SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

STIMOL® 1g/10ml, oral solution in sachet.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Citrulline malate 1g

For a 10ml sachet

(corresponding to 2g of 50% citrulline malate solution)

Excipient with known effect: sodium.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral solution.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Symptomatic treatment of functional asthenia.
STIMOL® 1g/10ml, oral solution in sachet is indicated in adults and children over 6 years of age.

4.2. Posology and method of administration

Posology

Treatment duration is limited to 4 weeks.
Adults: 3 sachets per day in several intakes.
Children above 6 years: 2 sachets per day in several intakes.

Method of administration

Oral route.
Dilute the contents of the sachet in a glass of water.

4.3. Contra-indications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4. Special warnings and precautions for use

- If symptoms persist, management must be reevaluated.
- This medicine contains sodium. In case of controlled salt free diet, take into account in the daily supply the quantity of 1.3mmol (or 30mg) of sodium per sachet.
- Due to the acid pH, the contents of the sachets should always be diluted in a glass of water.
- The treatment of asthenia in children under 6 requires a medical advice.

4.5. Interactions with other medicinal products and other forms of interactions

The data currently available do not suggest the existence of clinically significant interactions.

4.6. Fertility, pregnancy and lactation

Pregnancy

There are no reliable animal teratogenesis data.
There have been no clinical reports to date of any malformative or fetotoxic effect. However, the monitoring of pregnancies exposed to this medicine is insufficient to rule out any risk. Hence, as a precautionary measure, this medicine should not be used during pregnancy.

Breast-feeding

Due to the absence of data about the excretion of this drug in breast milk, the use of it has to be avoided during breast-feeding.

4.7. Effects on ability to drive and use of machines

Not relevant.

4.8. Undesirable effects

The side effects which have been reported are classified after by system-organ class and by frequency defined as: very common (>1/10), common (> 1/100, < 1/10), uncommon (> 1/1,000, < 1/100), rare (> 1/10,000, < 1/1,000) and very rare (< 1/10,000), frequency not known (cannot be estimated from the available data).
Within each frequency grouping, undesirable effects are presented in order of decreasing severity.

System-Organ	Rare
Gastrointestinal disorders	Light gastralgia at the beginning of the treatment

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 the national reporting system. ADR Reporting – Website: www.medicinesauthority.gov.mt/adrportal

4.9. Overdose

No case of overdose has been reported. However a possible overdose may cause exacerbation of adverse effects (gastrointestinal).

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Antiasthenic drug.
ATC code: A13A2 - (A: digestive tract and metabolism)

5.2. Pharmacokinetic properties

The digestive absorption of citrulline malate is rapid.

Peak concentrations are observed 45 minutes after ingestion with concentrations 6 to 15 times the baseline plasma levels. The decrease to the baseline needs 5 to 6 hours.

The compound disappears rapidly from the plasma compartment before being excreted in the urine.

5.3. Preclinical safety data

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6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Natural sangria orange solution, concentrated sodium hydroxide solution, purified water.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

3 years.

6.4. Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5. Nature and contents of container

Sachet (paper/aluminium/polyethylene) of 10ml. Box of 18 sachets.

6.6. Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORIZATION HOLDER

BIOCODEX
22 rue des Aqueducs
94250 GENTILLY - France
Tel.: 33 1 41 24 30 00
Fax: 33 1 41 24 30 04

8. MARKETING AUTHORIZATION NUMBER(S)

MA239/00302: Box of 18 sachets (paper/aluminium/polyethylene).

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORISATION

28th February 2006

10. DATE OF REVISION OF THE TEXT

August 2025