

**For the use of a Registered Medical Practitioner or Hospital or a Laboratory only**

**NUALA E  
(DIETARY SUPPLEMENT)**



**COMPOSITION**

Each capsule contains approximately:

Energy	1 kcal
Carbohydrate	25 mg
Protein	25 mg
Fat	85 mg

**Ingredients** % w/w

Alpha Lipoic Acid	300 mg	63.4580
Benfotiamine	25 mg	5.3910
Enzogenol	25 mg	5.3140

(Extract of Pinus Radiata bark standardized to provide at least 80% Proanthocyanidins)

Vitamin B <sub>2</sub>	3 mg	0.7930
Vitamin B <sub>6</sub>	1.5 mg	0.3960
Methylcobalamin	750 mcg	0.2130
Folic Acid	300 mcg	0.1220
Chromium Picolinate	30 mcg	0.0068

(Appropriate overages of vitamins added)

**Other Ingredients :**

Maize Starch, Ethyl Cellulose, Di Calcium Phosphate, Lactose, Colloidal Silicon Dioxide, Sodium Lauryl Sulphate, Talcum, Magnesium Stearate, Sodium Metabisulphite, Sodium Methyl Paraben, Sodium Propyl Paraben, HPMC Capsules (Veg. empty capsule) contains permitted colours & Class II Preservatives.

**DESCRIPTION**

A dietary supplement is intended to provide nutrients that may otherwise not be consumed in sufficient quantities. This supplement is not intended to prevent or treat any disease.

**Alpha lipoic acid**

Alpha-lipoic acid is a vitamin-like chemical called an antioxidant. Yeast, liver, kidney, spinach, broccoli, and potatoes are good sources of alpha-lipoic acid. It is also made in the laboratory for use as medicine.

**Benfotiamine**

Benfotiamine, a fat-soluble form of vitamin B1 (thiamine), supports healthy blood sugar metabolism and helps protect the body's tissues against advanced glycation end products and oxidative stress. Benfotiamine is fat-soluble and can easily penetrate into the inside of cells. It is also more bioavailable than the water-soluble thiamine.

### **Enzogenol**

Enzogenol is a a broad-spectrum polyphenol extract,containing many different flavonoid compounds, particularly high in oligomeric proanthocyanidins (OPCs), with exceptional antioxidant and natural anti-inflammatory properties. Extensive research has demonstrated Enzogenol's health promoting properties. These include lowering oxidation and inflammation in the body, supporting cardiovascular, brain and eye function, and protecting the skin from oxidative stress. This combination of benefits makes Enzogenol an outstanding health and anti-ageing supplement.

### **Vitamin B<sub>2</sub> (Riboflavin)**

It can be found in certain foods such as milk, meat, eggs, nuts, enriched flour, and green vegetables. Riboflavin is frequently used in combination with other B vitamins in vitamin B complex products.

### **Vitamin B<sub>6</sub> (Pyridoxine)**

It can be found in certain foods such as cereals, beans, vegetables, liver, meat, and eggs. It can also be made in a laboratory.

### **Methylcobalamin (Vitamin B<sub>12</sub>)**

Vitamin B<sub>12</sub> is a vitamin. It can be found in foods such as meat, fish, and dairy products. It can also be made in a laboratory.

### **Folic acid**

Folate and folic acid are forms of a water-soluble B vitamin. Folate occurs naturally in food, and folic acid is the synthetic form of this vitamin. Foods that are naturally high in folate include leafy vegetables (such as spinach, broccoli, and lettuce), okra, asparagus, fruits (such as bananas, melons, and lemons) beans, yeast, mushrooms, meat (such as beef liver and kidney), orange juice, and tomato juice.

### **Chromium Picolinate**

Chromium is a metal. It is called an "essential trace element" because very small amounts of chromium are necessary for human health.

### **INDICATION**

NUALA E is indicated as a Dietary food supplement.

