LACTULOSE SOLUTION USP - lactulose solution
Hi-Tech Pharmacal Co., Inc.

DESCRIPTION
Lactulose is a synthetic disaccharide in solution form for oral administration. Each 15 mL of lactulose solution contains: 10 g lactulose (and less than 1.6 g galactose, less than 1.2 g lactose, and 1.2 g or less of other sugars). Lactulose solution contains potassium sorbate as an inactive ingredient.
Lactulose is a colonic acidifier which promotes laxation.
The chemical name for lactulose is 4-O-β-D-galactopyranosyl-D-fructofuranose. It has the following structural formula:

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Laboratory Tests
Elderly, debilitated patients who receive lactulose for more than six months should have serum electrolytes (potassium, chloride, carbon dioxide) measured periodically.

Drug Interactions
Results of preliminary studies in humans and rats suggest that non-absorbable antacids given concurrently with lactulose may inhibit the desired lactulose-induced drop in colonic pH. Therefore, a possible lack of desired effect of treatment should be taken into consideration before such drugs are given concomitantly with lactulose solution.

Carcinogenesis, Mutagenesis, Impairment of Fertility
There are no known human data on long-term potential for carcinogenicity, mutagenicity, or impairment of fertility. There are no known animal data on long-term potential for mutagenicity. Administration of lactulose solution in the diet of mice for 18 months in concentrations of 3 and 10 percent (v/w) did not produce any evidence of carcinogenicity. In studies of mice, rats, and rabbits, doses of lactulose solution up to 6 or 12 mL/kg/day produced no deleterious effects in breeding, conception, or parturition.

Pregnancy
Teratogenic Effects
Pregnancy category B. Reproduction studies have been performed in mice, rats, and rabbits at doses up to 3 or 6 times the usual human oral dose and have revealed no evidence of impaired fertility or harm to the fetus due to lactulose. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Nursing Mothers
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when lactulose solution is administered to a nursing woman.

Pediatric Use
Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS
Precise frequency data are not available. Initial dosing may produce flatulence and intestinal cramps, which are usually transient. Excessive dosage can lead to diarrhea with potential complications such as loss of fluids, hypokalemia, and hypernatremia. Nausea and vomiting have been reported. To report SUSPECTED ADVERSE REACTIONS, contact Hi-Tech Pharmacal Co., Inc. at 1-800-262-9010 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

OVERDOSAGE
Signs And Symptoms:
There have been no reports of accidental overdosage. In the event of overdosage, it is expected that diarrhea and abdominal cramps would be the major symptoms. Medication should be terminated. Oral LD50: The acute oral LD50 of the drug is 48.8 mL/kg in mice and greater than 30 mL/kg in rats. Dialysis: Dialysis data are not available for lactulose. Its molecular similarity to sucrose, however, would suggest that it should be dialyzable.

DOSAGE AND ADMINISTRATION
The usual dose is 1 to 2 tablespoonsfuls (15 to 30 mL, containing 10 g to 20 g of lactulose) daily. The dose may be increased to 60 mL daily if necessary. Twenty-four to 48 hours may be required to produce a normal bowel movement. Note: Some patients have found that lactulose solution may be more acceptable when mixed with fruit juice, water or milk.

HOW SUPPLIED
Lactulose Solution USP 10 g/15 mL is available as follows:
8 fl oz (237 mL) bottle
16 fl oz (473 mL) bottle
32 fl oz (946 mL) bottle
15 mL unit dose cups in trays of 10 cups
30 mL unit dose cups in trays of 10 cups
Lactulose Solution contains lactulose 667 mg/mL (10 g/15 mL). Store at controlled room temperature 15°-30°C (59° to 86°F). Do not freeze.

Under recommended storage conditions, a normal darkening of color may occur. Such darkening is characteristic of sugar solutions and does not affect therapeutic action. Prolonged exposure to temperatures above 86°F (30°C) or to direct light may cause extreme darkening and turbidity which may be pharmaceutically objectionable. If this condition develops, do not use. Prolonged exposure to freezing temperatures may cause change to a semi-solid, too viscous to pour. Viscosity will return to normal upon warming to room temperature.

Dispense in original container or in a tight, light-resistant container as defined in the USP, with a child-resistant closure.

Rx only
Distributed by:
Hi-Tech Pharmacal Co., Inc.
Amityville, NY 11701
Rev. 779:03 2/09

PRINCIPLE DISPLAY PANEL

Unit Dose Lid
LACTULOSE
SOLUTION USP 20 g/30 mL

Indications: For the treatment of constipation. See Insert.

UNIT DOSE
Delivers 30 mL
NDC 50383-779-30

Rx ONLY
Hi-Tech Pharmacal Co., Inc.
Amityville, NY 11701
Rev. 779:00 2/09

Each 15 mL of solution contains: 10 g lactulose (and less than 1.8 g galactose, less than 1.2 g lactose and 1.2 g or less of other sugars). Also contains water.

USUAL ADULT DOSAGE: 1 to 2 tablespoonsfuls (15 to 30 mL) daily. See package insert for full prescribing information.

Since lactulose does not exert its effect until it reaches the colon, and since transit time through the colon may be slow, 24 to 48 hours may be required to produce a normal bowel movement.

Some patients have found that lactulose solution may be more acceptable when mixed with fruit juice, water or milk.

Dispense in original container or tight, light-resistant container with child-resistant closure.

Store at controlled room temperature 15° to 30°C (59° to 86°F). Do not freeze.

Product may darken slightly but therapeutic action is not affected. Do not use if extreme darkening or turbidity occurs. See accompanying product information.

Keep tightly closed.

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Hi-Tech Pharmacal Co., Inc.
Amityville, NY 11701
Each 15 mL of lactulose solution contains: 10 g lactulose (and less than 1.6 g galactose, less than 1.2 g lactose and 1.2 g or less of other sugars). Also contains water.

USUAL ADULT DOSAGE: 1 to 2 tablespoonsfuls (15 to 30 mL) daily. See attached insert for full prescribing information.

Since Lactulose does not exert until it reaches the colon, and since transit time through the colon may be slow, 24 to 48 hours may be required to produce normal bowel movement.

Some patients have found that lactulose solution may be more acceptable when mixed with fruit juice, water, or milk.

Dispense in a tight, light-resistant container with child-resistant closure.

Store at controlled room temperature 15° to 30°C (59° to 86°F). Do not freeze.

Product may darken slightly but therapeutic action is not affected. Do not use if extreme darkening or turbidity occurs. See accompanying product information.

Keep tightly closed.

PHARMACIST: When ordering this product, include the NDC number in the description.

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Each 15 mL of solution contains: 10 g lactulose (and less than 1.6 g galactose, less than 1.2 g lactose and 1.2 g or less of other sugars). Also contains water.

USUAL ADULT DOSAGE: 1 to 2 tablespoonsfuls (15 to 30 mL) daily. See package insert for full prescribing information.

Since lactulose does not exert its effect until it reaches the colon, and since transit time through the colon may be slow, 24 to 48 hours may be required to produce normal bowel movement.

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