

## PROFESSIONAL INFORMATION

### COMPLEMENTARY MEDICINE – Health supplement

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

**SCHEDULING STATUS:** **S0**

#### 1. NAME OF THE MEDICINE

**MEGAMINO** capsules

#### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each capsule contains:

Isoleucin	7 mg
Leucin	8 mg
Lysine	12 mg
Methionine	12 mg
Threonine	6 mg
Valine	8 mg
Chromium picolinate	45 mcg
providing Chromium (elemental)	5,58 mcg
Copper sulphate	1 mg
providing Copper (elemental)	0,4 mg
Ferrous fumarate	14 mg
providing Iron (elemental)	4,62 mg
Magnesium oxide	100 mg
providing Magnesium (elemental)	39,7 mg
Manganese glycerophosphate	1,5 mg
providing Manganese (elemental)	360 mcg
Molybdenum amino acid chelate 0.2%	70 mcg
providing Molybdenum (elemental)	0,14 mcg
Selenium amino acid chelate 0.2%	70 mcg
providing Selenium (elemental)	0,14 mcg
Zinc gluconate	10 mg
providing Zinc (elemental)	1,435 mg
Vitamin A	1,4 mg
Vitamin B1 (Thiamine Hydrochloride)	20 mg
Vitamin B2 (Riboflavin)	20 mg
Calcium Pantothenate	20 mg
Vitamin B6 (Pyridoxine Hydrochloride)	20 mg
Vitamin B12	20 mcg
Vitamin C (Ascorbic Acid)	150 mg
Vitamin D3	10 mcg
Vitamin E	25 mg
Biotin	380 mcg
Folic Acid	450 mcg
Nicotinamide	18 mg

Sugar free

For the full list of excipients, see section 6.1

#### 3. PHARMACEUTICAL FORM

Royal Blue Capsules

#### **4. CLINICAL PARTICULARS**

##### **4.1 Therapeutic indications**

A fast and stressful lifestyle as well as an unbalanced diet can deplete and exhaust you physically and mentally. MEGAMINO contains the essential Amino Acids, Minerals and Vitamins to assist in the maintenance of general well being.

##### **4.2 Posology and method of administration**

Adults:

One capsule with your main meal. Avoid taking capsule with hot liquids.

Paediatric population

Not recommended for children.

Method of administration

Oral use.

##### **4.3 Contraindications**

Contraindicated in patients with an allergic hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

It is a supplement and is not intended for a specific vitamin deficiency.

Not suitable for children.

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

Do not take MEGAMINO on an empty stomach.

Do not exceed the stated dose.

Keep out of the reach of children.

Vitamin and mineral supplements should not replace a balanced diet.

##### **4.5 Interaction with other medicines and other forms of interaction**

None known.

##### **4.6 Fertility, pregnancy, and lactation**

Safety during pregnancy and lactation has not been established.

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

MEGAMINO should not affect the ability of individuals to drive or operate machines.

##### **4.8 Undesirable effects**

Allergic reactions have been reported with vitamin use and may include rash and pruritis.

##### **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 to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications:  
<https://www.sahpra.org.za>

#### **4.9 Overdose**

Treatment is supportive and symptomatic.  
Should accidental overdose occur, discontinue use and consult a pharmacist or doctor.

### **5. PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Category D: Complementary Medicines: Health Supplement 34.12 Multiple substance formulation.

#### **5.2 Pharmacokinetic properties**

Zinc is absorbed from the gastrointestinal tract and distributed throughout the body. It is excreted in the faeces with traces appearing in the urine.

##### **Vitamin B1 (Thiamine)**

Thiamine is absorbed from the gastro-intestinal tract and is widely distributed to most body tissues. Amounts in excess of the body’s requirements are not stored but excreted in the urine as unchanged thiamine or its metabolites.

##### **Vitamin B2 (Riboflavin)**

Riboflavin is absorbed from the gastro-intestinal tract and in the circulation is bound to plasma proteins. It is widely distributed. Little is stored and excess amounts are excreted in the urine. In the body riboflavin is converted to flavine mononucleotide (FMN) and then to flavine adenine dinucleotide (FAD).

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

Pyridoxine is absorbed from the gastro-intestinal tract and converted to the active pyridoxal phosphate which is bound to plasma proteins. It is excreted in the urine as 4-pyridoxic acid.

##### **Vitamin B12**

Vitamin B12 is absorbed from the gastro-intestinal tract and is extensively bound to specific plasma proteins. A study with labelled Vitamin B12 showed it was quickly taken up by the intestinal mucosa and held there for 2 - 3 hours. Peak concentrations in the blood and tissues did not occur until 8 - 12 hours after dosage with maximum concentrations in the liver within 24 hours. Cobalamins are stored in the liver, excreted in the bile and undergo enterohepatic recycling. Part of a dose is excreted in the urine, most of it in the first eight hours.

##### **Vitamin C**

Vitamin C (Ascorbic Acid) is well absorbed from the gastrointestinal tract. Ascorbic Acid is widely distributed to all tissues. Body stores of ascorbic acid normally are about 1,5 g. The concentration is higher in leucocytes and platelets than in erythrocytes and plasma. Ascorbic acid additional to the body’s needs, generally amounts above 200 mg daily, is rapidly eliminated; unmetabolized ascorbic acid and its inactive metabolic products are chiefly excreted in the urine. The amount of ascorbic acid excreted unchanged in the urine is dose-dependent and may be accompanied by mild diuresis.

### **5.3 Preclinical safety data**

Not known.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Magnesium Stearate  
Soy Protein Isolate 90%  
Talc

### **6.2 Incompatibilities**

Unknown

### **6.3 Shelf life**

24 months

### **6.4 Special precautions for storage**

Keep in a dry, cool place at or below 25 °C.  
Protect from direct light.  
KEEP OUT OF REACH OF CHILDREN.

### **6.5 Nature and contents of the container**

30 and 60 capsules in a tabtainer with white lid.  
Not all pack sizes may be marketed.

### **6.6 Special precautions for disposal**

No special requirements for disposal. Any unused product should be disposed of in accordance with local requirements.

## **7. HOLDER OF THE CERTIFICATE OF REGISTRATION**

Crux Pharmaceuticals (Pty) Ltd  
630 Jacqueline Drive  
Garsfontein  
Pretoria  
0042

### **Marketed by:**

Cedarpharm (Pty) Ltd  
3798 Jan Frederick Avenue  
Randpark Ridge  
2169

## **8. REGISTRATION NUMBER**

To be allocated.

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

To be determined.

**10. DATE OF REVISION OF TEXT**

March 2023.