### **DOSE AND METHOD OF ADMINISTRATION**

One capsule daily half an hour before meal. It is for adult use only

### **USE IN SPECIAL POPULATIONS**

When using nutritional supplements, please consult with your physician if you are undergoing treatment for a medical condition or if you are pregnant or lactating. Stay on the safe side and avoid use.

## **WARNINGS AND PRECAUTIONS**

### **General Warnings**

- Keep out of reach of children
- Do not exceed recommended dose
- When using nutritional supplements, please consult with your physician if you are undergoing treatment for a medical condition or if you are pregnant or lactating.

### **Alpha lipoic acid**

#### ***Diabetes***

Alpha-lipoic acid can decrease blood sugar levels. Your diabetes medications might need to be adjusted by your healthcare provider. Tell your doctor, pharmacist, herbalist, or other healthcare provider if you have symptoms such as hunger, weakness, nausea, irritability, dizziness, headache, blurred vision, confusion, sweating, fast heart rate, or fainting.

#### ***Excessive use of alcohol/thiamine deficiency***

Alcohol can lower the amount of thiamine (vitamin B1) in the body. Taking alpha-lipoic acid when there is a shortage of thiamine might cause serious health problems. Thiamine supplement is required additionally while taking a lot of alcohol concomitantly with alpha-lipoic acid

#### ***Thyroid disease***

Taking alpha-lipoic acid might interfere with treatments for under-active or over-active thyroid.

### **Methylcobalamin (Vitamin B<sub>12</sub>)**

#### ***High numbers of red blood cells (polycythemia vera)***

The treatment of vitamin B<sub>12</sub> deficiency can unmask the symptoms of polycythemia vera.

#### ***Abnormal red blood cells (megaloblastic anemia)***

Megaloblastic anemia is sometimes corrected by treatment with vitamin B<sub>12</sub>. However, this can have very serious side effects. Don't attempt vitamin B<sub>12</sub> therapy without close supervision by your healthcare provider.

#### ***Leber's disease, a hereditary eye disease***

Do not take vitamin B<sub>12</sub> if you have this disease. It can seriously harm the optic nerve, which might lead to blindness.

#### ***Allergy or sensitivity to cobalt or cobalamin***

Do not use vitamin B<sub>12</sub> if you have this condition.

#### ***Post-surgical stent placement***

Avoid using a combination of vitamin B<sub>12</sub>, folate, and vitamin B<sub>6</sub> after receiving a coronary stent. This combination may increase the risk of blood vessel narrowing.

### **Chromium Picolinate**

#### ***Kidney disease***

There are at least three reports of kidney damage in patients who took chromium picolinate. Don't take chromium supplements, if you already have kidney disease.

### ***Liver disease***

There are at least three reports of liver damage in patients who took chromium picolinate. Don't take chromium supplements, if you already have liver disease.

### ***Diabetes***

Chromium might lower blood sugar levels too much if taken along with diabetes medications. If you have diabetes, use chromium products cautiously and monitor blood glucose levels closely. Dose adjustments to diabetes medications might be necessary.

### ***Chromate/leather contact allergy***

Chromium supplements can cause allergic reactions in people with chromate or leather contact allergy. Symptoms include redness, swelling, and scaling of the skin.

### ***Behavioral or psychiatric conditions***

*Depression, anxiety, or schizophrenia:* Chromium might affect brain chemistry and might make behavioral or psychiatric conditions worse. If you have one of these conditions, be careful when using chromium supplements. Pay attention to any changes in how you feel.

## **DRUG INTERACTIONS**

### **Alpha lipoic acid**

#### ***Medications for cancer (Chemotherapy)***

Alpha-lipoic acid is an antioxidant. There is some concern that antioxidants might decrease the effectiveness of some medications used for cancers. But it is too soon to know if this interaction occurs.

#### ***Medications for diabetes (Antidiabetes drugs)***

Alpha-lipoic acid might decrease blood sugar. Diabetes medications are also used to lower blood sugar. Taking alpha-lipoic acid along with diabetes medications might cause your blood sugar to go too low. But more evidence is needed to know if this interaction is a big concern. Monitor your blood sugar closely.

