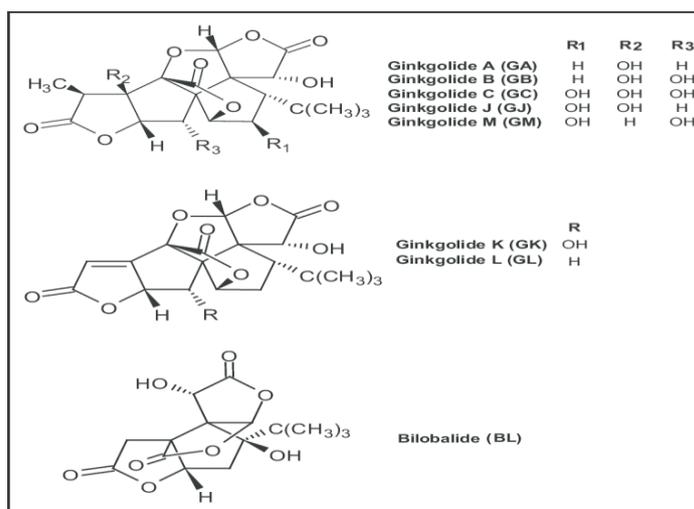
Class: Water-Soluble Vitamins, Hematinics

Chemical Name: cyanocobalamin; cobalt(3+); [(2R,3S,4R,5S)-5-(5,6 dimethylbenzimidazol-1-yl)-4-hydroxy-2-(hydroxymethyl)oxolan-3-yl]-1-[3-[(1R,2R,3R,5Z,7S,10Z,12S,13S,15Z,17S,18S,19R)-2,13,18-tris(2-amino-2-oxoethyl)-7,12,17-tris(3-amino-3-oxopropyl)-3,5,8,8,13,15,18,19-octamethyl-2,7,12,17-tetrahydro-1H-corrin-24-ylidene]propanoylamino]propan-2-yl phosphate

Empirical formula: $C_{63}H_{88}CoN_{14}O_{14}P$ or $C_{63}H_{91}CoN_{13}O_{14}P$

Molecular weight: 1344.405 g/mol

Ginkgo biloba contains important substances like flavonoids (ginkgo flavone glycosides) and terpenoids (ginkgolides and bilobalide). The compounds in ginkgo act to varying degrees as scavengers for free radicals.

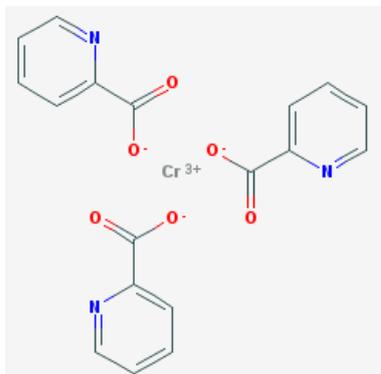


Class: Anti-oxidant



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Chromium picolinate is used as a nutritional supplement for optimal insulin function in patients with Type 2 diabetes or promotion of weight loss.



Class: essential trace element

Chemical Name: chromium(3+);pyridine-2-carboxylate

Empirical formula: $C_{18}H_{12}CrN_3O_6$

Molecular weight: 418.305 g/mol

Magnesium

Magnesium (Mg) is the eighth most abundant element and constitutes about 2% of the Earth's crust, and it is the third most plentiful element dissolved in seawater. It is important for the activity of many enzymes, especially those involved in OXIDATIVE PHOSPHORYLATION.

Class: metallic element

Chemical Name:

Empirical formula: Mg

Molecular weight: 24.305 g/mol

Zinc

It is a necessary trace element in the diet, forming an essential part of many enzymes, and playing an important role in protein synthesis and in cell division. Zinc deficiency is

associated with anaemia, short stature, hypogonadism, impaired wound healing, and geophagia.

Zinc is involved in various aspects of cellular metabolism. It has been estimated that approximately 10% of human proteins may bind zinc. It is thought to have antioxidant properties, which may be protective against accelerated aging and helps to speed up the healing process after an injury.

