

COMPOSITION:**Liquid:**

Each 5 ml contains 3.3 gm Lactulose (USP).

CLINICAL PHARMACOLOGY:

RIALAC® causes a decrease in blood ammonia concentration and reduces the degree of portal-systemic encephalopathy.

These actions are considered to be results of the following:

Bacterial degradation of Lactulose in the colon acidifies the colonic contents.

This acidification of colonic contents results in the retention of ammonia in the colon as the ammonium ion. Since the colonic contents are then more acid than the blood, ammonia can be expected to migrate from the blood into the colon to form the ammonium ion.

The acid colonic contents convert NH₃ to the ammonium ion (NH₄)⁺, trapping it and preventing its absorption.

The laxative action of the metabolites of RIALAC® then expels the trapped ammonium ion from the colon.

Oral administration, less than 3% of a dose of lactulose are absorbed from the small intestine. Absorbed lactulose is not metabolized and is excreted in the urine unchanged within 24 hours.

INDICATIONS:

RIALAC® is used for the following:

- Chronic constipation.
- Hepatic Encephalopathy (Portal Systemic Encephalopathy, Precoma, Coma).

CONTRAINDICATIONS:

Do not take RIALAC® if you:

- Are allergic to lactulose, galactose, lactose or any other sugar.
- Have galactosaemia.
- Have a disaccharidase deficiency.
- Are on a low-galactose or galactose-free diet.
- Are on a lactose-free diet.
- Have a bowel obstruction (blockage other than normal constipation).

PRECAUTIONS:

RIALAC® should be administered with care to patients who are intolerant to lactose.

The dose normally used in constipation should not cause a problem for diabetics. The dose used in the treatment of (pre)coma hepaticum is usually much higher and may need to be taken into consideration for diabetics.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Consultation of a physician is advised, if the treatment does not give the desired effect after few days of use.

ADVERSE REACTIONS:

During the first few days of treatment, you may feel bloated as a result of increased gases; these symptoms usually disappear after a few days.

At high doses, you may suffer from stomach ache and diarrhea, if this happens, should reduce your dose.

USE DURING PREGNANCY AND LACTATION:

RIALAC® is used to treat chronic constipation. It can be taken by pregnant woman.

Lactation:

No effects on the breastfeed newborn/infant, RIALAC® can be used during breast-feeding.

DOSAGE:**CONSTIPATION:**

Initially RIALAC® may be given twice daily. In due course the dose should be adjusted to the needs of the individual, but the following serves as a guide.

Starting dose:

Adults (including the elderly): 15 ml twice daily.

Children 5 to 10 years: 10 ml twice daily.

Children 2 to 5 years: 5 ml twice daily.

Babies 1 to 2 years: 2.5 - 5 ml twice daily.

Babies under 1 year: 2.5 ml twice daily.

RIALAC® may, be taken with water or fruit juices.

HEPATIC ENCEPHALOPATHY:

Adults (including the elderly): Initial dose: 30-50 ml three times daily.

Maintenance dose: to be adjusted to the individual response.

Children: No dosage recommendation for this indication.

STORAGE:

Store RIALAC® below 25 °C.

Do not refrigerate or freeze.

Do not use RIALAC® after the expiry date printed on the package.

PRESENTATION:

Liquid: 200 ml and 300 ml glass bottles.

To Report any side effect(s) or Quality Problems:

- National Pharmacovigilance Center (NPC)
 - Fax: +966-1-205-7662
 - E-mail: npc.drug@sfd.gov.sa
 - website: www.sfd.gov.sa/npc

This is a medicament

- A medicament is a product, which affects your health, and its consumption contrary to instructions is dangerous for you
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament
- The doctor and the pharmacist are experts in medicine, its benefits and risks
- Do not by yourself interrupt the period of treatment prescribed for you
- Do not repeat the same prescription without consulting your doctor

Keep medicaments
out of the reach of children
Council of Arab Health Ministers
Union of Arab Pharmacists



Manufactured by RIYADH PHARMA

Medical and Cosmetic Products Co. Ltd.
Riyadh, Saudi Arabia.