

PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

STAMINOGRO (Tablets)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredient	Per tablet
Amino Acids	
L-Arginine (L-Arginine Hydrochloride)	187,5 mg
L-Glutamine (L-Glutamine)	150 mg
Glycine (L-Glycine)	75 mg
L-Lysine (L-Lysine hydrochloride)	50 mg
L-Ornithine (L-Ornithine Hydrochloride)	45 mg
Antioxidants	
Vitamin C (Ascorbic Acid 90%)	75 mg
Zinc (Zinc oxide)	5,62 mg
Alpha-lipoic Acid (Alpha-lipoic Acid)	5 mg
Beta-carotene (Beta-carotene 10 %)	450 µg
Selenium (Selenium glycinate 2%)	15 µg
Glycine (Selenium glycinate 2%)	4,95 µg
Vitamin E (Vitamin E 50%)	5 IU
B Vitamins	
Vitamin B3 (Nicotinamide)	6 mg
Vitamin B5 (Calcium D-Pantothenate)	6 mg
Calcium (Calcium D-Pantothenate)	0,63 mg
Vitamin B6 (Pyridoxine Hydrochloride)	6 mg
Vitamin B2 (Riboflavin)	1,25 mg
Vitamin B1 (Thiamine Mononitrite)	0,75 mg
Folic Acid (Folic Acid)	125 µg
Vitamin B12 (Vitamin B12 1%)	6 µg
Calcium & Vitamin D	
Calcium (Calcium Carbonate)	100 mg
Vitamin D3 (Vitamin D3 100 000 IU/g)	75 IU (1,875 µg)
Other Vitamins and Minerals	
Magnesium (Magnesium oxide)	60 mg
Choline (Choline bitartrate 1%)	4,1 mg
Manganese (Manganese Sulphate)	1 mg
Copper (Copper glycinate 10%)	500 µg
Biotin (Biotin)	20 µg

Sugar free

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oblong, red film-coated tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

STAMINOGRO is a health supplement for adults that provides the body with a range of amino acids, antioxidants, B-vitamins and other essential vitamins and minerals to help with energy, immune defence, well-being and mental vitality.

STAMINOGRO supports reproductive health in men and women.

4.2 Posology and method of administration

Adults: Take 1 – 4 tablets daily with food, as recommended by a healthcare provider.

Athletes and sports individuals taking STAMINOGRO for muscle repair should take their STAMINOGRO no later than 90 minutes after exercising.

The recommended dose should not be exceeded.

4.3 Contraindications

Do not use in patients who are hypersensitive to any of the ingredients, including excipients.

Do not use in patients who have had a heart attack (myocardial infarction).

4.4 Special warnings and precautions for use

- Sufficient protein is provided in normal well-balanced daily meals.
- Caution is advised in patients with renal and/or cardiovascular disease.
- Use in children under the age of 18 years should be at the discretion of a healthcare professional.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies were performed on **STAMINOGRO**. The following interactions are noted in the monographs of the active ingredients:

- ❖ Antihypertensive medicines:
 - L-arginine increases nitric oxide, which causes vasodilation. Combining L-arginine with angiotensin receptor blockers, angiotensin-converting enzyme (ACE) inhibitors or other anti-hypertensive medicines may increase L-arginine-induced vasodilation and cause blood pressure to fall too low.
 - Potassium-sparing diuretics can increase potassium levels. Concomitant use of potassium-sparing diuretics with L-arginine may increase the risk of hyperkalemia. Caution is advised with other anti-hypertensive medicines which may also increase potassium levels.
- ❖ Concomitant use of L-arginine with anticoagulant and antiplatelet drugs may have additive effects and increase the risk of bleeding.
- ❖ L-arginine decrease blood glucose levels in patients with type 2 diabetes.
- ❖ L-Arginine should be used carefully with medicines such as nitroglycerin or sildenafil, because blood pressure may fall too low.
- ❖ L-glutamine is metabolized to the excitatory neurotransmitter glutamate, might antagonize the anticonvulsant effects of medications taken for epilepsy

4.6 Fertility, pregnancy and lactation

Safety of STAMINOGRO during pregnancy and lactation has not been established. STAMINOGRO supports reproductive health in men and women.

4.7 Effects on ability to drive and use machines

The effects on ability to drive and use machines has not been studied.

4.8 Undesirable effects

Possible side effects are:

- gastrointestinal discomfort (nausea, vomiting, abdominal pain, heartburn, diarrhoea, constipation, bloating)
- skin rash or flushing of the skin
- headache, dizziness or light-headedness
- sleep disturbances, night sweats
- delayed menstruation

4.9 Overdose

Treatment is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACOLOGICAL CLASSIFICATION

Complementary Medicines: Health Supplement
D34.12 Multiple substance formulation

5.2 PHARMACOLOGICAL ACTION

- Amino acids are involved in muscle protein synthesis. They assist in muscle cell repair after exercise and help support the immune system after periods of physical stress.
- L-Arginine may help support a modest improvement in exercise capacity in individuals with stable cardiovascular diseases.
- L-Arginine supports sperm count and motility and supports reproductive health in men and women.
- Antioxidants contributes to cell protection from free radical damage.
- B vitamins help to metabolise carbohydrates, fats and proteins, contribute to normal psychological function, normal functioning of the nervous system, maintenance of normal mucous membranes, maintenance of normal skin, regulation of hormonal activity, normal function of the heart, and the reduction of tiredness and fatigue.
- Calcium and Vitamin D contribute to the maintenance of normal muscle function and help in the development of healthy bones and teeth.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cochineal red A, copovidone, colloidal anhydrous silica, croscarmellose sodium, magnesium stearate, microcrystalline cellulose.

Coating: castor oil, flexicoat bright red, and shellac

SUGAR FREE

6.2 Incompatibilities

Unknown

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store at or below 25 °C. Keep bottle tightly closed and protect from sunlight and moisture.

KEEP OUT OF THE REACH OF CHILDREN.

6.5 Nature and contents of container

Plastic containers containing 30, 60 and 120 tablets.

6.6 Special precautions for disposal and other handling

No special requirements

7 HOLDER OF CERTIFICATE OF REGISTRATION

iNova Pharmaceuticals (Pty) Ltd, 15E Riley Road, Bedfordview, 2007

Tel: (011) 087 0000 www.inovapharma.co.za

8 REGISTRATION NUMBER

To be allocated.

This unregistered medicine has not been evaluated by the South African Health Products Regulatory Authority for its quality, safety or intended use.

9 DATE OF PUBLICATION OF PROFESSIONAL INFORMATION

September 2020