

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

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TRINERGIC-L

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**1. Generic Name**

Ginseng, Lycopene, Benfotiamine, Vitamin B6, B12, Zinc, Wheat Germ Oil, Chromium and Selenium Capsules

**2. Qualitative and quantitative composition**

Each hard gelatin capsule contains:

Ginseng Dry Extract I.P. ....42.5 mg

(Concentrated Ginseng extract corresponding to 212.5 mg of Root of Panax Ginseng)

Lycopene U.S.P.....2000 mcg

Benfotiamine .....5 mg

Vitamin B6 I.P. ....3 mg

Vitamin B12 I.P. ....15 mcg

Zinc sulphate Monohydrate I.P.....20 mg

equivalent to Elemental Zinc.....7.29 mg

Wheat Germ Oil B.P. ....25 mg

Chromium Picolinate U.S.P.

equivalent to Elemental Chromium.....50 mcg

Selenium Dioxide U.S.P.

equivalent to Elemental Selenium.....50 mcg

Approved colours used in capsule shell.

The excipients used are ready to use pellets of Ginseng, Lycopene, Benfotiamine, Vitamin B6, B12, Zinc, Wheat Germ Oil, Chromium and Selenium.

**3. Dosage form and strength**

**Dosage form:** Capsule

**Strength:** Ginseng Dry Extract 42.5 mg, Lycopene U.S.P 2000 mcg, Benfotiamine 5 mg, Vitamin B6 I.P 3 mg, Vitamin B12 I.P. 15 mcg, Zinc sulphate Monohydrate I.P 20 mg, Wheat Germ Oil B.P. 25 mg, Chromium 50 mcg and Selenium 50 mcg.

**4. Clinical particulars**

**4.1 Therapeutic indication**

As a therapeutic nutritional adjunct

**4.2 Posology and method of administration**

Dose: As suggested by physician

### **4.3 Contraindications**

Hypersensitivity to any of the ingredients.

### **4.4 Special warnings and precautions for use**

If symptoms persist or worsen, seek medical advice. Do not exceed the stated dose.

### **4.5 Drugs interactions**

Many drugs may alter the metabolism or bioavailability, including isoniazid, penicillamine and oral contraceptives, which may increase the requirements for vitamins. Pyridoxine may reduce the effect of levodopa, a drug used in the treatment of Parkinsons Disease unless a dopa decarboxylase inhibitor is also given.

In case of concomitant intake of ginseng preparations and anticoagulants, the effect of oral blood thinning medication (e.g. warfarin) may potentially be reduced. Patients on blood thinning medications should seek medical advice before starting this product.

### **4.6 Use in special populations**

TRINERGIC L capsules may be administered during pregnancy and lactation at the recommendation of the physician.

In the reported study, reproduction studies with animals using the standardized Panax ginseng extract showed no teratogenic effects. However, controlled studies with pregnant women are not available.

#### Fertility

No studies on the effect on human fertility have been conducted with TRINERGIC L capsules. Reproduction studies with animals using the standardized Panax ginseng extract showed no adverse effects on fertility.

### **4.7 Effects on ability to drive and use machines**

None known.

### **4.8 Undesirable effects**

Long-term administration of large doses of pyridoxine is associated with the development of severe peripheral neuritis.

### **4.9 Overdose**

- a) Symptoms – None reported
- b) Treatment – no treatment necessary.

## **5. Pharmacological properties**

### **5.1 Mechanism of Action**

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

Pyridoxine, once absorbed, is rapidly converted to the co-enzymes pyridoxal phosphate and pyridoxamine phosphate, which play an essential role in protein metabolism. Convulsions and hypochromic anaemia have occurred in infants deficient in pyridoxine.

#### Vitamin B<sub>12</sub> (Cyanocobalamin)

Vitamin B<sub>12</sub> is present in the body mainly as methylcobalamin and as adenosylcobalamin and hydroxocobalamin. These act as co-enzymes in the Trans methylation of homocysteine to methionine; in the isomerisation of methylmalonyl co-enzyme to succinyl co-enzyme and with folate in several metabolic pathways respectively. Deficiency of Vitamin B<sub>12</sub> interferes with haemopoiesis and produces megaloblastic anaemia.

#### Zinc (Zinc Sulfate)

Zinc is a constituent of many enzymes and is, therefore, essential to the body. It is present with insulin in the pancreas. It plays a role in DNA synthesis and cell division. Reported effects of deficiency include delayed puberty and hypogonadal dwarfism.

#### Selenium

Selenium is an essential trace element, deficiency of which has been reported in man. It is thought to be involved in the functioning of membranes and the synthesis of amino acids. Deficiency of selenium in the diet of experimental animals produces fatty liver followed by necrosis.

#### Chromium (Chromium Amino Acid Chelate 10%)

Chromium is an essential trace element involved in carbohydrate metabolism.

#### Ginseng Dry Extract

Ginseng extract raises the general level of cellular activity, which is expressed by a pronounced increase in the physical and mental capacity.

In animal experiments, it caused a reduction of lactic acid concentration in muscles during exercise. An increase in the dopamine and noradrenaline content and a reduction in the serotonin content in the brain stem could be observed.

