

LEAFLET

ROCMALINE, oral solution, ampoule

Arginine / malic acid

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

If you have any further questions or doubts, ask your doctor or pharmacist.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need further information or advice.
- You must talk to your doctor if you do not feel better or if you feel worse.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. WHAT ROCMALINE, oral solution, ampoule IS AND WHAT IT IS USED FOR?
2. WHAT YOU NEED TO KNOW BEFORE USING ROCMALINE, oral solution, ampoule ?
3. HOW TO TAKE ROCMALINE, oral solution, ampoule?
4. POSSIBLE SIDE EFFECTS
5. HOW TO STORE ROCMALINE, oral solution, ampoule?
6. CONTENTS OF THE PACK AND OTHER INFORMATION

1. WHAT ROCMALINE, oral solution, ampoule IS AND WHAT IT IS USED FOR?

Pharmacotherapeutic group

Not applicable.

Therapeutic indications

This medicine is recommended for the treatment of symptoms considered to be due to liver disorders.

2. WHAT YOU NEED TO KNOW BEFORE USING ROCMALINE, oral solution, ampoule ?

List of information necessary before using this medicinal product

If your doctor has told you that you are intolerant to certain sugars, talk to your doctor before taking this medicine.

Contraindications

Do not take ROCMALINE, oral solution, ampoule:

If you are allergic to the active substance or any of the other ingredients of this medicine.

YOU SHOULD CHECK WITH YOUR DOCTOR OR PHARMACIST IF YOU ARE NOT SURE.

Precautions for use; special warnings

Warnings and precautions:

Special warnings

This medicine contains sulphites.

Use of this medicine is not recommended in patients with fructose intolerance, glucose-galactose malabsorption syndrome or sucraseisomaltase deficiency (rare hereditary diseases).

Precautions for use

Patients with diabetes or on a low-sugar diet should take the sugar content of one ampoule (1g) into account in their daily intake.

TALK WITH YOUR DOCTOR OR PHARMACIST BEFORE TAKING ROCMALINE, ORAL SOLUTION, AMPOULE.

[Interactions with other medicinal products](#)

Other medicines and ROCMALINE, oral solution, ampoule:

TELL YOUR DOCTOR OR PHARMACIST IF YOU ARE TAKING, HAVE RECENTLY TAKEN OR MIGHT TAKE ANY OTHER MEDICINES.

[Interactions with food and drink](#)

Not applicable.

[Interactions with herbal or alternative therapies](#)

Not applicable.

[Use by pregnant or breast-feeding women](#)

Pregnancy, breast-feeding and fertility

Caution is advised when taking this medicine during pregnancy or while breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

[Effects on the ability to drive or to use machines](#)

Not applicable.

[Excipients warnings](#)

Excipients with known effects: sucrose, sulphites.

3. HOW TO TAKE ROCMALINE, oral solution, ampoule?

Dosage, Method and/or route of administration. Frequency of administration. Duration of treatment

Dosage

Take with meals, diluted in a glass of water.

3 ampoules per day

Symptoms in case of overdose and actions to be taken

If you take more ROCMALINE, oral solution, ampoule than you should:

Risk of diarrhoea at high doses.

[Actions to be taken when one or more doses have been missed](#)

Not applicable.

4. POSSIBLE SIDE EFFECTS?

Description of side effects

Like all medicines, ROCMALINE, oral solution, ampoule can cause side effects, although not everyone gets them:

Risk of diarrhoea at high doses.

If you get any side effects, talk to your doctor or pharmacist or nurse.

This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE ROCMALINE, oral solution, ampoule?

Keep out of the reach and sight of children

Expiry date

Do not use PHENERGAN 2% cream after the expiry date stated on the carton.

Storage conditions

This medicine does not require any special storage conditions.

Where appropriate, warning against certain visible signs of deterioration

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

Full statement of the active substances and excipients

What ROCMALINE, oral solution, ampoule contains?

The active substance is:

L (+) arginine anhydrous basis413, 00 mg
DL malic acid 1500, 00 mg

For one 10 ml ampoule.

The other ingredients are:

Anhydrous sodium sulfite, sucrose, sodium cyclamate, sodium saccharin, plum flavor⁽¹⁾, purified water.

⁽¹⁾Composition of plum flavor: alcoholic tincture of plum, vanilla extract, alcoholic tincture of maraschino cherry and orange, vanillin, ethylvanillin, lactones, dimethylbenzylcarbinol acetyl and butyl esters.

Pharmaceutical form and contents

What ROCMALINE, oral solution, ampoule looks like and contents of the pack

This medicine is an oral solution supplied in 10 ml ampoules. Packs of 20 ampoules.

Pharmaceutical company

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

Manufacturer

Biocodex MAROC
Technipôle Mohamed V Airport
Casablanca Nouaceur
Morocco

Names of the medicine in Member States of the European Economic Area

Not applicable.

Date of approval of the package leaflet

This leaflet was last revised in : October 2011

Marketing authorisation under exceptional circumstances

Not applicable.

Internet information

Detailed information on this medicine is available from the ANSM website (France).

The following information is intended for medical or healthcare professionals only

Not applicable.

Other

Not applicable.