SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

ROCMALINE oral solution, ampoule

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

L (+) arginine anhydrous basis ....413, 00 mg
DL malic acid .... 1500, 00 mg
For a 10 ml ampoule.
Excipients with known effect: sucrose, sulphites.
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral solution.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Used in suspected functional disorders of hepatic origin.

4.2. Posology and method of administration

Take the product at the time of the meal, diluted in a glass of water. 3 ampoules per day.

4.3. Contraindications

Hypersensitivity to the active substances or any of the excipients.

4.4. Special warnings and precautions for use

Special warnings

This medicine contains "sulphites".
This medicine contains sucrose. Its use is not recommended in patients with fructose intolerance, malabsorption of glucose and galactose or sucrase / isomaltase deficiency.

Precautions

In case of diabetes, of low carbohydrate diet, take into account in the daily ration of the sucrose content of an ampoule (1 g).

4.5. Interaction with other medicinal products and other forms of interaction

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

4.6. Fertility, pregnancy and lactation

Use cautiously in pregnant or nursing women, lack of usable clinical data.

4.7. Effects on ability to drive and use machines

Not applicable.

4.8. Undesirable effects

Arginine can cause diarrhea in large doses. Furthermore, it has been reported in the literature cases of hypotension after intravenous administration of arginine.

4.9. Overdose

No case of overdose has been reported. However, risk of diarrhea at high doses (see section 4.8).

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group:
LIVER THERAPY
Code ATC : A05BA

5.2. Pharmacokinetic properties

Not specified.

5.3. Preclinical safety data

Not specified.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Anhydrous sodium sulfite, sucrose, sodium cyclamate, sodium saccharin, plum flavor(1),purified water.
(1)Composition of the plum flavor: plum tincture, vanilla extract, alcoholate marasca and orange, vanillin, ethyl vanillin, lactones, acetic esters and butyric dimethyl benzyl carbinol.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

3 years.

6.4. Special precautions for storage

Store at a temperature below 25 ° C.

6.5. Nature and contents of container

Ampoule (yellow glass) of 10 ml. Box of 20 ampoules.

6.6. Special precautions for disposal and handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

OWNER AND OPERATOR TO INTERNATIONAL:
FRILAB SA
17, rue des Pierres du Niton
1207 Genève SWITZERLAND

Production site:
Biocodex, Technipôle Mohamed V Airport, Casablanca Nouaceur, Morocco

8. DATE OF REVISION OF THE TEXT

02.08.2021

9. DOSIMETRY

Not applicable.

10. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

CONDITIONS OF PRESCRIPTION AND DELIVERY

Medicinal product not subject to medical prescription.