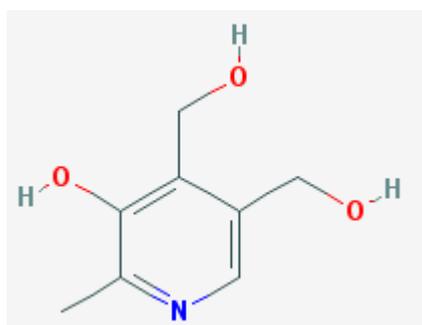
Class: Essential mineral

Chemical Name: Zinc

Empirical formula: Zn

Molecular weight: 65.38 g/mol

Vitamin B6



Class: water-soluble vitamin

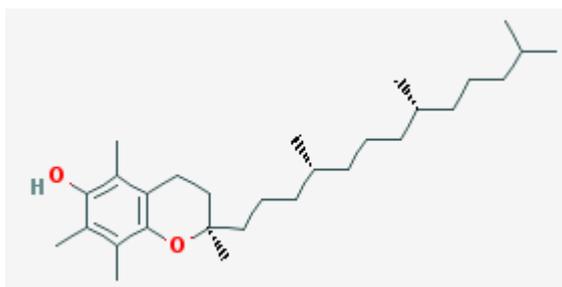
Chemical Name: 4,5-bis(hydroxymethyl)-2-methylpyridin-3-ol

Empirical formula: C₈H₁₁NO₃

Molecular weight: 169.18 g/mol

Vitamins E

Vitamin E (alpha tocopherol) is a fat soluble vitamin and potent antioxidant that is believed to be important in protecting cells from oxidative stress, regulating immune function, maintaining endothelial cell integrity and balancing normal coagulation.



Class: Anti-oxidant

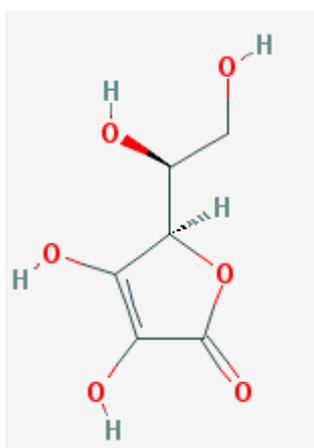
Chemical Name: (2R)-2,5,7,8-tetramethyl-2-[(4R,8R)-4,8,12-trimethyltridecyl]-3,4-dihydrochromen-6-ol

Empirical formula: $C_{29}H_{50}O_2$

Molecular weight: 430.717 g/mol

Vitamin C

It is found naturally in citrus fruits and many vegetables. Ascorbic acid is a potent reducing and antioxidant agent that functions in fighting bacterial infections, in detoxifying reactions, and in the formation of collagen in fibrous tissue, teeth, bones, connective tissue, skin, and capillaries. Found in citrus and other fruits, and in vegetables, vitamin C cannot be produced or stored by humans and must be obtained in the diet.



Class: Anti-oxidant

Chemical Name: (2R)-2-[(1S)-1,2-dihydroxyethyl]-3,4-dihydroxy-2H-furan-5-one

Empirical formula: $C_6H_8O_6$ or $HC_6H_7O_6$

Molecular weight: 176.124 g/mol

8. Pharmaceutical particulars

8.1 Incompatibilities

There are no known incompatibilities.

8.2 Shelf-life

18 months.

8.3 Packaging Information

Otocap capsules are available in blister pack of 10 capsules

8.4 Storage and handling instructions

Store in cool and dry place.

9. Patient Counselling Information

9.1 Adverse Reactions

Refer part 4.8

9.2 Drug Interactions

Refer part 4.5

9.3 Dosage

Refer part 4.2

9.4 Storage

Refer part 8.4

9.5 Risk Factors

Refer part 4.4



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9.6 Self-monitoring information

NA

9.7 Information on when to contact a health care provider or seek emergency help

Patient is advised to be alert for the emergence or worsening of the adverse reactions and contact the prescribing physician.

9.8 Contraindications

Refer part 4.3

10. Manufactured by Ishaana Nutraceuticals Pvt. Ltd..

11. Details of permission or license number with date

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