

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF DRUG

ROCMALINE oral solution, ampoule

2. Qualitative and quantitative composition

L (+) arginine anhydrous basis 413,00 mg
DL malic acid 1500,00 mg
To a 10 ml ampoule.

Excipients with known effect: sucrose, sulphites.

For a full list of excipients, [see section 6.1](#).

3. PHARMACEUTICAL FORM

Drinkable solution.

4. CLINICAL DATA

4.1. Therapeutic indications

Used in suspected functional disorders of hepatic origin.

4.2. Dosage and administration

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

4.3. Cons-indications

Hypersensitivity to the active substances or any of the excipients.

4.4. Special warnings and precautions

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.

Precautions

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

4.5. Interactions with other drugs and other forms of interaction

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

4.6. Pregnancy and breast feeding

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. Side effects

Arginine can cause diarrhea in large doses. Furthermore it has been reported in the literature of 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:
REFERRED A DRUG LIVER.

5.2. pharmacokinetic properties

Not specified.

5.3. Preclinical safety data

Not specified.

6. PHARMACEUTICAL DATA

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. incompatibility

Not applicable.

6.3. The duration of the conversation

3 years.

6.4. Special precautions for storage

No special storage conditions.

6.5. Nature and contents of container

Bulb (brown glass) of 10 ml. Box of 20 vials.

6.6. Special precautions for disposal and handling

No special requirements.

7. HOLDER OF MARKETING AUTHORIZATION

OPERATOR TO INTERNATIONAL AND MANUFACTURERS:

FRILAB SA
17, rue des Pierres du Niton
1207 Genève SWITZERLAND

Maker :

Biocodex, Technipôle Mohamed V Airport, Casablanca Nouaceur, Morocco

8. DOSIMETRY

Not applicable.

9. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

CONDITIONS OF PRESCRIPTION AND DELIVERY

Medicinal product not subject to medical prescription.