### **Benfotiamine**

There are no reports of benfotiamine-drug interactions.

### **Vitamin B<sub>2</sub> (Riboflavin)**

#### ***Drying medications (Anticholinergic drugs)***

Some drying medications can affect the stomach and intestines. Taking these drying medications with riboflavin (vitamin B<sub>2</sub>) can increase the amount of riboflavin that is absorbed in the body. But it's not known if this interaction is important.

### ***Medications for depression (Tricyclic antidepressants)***

Some medications for depression can decrease the amount of riboflavin in the body. This interaction is not a big concern because it only occurs with very large amounts of some medications for depression.

### ***Phenobarbital***

Riboflavin is broken down by the body. Phenobarbital might increase how quickly riboflavin is broken down in the body. It is not clear if this interaction is significant.

### ***Probenecid***

Probenecid can increase how much riboflavin is in the body. This might cause there to be too much riboflavin in the body. But it's not known if this interaction is a big concern.

### **Vitamin B<sub>6</sub> (Pyridoxine)**

#### ***Amiodarone***

Amiodarone might increase your sensitivity to sunlight. Taking vitamin B<sub>6</sub> (pyridoxine) along with amiodarone might increase the chances of sunburn, blistering, or rashes on areas of skin exposed to sunlight. Be sure to wear sunblock and protective clothing when spending time in the sun.

#### ***Phenobarbital***

The body breaks down phenobarbital to get rid of it. Pyridoxine might increase how quickly the body breaks down phenobarbital. This could decrease the effectiveness of Phenobarbital.

#### ***Phenytoin***

The body breaks down phenytoin to get rid of it. Pyridoxine (vitamin B<sub>6</sub>) might increase how quickly the body breaks down phenytoin. Taking pyridoxine (vitamin B<sub>6</sub>) and taking phenytoin might decrease the effectiveness of phenytoin and increase the possibility of seizures. Do not take large doses of pyridoxine (vitamin B<sub>6</sub>) if you are taking phenytoin.

#### ***Levodopa***

The body breaks down levodopa to get rid of it. Vitamin B<sub>6</sub> (pyridoxine) can increase how quickly the body breaks down and gets rid of levodopa. But this is only a problem if you are taking levodopa alone. Most people take levodopa along with carbidopa. Carbidopa prevents this interaction from occurring. If you are taking levodopa without carbidopa do not take vitamin B<sub>6</sub>.

### **Methylcobalamin (Vitamin B<sub>12</sub>)**

#### ***Chloramphenicol***

Vitamin B<sub>12</sub> is important for producing new blood cells. Chloramphenicol might decrease new blood cells. Taking chloramphenicol for a long time might decrease the effects of vitamin B<sub>12</sub> on new blood cells. But most people only take chloramphenicol for a short time so this interaction isn't a big problem.

## **Folic acid**

### ***Fosphenytoin***

Fosphenytoin is used for seizures. The body breaks down fosphenytoin to get rid of it. Folic acid can increase how quickly the body breaks down fosphenytoin. Taking folic acid along with fosphenytoin might decrease the effectiveness of fosphenytoin for preventing seizures.

### ***Methotrexate***

Methotrexate works by decreasing the effects of folic acid in the body's cells. Taking folic acid pills along with methotrexate might decrease the effectiveness of methotrexate.

### ***Phenobarbital***

Phenobarbital is used for seizures. Taking folic acid can decrease how well Phenobarbital works for preventing seizures.

### ***Phenytoin***

The body breaks down phenytoin to get rid of it. Folic acid might increase how quickly the body breaks down phenytoin. Taking folic acid and taking phenytoin might decrease the effectiveness of phenytoin and increase the possibility of seizures.

### ***Primidone***

Primidone is used for seizures. Folic acid might cause seizure in some people. Taking folic acid can along with primidone might decrease how well primidone works for preventing seizures.

