SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

ROCMALINE, oral solution, ampoule

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

L(+) arginine anhydrous base .....413.00 mg
DL-malic acid .....1500.00 mg
For a 10ml ampoule.
Excipients with known effects: sucrose, sulfites.
For the full list of excipients, see section 6.1 .

3. PHARMACEUTICAL FORM

Oral solution.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Used in presumed functional disorders of hepatic origin.

4.2. Posology and method of administration

Take the product with meals, diluted in a glass of water. 3 ampoules per day.

4.3. Contraindications

Hypersensitivity to the active substances or to any of the excipients.

4.4. Special warnings and precautions for use

Special warnings

This medicine contains "sulfites".
This medicine contains sucrose. Its use is not recommended in patients with fructose intolerance, glucose-galactose malabsorption syndrome, or sucrase-isomaltase deficiency.

Precautions for use

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

4.5. Interactions 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. Pregnancy and breastfeeding

Use with caution in pregnant or breastfeeding women, due to a lack of usable clinical data.

4.7. Effects on the ability to drive vehicles and use machinery

Not applicable.

4.8. Undersirable effects

Arginine can cause diarrhea at high doses. Furthermore, cases of hypotension following intravenous administration of arginine have been reported in the literature.

4.9. Overdose

No cases of overdose have been reported. However, there is a risk of diarrhea at high doses (see section 4.8).

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmatherapeutic class : HEPATIC MEDICINE, ATC code: A05B0 .

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 flavour (1), purified water.
(1) Composition of the plum flavour: plum tincture, vanilla extract, marasca and orange tincture, vanillin, ethyl vanillin, lactones, acetic and butyric esters of 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 30°C.

6.5. Nature and contents of container

10 ml ampoule (brown glass). Box of 20 ampoules.

6.6. Special precautions for disposal and handling

No special requirements. Any unused medicinal product or waste material should be disposed of in accordance with local regulations.

7. OPERATOR AND MANUFACTURER

Operator of the export marketing authorization
FRILAB SA
17, rue des Pierres du Niton
1207 Geneva SWITZERLAND

Manufacturer :
BIOCODEX MOROCCO

Technopole Airport Mohamed V, 20240 Nouaceur
Casablanca, Morocco

8. DATE OF TEXT UPDATE

29 July 2022

9. DOSIMETRY

Not applicable.

CONDITIONS FOR PRESCRIPTION AND DISPENSING

This medication is not subject to medical prescription.