#### Lycopene

The main activity profile of lycopene includes ant atherosclerotic, antioxidant, anti-inflammatory, antihypertensive, antiplatelet, anti-apoptotic, and protective endothelial effects, the ability to improve the metabolic profile, and reduce arterial stiffness.

#### Benfotiamine

Benfotiamine acts by modulating the advanced glycation end products (AGEs). It can also act through non-AGE dependent pathways.

Advanced glycation end products are modified proteins or lipids that become non-enzymatically glycated on exposure to sugars such as aldose. AGEs may generate reactive oxygen species, attach to specific receptors, and form cross-linking structures.

AGEs are present in the diabetic vasculature and involved in the progression of atherosclerosis. Benfotiamine inhibits the synthesis of AGEs and thus decrease the

metabolic stress. Benfotiamine thus helps in vascular complications associated with diabetes.

### Wheat Germ Oil

This study indicated that minor components in wheat-derived oils such as wheat germ oil formed the richest source of total tocopherols, lutein and smaller amount of other carotenoids among the vegetable oils and also contains oryzanol like compounds along with high amount of polyunsaturated fatty acids (PUFA). The presence of ideal amount of oryzanol like compounds (steryl ferulates), total tocopherols and lutein in WBO might be of sufficient quantity to prevent diseases like, cardiovascular disease, diabetes and cancer. Therefore, the oils from wheat bran and wheat germ may be used as a source of minor components in our daily food menu to promote good health.

## **5.2 Pharmacodynamic properties**

TRINERGIC L capsules exert a stimulant effect at physical and psychological levels through the combined action of various substances on the basic metabolic processes.

The ginseng extract raises the general level of cellular activity, which is expressed by a pronounced increase in the physical and mental capacity.

In animal experiments, it caused a reduction of lactic acid concentration in muscles during exercise. An increase in the dopamine and noradrenaline content and a reduction in the serotonin content in the brain stem could be observed.

Vitamins, minerals and trace elements correct and prevent impairment of the cell metabolism in situations with increased demands. Low supply of vitamins, minerals, and trace elements may cause disturbances, such as debility, tiredness, decrease in vitality, reduced force of resistance, and decelerated convalescence. The composition and dosages of the preparation were chosen according to the European RDA-requirements for food supplements.

## **5.3 Pharmacokinetic properties**

Pharmacokinetic studies of TRINERGIC L capsules have not been carried out, because of the complex composition of the product and the small quantities of the active ingredients contained. Moreover, these substances are well known.

Pharmacokinetic studies of the Ginseng extract are not possible, because it is a complex extract. In the ginseng root, more than 200 substances have been identified to date. Pharmacokinetic studies of individual purified ginsenosides have been carried out in various animal species:

## **6. Nonclinical properties**

There are no preclinical data of relevance to the prescriber, which are additional to those already included in other sections of the Summary of Product Characteristics.

## **7. Description**

Ginseng, Lycopene, Benfotiamine, Vitamin B6, B12, Zinc, Wheat Germ Oil, Chromium and Selenium Capsules are clear transparent body/ red transparent cap '0' size hard gelatin capsules containing white to off-white coloured and pink

coloured pellets. The excipients used are ready to use pellets of Ginseng, Lycopene, Benfotiamine, Vitamin B6, B12, Zinc, Wheat Germ Oil, Chromium and Selenium.

## **8. Pharmaceutical particulars**

### **8.1 Incompatibilities**

None stated

### **8.2 Shelf-life**

Do not use later than date of expiry

### **8.3 Packaging information**

TRINERGIC L capsules is available in Blister strip of 15 Capsules

### **8.4 Storage and handing instructions**

Store below 25°C. Protect from light and moisture.

Keep all medicines out of reach of children.

## **9. Patient counselling information**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- **This medicine has been prescribed for you only.** Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

### **What is in this leaflet?**

9.1. What TRINERGIC L capsules is and what it is used for

9.2. What you need to know before you take TRINERGIC L capsules

9.3. How to take TRINERGIC L capsules

9.4. Possible side effects

9.5. How to store TRINERGIC L capsules

9.6. Contents of the pack and other information

#### **9.1 What TRINERGIC L capsules is and what it is used for**

TRINERGIC L capsules are a multivitamin and mineral supplement. They contain a combination of essential vitamins, minerals and trace elements. The human body requires a wide variety of vitamins, minerals and trace elements to perform crucial daily tasks such as releasing energy from food and repairing cell damage. During certain illnesses, your body either cannot get or cannot efficiently use all of the vitamins, minerals and trace elements it needs. Your doctor, dietician will give you TRINERGIC L capsules if your diet has not provided you with enough vitamins, minerals and trace elements.

TRINERGIC L capsules are a multivitamin, mineral and ginseng supplement. Each capsule contains Ginseng, Lycopene, Benfotiamine, Vitamin B6, B12, Zinc, Wheat Germ Oil, Chromium and Selenium Capsules.