### ***Pyrimethamine***

Pyrimethamine is used to treat parasite infections. Folic acid might decrease the effectiveness of pyrimethamine for treating parasite infections.

## **Chromium Picolinate**

### ***Insulin***

Chromium might decrease blood sugar. Insulin is also used to decrease blood sugar. Taking chromium along with insulin might cause your blood sugar to be too low. Monitor your blood sugar closely. The dose of your insulin might need to be changed.

### ***Levothyroxine***

Taking chromium with levothyroxine might decrease how much levothyroxine that the body absorbs. This might make levothyroxine less effective. To help avoid this interaction, levothyroxine should be taken 30 minutes before or 3-4 hours after taking chromium.

### ***NSAIDs (Nonsteroidal anti-inflammatory drugs)***

NSAIDs are anti-inflammatory medications used for decreasing pain and swelling. NSAIDs might increase chromium levels in the body and increase the risk of adverse effects. Avoid taking chromium supplements and NSAIDs at the same time.

## **UNDESIRABLE EFFECTS**

Alpha-lipoic acid is possibly safe for most adults when taken by mouth, when used intravenously or when applied to the skin. People taking alpha-lipoic acid by mouth might get a rash. People at risk for thiamine deficiency should take a thiamine supplement.

People with diabetes should be careful to check their blood sugar levels because alpha-lipoic acid might lower blood sugar.

Benfotiamine administration appears to be safe with no reports of toxicity in the scientific literature.

Riboflavin (Vitamin B<sub>2</sub>) is likely safe for most people. In some people, riboflavin can cause the urine to turn a yellow-orange color. When taken in high doses, riboflavin might cause diarrhea, an increase in urine, and other side effects.

Pyridoxine (Vitamin B<sub>6</sub>) is likely safe for most people when used appropriately.

Pyridoxine is possibly safe when taken by mouth in amounts greater than the recommended dietary allowance. In some people, pyridoxine might cause nausea, vomiting, stomach pain, loss of appetite, headache, tingling, sleepiness, and other side effects.

Long-term use of high doses of Pyridoxine (Vitamin B<sub>6</sub>) is possibly unsafe. It might cause certain brain and nerve problems.

Vitamin B<sub>12</sub> is likely safe for most people when taken by mouth, applied to the skin, taken through the nose, or administered as a shot.

Folic acid is likely safe for most people. Most adults do not experience any side effects when consuming the recommended amount each day, which is 400 mcg.

High doses of folic acid might cause abdominal cramps, diarrhea, rash, sleep disorders, irritability, confusion, nausea, stomach upset, behavior changes, skin reactions, seizures, gas, excitability, and other side effects.

There is some concern that taking too much folic acid for a long period of time might cause serious side effects. Some research suggests that taking folic acid in doses of 800-1200 mcg might increase the risk of heart attack in people who have heart problems. Other research suggests that taking these high doses might also increase the risk of cancer such as lung or prostate cancer. Don't take more than 400 mcg per day unless directed by your healthcare provider.

Chromium is likely safe for most adults when taken by mouth in doses up to 1000 mcg daily for up to 6 months. Chromium is possibly safe for most adults when used for longer periods of time. Some people experience side effects such as skin irritation, headaches, dizziness, nausea, mood changes and impaired thinking, judgment, and coordination. High doses have been linked to more serious side effects including blood disorders, liver or kidney damage, and other problems.

It is not known for sure if chromium is the actual cause of these side effects.

## **PHARMACOLOGICAL PROPERTIES**

### **Alpha lipoic acid**

Alpha-lipoic acid seems to help prevent certain kinds of cell damage in the body, and also restores vitamin levels such as vitamin E and vitamin C. There is also evidence that alpha-lipoic acid can improve the function and conduction of neurons in diabetes.

Alpha-lipoic acid is used in the body to break down carbohydrates and to make energy for the other organs in the body.

