

PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

STAMINOGRO WOMAN (Tablets)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredient (Approved Name)	Per tablet
Amino Acids	
L-Arginine (L-Arginine)	93,75 mg
L-Glutamine (L-Glutamine)	75 mg
L-Glycine (L-Glycine)	37,5 mg
L-Lysine (L-Lysine hydrochloride)	25 mg
L-Ornithine (L-Ornithine hydrochloride)	22,5 mg
Antioxidants	
Vitamin C (Ascorbic acid 90 %)	50 mg
Zinc (Zinc oxide)	10 mg
Beta-Carotene (Beta carotene 10 %)	450 µg
Selenium (Selenium glycinate 2 %)	15 µg
Glycine (Selenium glycinate 2 %)	4,95 ug
Vitamin E (Vitamin E 50%)	30 IU
B Vitamins	
Vitamin B6 (Pyridoxine hydrochloride)	10 mg
Vitamin B3 (Nicotinamide)	6 mg
Vitamin B5 (Calcium-D pantothenate)	6 mg
Calcium (Calcium-D pantothenate)	0,63 mg
Vitamin B2 (Riboflavin)	1,25 mg
Vitamin B1 (Thiamine hydrochloride)	0,75 mg
Folic Acid (Folic acid)	250 µg
Vitamin B12 (Methylcobalamin)	6 µg
Calcium & Vitamin D	
Calcium (Calcium carbonate)	100 mg
Vitamin D3 (Vitamin D3 100000 IU/g)	400 IU (10 µg)
Other Vitamins & minerals	
Magnesium (Magnesium oxide)	70 mg
Iron (Iron II bisglycinate 20 %)	5 mg
Glycine (Iron II bisglycinate 20 %)	1,84 mg
Choline (Choline bitartrate 1 %)	4,1 mg
Manganese (Manganese sulphate monohydrate)	1 mg
Copper (Copper glycinate 10%)	500 µg
Biotin (D-Biotin)	20 µg

Sugar free

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oblong, lilac film-coated tablet.

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

Health supplement for women 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.

4.2 Posology and method of administration

Adults and children over 13 years: Take 1 – 2 tablets daily with a meal, or 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.

4.3 Contraindications

- Not for use in patients who are hypersensitive to any of the ingredients, including excipients.
- Not for use in patients who have had a heart attack (myocardial infarction).

4.4 Special warnings and precautions for use

- Caution is advised in patients with renal and/or cardiovascular disease.
- Sufficient protein is provided in normal well-balanced daily meals.
- Contact a healthcare provider prior to use in children under 13 years.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies were performed on **STAMINOGRO WOMAN**. 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 may 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 which may antagonize the anticonvulsant effects of medications taken for epilepsy

4.6 Fertility, pregnancy and lactation

Safety of STAMINOGRO woman during pregnancy and lactation has not been established.

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 reproductive health in women
- Antioxidants contribute 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.
- Iron contributes to normal formation of red blood cells and haemoglobin, helps with oxygen transport in the body, contributes to normal cognitive function, and reduces fatigue.
- Zinc, Vitamin A & Selenium contribute to the normal functioning of the immune system.
- Zinc contributes to normal cognitive function

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Colloidal silica, croscarmellose sodium, isopropyl alcohol, magnesium stearate, microcrystalline cellulose, opaglos regular, opadry purple, povidone, purified talc, purified water, shellac, stearic acid and sodium starch glycolate. 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 to protect from sunlight and moisture.

KEEP OUT OF THE REACH OF CHILDREN.

6.5 Nature and contents of container

White plastic containers with 30 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