See Section 2 (Further information) for a complete list of the ingredients and quantities in each capsule. TRINERGIC L capsules are for:

- Relief of short periods of daily fatigue associated with a busy, hectic lifestyle. Symptoms of daily fatigue include temporary periods of exhaustion (for example caused by stress), tiredness and a feeling of weakness or lack of vitality (loss of energy).
- Prevention and treatment of symptoms caused by an unbalanced diet.

TRINERGIC L capsules work by enhancing mental and physical performance through the combined action of Ginseng, vitamins and minerals on the basic metabolic processes.

More information about daily fatigue Daily fatigue is associated with a busy, hectic lifestyle, and symptoms may include:

- Lack of energy
- Increase in rest requirements
- Energy not restored even after sleep
- Decreased mental and physical performance
- Lethargy
- Lack of concentration

Lifestyle changes that may help to overcome daily fatigue include:

- Healthy eating
- Regular exercise, such as a midday stroll
- Take time out to allow for relaxation
- Prioritise workloads, instead of cramming too much into one day
- Delegate tasks at work and home
- Find new ways to deal with stress
- Learn to say no when there are too many demands on personal time
- Reduce the intake of alcohol, caffeine, and cigarettes

## **9.2 What you need to know before you take TRINERGIC L capsules**

Do not take TRINERGIC L capsules if:

- You are allergic to any of the ingredients listed.
- You have problems with your kidneys
- You have high iron levels, such as in “haemochromatosis“, which is caused by a problem that may run in your family
- You have problems with high levels of Vitamin A or D in your body
- You have problems with high levels of calcium in your blood or urine

Do not take this medicine if any of the above applies to you.

If you are not sure, talk to your pharmacist or doctor before taking this medicine.\

Do not take TRINERGIC L capsules:

- If you are allergic (hypersensitive) to any of the ingredients of TRINERGIC L capsules
- If you suffer from hypercalcaemia (high level of calcium in the blood)

Take special care with TRINERGIC L capsules. Before you are given TRINERGIC L capsules, tell your doctor, dietician or pharmacist if:

- You are pregnant or thinking of becoming pregnant
- You are a smoker
- You have an asbestos related illness such as asbestosis
- You suffer from thyroid problems.

If any of the above applies to you, or if you are not sure, speak to your doctor or pharmacist before taking **TRINERGIC L capsules**.

Taking other medicines, Tell your doctor if you are taking or have recently taken/used any of the following medicines as they may interfere with **TRINERGIC L capsules**:

- Phenytoin (used to treat epilepsy)
- Tetracycline antibiotics (used to treat infections) such as doxycycline and minocycline. Please tell your doctor if you are taking or have recently taken/used any other medicines including other vitamin or mineral products medicines obtained without a prescription.

### **9.3 How to take TRINERGIC L capsules**

Follow the instructions printed in this leaflet. Talk to your pharmacist, doctor if you develop new symptoms or if your symptoms get much worse, or have not shown any sign of improvement over four weeks.

Adults and Elderly: As prescribed by the doctor. The capsules should be swallowed completely with a glass of water.

#### **What to do if you take more TRINERGIC L capsules than you should**

If you (or someone else) accidentally take too many tablets, you should tell your doctor at once or contact the nearest accident and emergency department. Show any left-over medicines or the empty packet to the doctor.

#### **If you forget to take TRINERGIC L CAPSULES**

Do not worry. If you forget to take a dose, take it as soon as possible, unless it is almost time to take the next dose. Do not take a double dose. Then go on as before.

### **9.4 Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. TRINERGIC L capsules may cause allergic reactions (such as rash), and problems related to your stomach and intestines (such as feeling or being sick and stomach pains).

#### **Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the

medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via any point of contact of Torrent Pharma available at: [http://www.torrentpharma.com/Index.php/site/info/adverse\\_event\\_reporting](http://www.torrentpharma.com/Index.php/site/info/adverse_event_reporting).

### **9.5 How to store TRINERGIC L capsules**

Store below 25°C. Protect from light and moisture.

### **9.6 Contents of the pack and other information**

The active ingredients in this medicine are:

Ginseng Dry 42.5 mg, , Lycopene U.S.P.2000 mcg, Benfotiamine 5 mg, Vitamin B6 I.P. 3 mg, Vitamin B12 I.P. 15 mcg, Zinc sulphate Monohydrate I.P 20 mg, equivalent to Elemental Zinc 7.29 mg Wheat Germ Oil B.P. 25 mg Chromium Picolinate U.S.P. Chromium 50 mcg, Selenium Dioxide U.S.P. 50 mcg.

Approved colours used in capsule shell.

TRINERGIC L capsules is available in Blister strip of 15 Capsules

### **10. Details of manufacturer**

Manufactured in India by:

Ordain Health Care Global Pvt. Ltd.

Survey No. 532, Uthiramerur Road, Melavalampettal, Karunguzhi – 6033303,  
Kanchipuram District, Tamil nadu.

### **11. Details of permission or licence number with date**

Mfg Lic. No. TN00003297 issued on 11.03.2014.

### **12. Date of revision**

NA

### **MARKETED BY**



TORRENT PHARMACEUTICALS LTD.

**IN/TRINERGIC L capsules /January -21/01 /PI**