

## PROFESSIONAL INFORMATION

### SCHEDULING STATUS

S0

### 1 NAME OF THE MEDICINE

STAMINOGRO KIDS (fizzy)

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredient	Per fizzy
<b>Amino Acids</b>	
L-Arginine (L-Arginine Hydrochloride)	93,8 mg
L-glutamine (L-Glutamine)	75 mg
L-Glycine (L-Glycine)	37,5 mg
L-Lysine (L-Lysine)	25 mg
L-Ornithine (L-Ornithine Hydrochloride)	22,5 mg
<b>Antioxidants</b>	
Vitamin C (Ascorbic Acid)	70 mg
Zinc (Zinc glycinate 20 %)	3 mg
Glycine (Zinc glycinate 20 %)	1,054 mg
Vitamin E (Vitamin E acetate 50%)	9 IU
<b>Vitamins &amp; Minerals</b>	
Magnesium (Magnesium oxide D.C 59 %)	45 mg
Vitamin B3 (Nicotinamide)	10 mg
Vitamin B5 (Calcium D-Pantothenate)	5 mg
Calcium (Calcium D-Pantothenate)	0,52 mg
Iron (Ferrous bisglycinate chelate 20 %)	5 mg
Glycine (Ferrous bisglycinate chelate 20 %)	1,84 mg
Vitamin B6 (Pyridoxine Hydrochloride 82 %)	5 mg
Vitamin B2 (Riboflavin)	1,8 mg
Vitamin B1 (Thiamine Hydrochloride 84 %)	1,5 mg
Vitamin A (Vitamin A acetate)	1251 IU
Vitamin D3 (Vitamin D3 100 000 IU/g)	1000 IU
Folic Acid (Folic Acid)	199 ug
Biotin (D-Biotin)	110 ug
Vitamin B12 (Vitamin B12 0,2 %)	3 ug

For full list of excipients, see section 6.1

### 3 PHARMACEUTICAL FORM

**STAMINOGRO KIDS** fizzy tablets are available in cream soda raspberry flavours.

Cream soda: Round, light green effervescent tablet.

Raspberry: Round, light pink effervescent tablet.

### 4 CLINICAL PARTICULARS

#### 4.1 Therapeutic indication

**STAMINOGRO KIDS** is a health supplement for children 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

**Children 4 years and older:** Take one tablet daily, dissolved in water, after a meal, or as recommended by a healthcare provider. Wait for the tablet to completely dissolve before drinking.

#### 4.3 Contraindications

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

Not for use in children under the age of 4 years.

#### 4.4 Special warnings and precautions for use

Caution is advised in patients with renal and/or cardiovascular disease.

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

No interaction studies were performed on **STAMINOGRO KIDS**. 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, 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 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

### 4.7 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.
- 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.
- Vitamin D contributes to the maintenance of normal muscle function and helps 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.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

**STAMINOGRO KIDS** cream soda: Aerosil, citric acid anhydrous, cream soda flavour, effervescent, green colour C835, polyethylene glycol and vanilla. Contains sugar: Mannitol 0,688 g/tablet and sweetener: Sucralose 30 mg/tablet

**STAMINOGRO KIDS** raspberry: Aerosil, citric acid anhydrous, effervescent, polyethylene glycol, raspberry flavour, red beetroot juice powder and vanilla. Contains sugar: mannitol 0,304 g/tablet and sweetener: sucralose 30 mg/tablet

## **6.2 Incompatibilities**

Unknown

## **6.3 Shelf life**

2 years

## **6.4 Special precautions for storage**

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

KEEP OUT OF THE REACH OF CHILDREN.

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

Plastic tubes containing 10 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](http://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