Lactulose

Movelax®

3.3 g/5 mL Syrup

LAXATIVE

FORMULATION

Each 5 mL syrup contains:

Lactulose (as lactulose concentrate) ..... 3.3 g

PRODUCT DESCRIPTION

Lactulose (Movelax[1]) is a clear, colorless to slightly yellow, sweet, aqueous, orange-flavored syrup.

PHARMACODYNAMICS

Lactulose is a synthetic disaccharide osmotic laxative containing galactose and fructose. Colonic bacteria break lactulose primarily to lactic and acetic acid which results in an increased osmotic effect and slight acidification of the colonic contents. This results in an increased fecal bulk, softened stools and shortened transit time. It may take 48 hours before an effect is obtained.

Lactulose exerts its effect only in the colon. It decreases blood ammonia concentrations by acidifying the contents of the bowel reducing intraluminal pH to below 5. This reduces the degree of portal systemic encephalopathy since the absorption of ammonium ions and other toxic nitrogenous compounds into the blood is decreased.

PHARMACOKINETICS

Lactulose is poorly absorbed from the gastrointestinal tract after oral administration. No enzyme present in human gastrointestinal tissue is capable of hydrolysis of this disaccharide. Lactulose reaches the colon virtually unchanged with less than 2% being absorbed by non-mediated diffusion. Urinary excretion is less than or equal to 3% and is essentially complete within 24 hours.

INDICATIONS

- Treatment of chronic and habitual constipation.
- Prevention and treatment of portal systemic encephalopathy (PSE) including the stages of hepatic pre-coma and coma.
- For patients with hemorrhoids, after colon/anal surgery or other conditions where a soft stool is beneficial.

DOSAGE AND ADMINISTRATION

- **Treatment of chronic and habitual constipation and for patients who will benefit from soft stools.**

Age Group	Usual Initial Oral Dose
Adults and children over 10 years old	15 - 30 mL (given as a single dose or in two divided doses) Doses up to 45 mL/day have been used.
5 - 10 years old	10 mL two times daily
1 - 5 years old	5 mL two times daily
Under 1 year old	2.5 mL two times daily
	Dose may be increased or decreased according to patient's response.
	24 to 48 hours may be needed to produce normal bowel movement for those who are constipated
	Or, as prescribed by a physician.

- **Prevention and treatment of portal systemic encephalopathy**
  - Initial Dose in Adults and Elderly: 30- 50 mL three times daily.
  - Subsequent doses should be adjusted to produce 2 or 3 soft stools daily.

- **Prevention of hepatic coma**
  - Initial Dose in Adults: 25 mL three times daily.
  - Subsequent doses should be adjusted to obtain soft stools.

CONTRAINDICATIONS

- Hypersensitivity to lactulose or any ingredient of the product.
- Galactosemia or disaccharide deficiency
- Intestinal obstruction
- Patients on a galactose and/or lactose free diet

WARNINGS and PRECAUTIONS

- Lactulose may cause accumulation of hydrogen gas in significant concentrations, which in the presence of an electrical spark may theoretically result in an explosive reaction. Patients treated with lactulose who may be required to undergo electrocautery procedures during proctoscopy or colonoscopy should have a thorough bowel cleansing with a nonfermentable solution prior to these procedures.
- Lactulose contains some free galactose and lactose. Diabetic patients and those with lactose intolerance should use lactulose with caution since blood glucose may be elevated, usually after extended use.
- Patients should consult their physicians if any unusual diarrhea occurs.
- Elderly or debilitated patients using lactulose for more than 6 months should have their serum electrolytes (i.e., potassium, chloride, carbon dioxide) periodically measured.

DRUG INTERACTIONS

- Nonabsorbable antacids given concurrently with lactulose may inhibit the desired lactulose-induced drop in colonic pH.
- Lactulose may inactivate drugs that have a colon pH-dependent release (e.g., 5-ASA agents) when given concomitantly.
- Concomitant use of neomycin and possibly other anti-infective agents may eliminate colonic bacteria necessary to metabolize lactulose and thereby prevent acidification of the colon contents. However, lactulose appears to remain active when administered with neomycin to patients with PSE, and some reports suggest that such concomitant therapy may be more effective than either drug alone in the treatment of PSE.

HIGH RISK GROUPS

Use in Pregnancy

Pregnancy Category B

Reproduction studies in mice, rats and rabbits at doses up to 3 to 6 times the usual human oral dose did not produce any evidence of impaired fertility or harm to the fetus. Lactulose has been shown to be a safe and effective treatment of constipation in pregnant women. However, its use during pregnancy should be upon the advice of a physician.

Use in Breastfeeding Mothers

It is not known whether lactulose is excreted in human milk. Lactulose should only be used when clearly needed and when potential benefits outweigh the unknown hazards to the baby.

Use in Children

Lactulose has been shown to be effective and safe in the treatment of constipation in children. However, it is recommended that lactulose, when given to infants or children for periods greater than one month, should be under the supervision of a physician.

UNDESIRABLE EFFECTS

Initial dosing of lactulose may cause flatulence and abdominal cramps which are generally transient. Excessive dosage can lead to diarrhea with excessive loss of water and electrolytes (particularly potassium and sodium). Hypernatremia, nausea and vomiting have also been reported.

Some consider the taste unpleasant. This can be minimized by dilution of water, fruit juice, or milk, or by mixing the dose with food.

OVERDOSAGE AND TREATMENT

There is no information regarding lactulose overdose. However, diarrhea and abdominal cramps may be experienced. In cases of overdosage, discontinue lactulose and initiate symptomatic therapy.

CAUTION

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

AVAILABILITY

Lactulose (Movelax®) 3.3 g / 5 mL Syrup in amber glass bottles of 120 mL and 30 mL

STORAGE CONDITION

Store at temperatures not exceeding 30°C
Keep the product out of sight and reach of children. Protect from light.

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