Alpha-lipoic acid seems to work as an antioxidant, which means that it might provide protection to the brain under conditions of damage or injury. The antioxidant effects might also be helpful in certain liver diseases.

### **Benfotiamine**

Unlike thiamine, benfotiamine's structure contains an open thiazole ring that closes once it is absorbed, producing biologically active thiamine. Several clinical trials in healthy adults have demonstrated the superior absorption of lipid-soluble thiamine analogues, such as benfotiamine, compared to water-soluble thiamine salts. Higher plasma thiamine levels are achieved with oral benfotiamine administration, and blood and tissue concentrations are maintained longer. Benfotiamine is absorbed via passive diffusion through the intestinal mucosa and is rapidly converted to biologically active thiamine. Peak plasma concentrations of thiamine after oral benfotiamine administration are at least five times greater than those observed after oral administration of water-soluble thiamine salts. Half-life of benfotiamine is similar to thiamine salts, but bioavailability of benfotiamine eight days after administration is roughly 25 percent of the original dose, about 3.6 times greater than after an oral dose of a thiamine salt.

Benfotiamine can activate glucose metabolism and promote healthy blood glucose levels in those already within normal range. Benfotiamine also helps maintain healthy endothelial function and supports the health of the nerves, kidneys, eyes, blood vessels, and heart.

### **Enzogenol**

Enzogenol is a a broad-spectrum polyphenol extract, containing many different flavonoid compounds, particularly high in oligomeric proanthocyanidins (OPCs), with exceptional antioxidant and natural anti-inflammatory properties. Extensive research has demonstrated Enzogenol's health promoting properties. These include lowering oxidation and inflammation in the body, supporting cardiovascular, brain and eye function, and protecting the skin from oxidative stress. This combination of benefits makes Enzogenol an outstanding health and anti-ageing supplement.

### **Vitamin B<sub>2</sub> (Riboflavin)**

Riboflavin is required for the proper development and function of the skin, lining of the digestive tract, blood cells, and many other parts of the body. Vitamin B<sub>2</sub> is useful in preventing and treating riboflavin deficiency and conditions related to riboflavin deficiency.



**Vitamin B<sub>6</sub> (Pyridoxine)**

Pyridoxine is required for the proper function of sugars, fats, and proteins in the body. It is also required for the proper growth and development of the brain, nerves, skin, and many other parts of the body.

It is effective for Anemia (sideroblastic anemia). Taking pyridoxine by mouth is effective for treating an inherited type of anemia called sideroblastic anemia. Taking pyridoxine by mouth is effective for preventing and treating pyridoxine deficiency.

**Methylcobalamin (Vitamin B<sub>12</sub>)**

Vitamin B<sub>12</sub> is required for the proper function and development of the brain, nerves, blood cells, and many other parts of the body.

Injecting vitamin B<sub>12</sub> as a shot, as well as taking through the nose or by mouth, is effective for treating low red blood cell counts caused by poor absorption of vitamin B<sub>12</sub> in pernicious anemia.

Taking vitamin B<sub>12</sub> by mouth, through the nose, or as a shot is effective for treating vitamin B<sub>12</sub> deficiency.

**Folic acid**

Folic acid is needed for the proper development of the human body. It is involved in producing the genetic material called DNA and in numerous other bodily functions. Taking folic acid improves folate deficiency.

**Chromium Picolinate**

Chromium might help keep blood sugar levels normal by improving the way our bodies use insulin. Taking chromium by mouth is effective for preventing chromium deficiency.

**EPIRY DATE**

Do not use after the best before date.

**PAKAGING INFORMATION**

NUALA E is available as Strip of 10 Capsules.

**STORAGE AND HANDLING INSTRUCTIONS**

Store in a cool and dry place, protected from light. Keep out of reach of children.

**MARKETED BY**

TORRENT PHARMACEUTICALS LTD.

Torrent House, Off Ashram Road,

Ahmedabad-380 009, INDIA