TRIFLUENT PHARMA®




**Packets available in**
**10 g & 20 g**

**15 Single Dose Packets**

# Constipation Relief in a Convenient Packet

**vs. a Big Bottle**

## Lactulose
### For Oral Solution

10 g NDC: 73352-900-15
20 g NDC: 73352-905-15

**INDICATIONS:**
Lactulose for Oral Solution is indicated for the treatment of constipation. In patients with a history of chronic constipation, lactulose therapy increases the number of bowel movements per day and the number of days on which bowel movements occur.

**CONTRAINDICATIONS:**
Since Lactulose for Oral Solution contains galactose (less than 0.3 g/10 g as a total sum with lactose), it is contraindicated in patients who require a low-galactose diet.

**ADVERSE REACTIONS:**
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.

**For full Prescribing Information, see attached Product Insert.**

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit fda.gov/medwatch or call 1-800-FDA-1088.**

# WHEN OTC DOESN'T CUT IT

By the time patients present, they have often exhausted available over-the-counter options without adequate relief.




## Lactulose is a Treatment Option for Those Suffering from Constipation

### Consider Lactulose for:

- **Flexible Administration Needs**
- **Elderly Patients**
- **Trouble Swallowing Pills**
- **No OTC Success**
- **Long-Term Care Needs**

## COPAY INFORMATION

**PATIENTS May Pay As Little As $0***

*Full terms and conditions at trifluentpharma.com/copay

**HOW TO WRITE:**

**Lactulose**

Mix 1 packet with 4 oz of water and drink immediately daily.

☐ 10 grams ☐ 20 grams

*Dispense as written.*

Visit our website at:
**TRIFLUENTPHARMA.COM**

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*LB-TRI-03 Rev. 10/2026*

**LACTULOSE- lactulose powder, for solution**
**Trifluent Pharma, Inc.**

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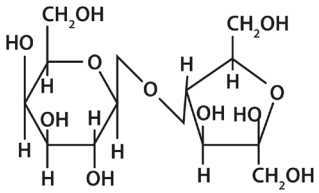
**LACTULOSE FOR ORAL SOLUTION**
**Rx only**

## DESCRIPTION

Lactulose for Oral Solution is a synthetic disaccharide in the form of crystals for reconstitution prior to use for oral administration. Each 10 g of lactulose contains less than 0.3 g galactose and lactose as a total sum. The pH range is 3.0 to 7.0.

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:




The molecular formula is $C_{12}H_{22}O_{11}$. The molecular weight is 342.30. It is freely soluble in water.

## CLINICAL PHARMACOLOGY

Lactulose is poorly absorbed from the gastrointestinal tract and no enzyme capable of hydrolysis of this disaccharide is present in human gastrointestinal tissue. As a result, oral doses of lactulose reach the colon virtually unchanged. In the colon, lactulose is broken down primarily to lactic acid, and also to small amounts of formic and acetic acids, by the action of colonic bacteria, which results in an increase in osmotic pressure and slight acidification of the colonic contents. This in turn causes an increase in stool water content and softens the stool.

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 desired bowel movement.

Lactulose given orally to man and experimental animals resulted in only small amounts reaching the blood. Urinary excretion has been determined to be 3% or less and is essentially complete within 24 hours.

## INDICATIONS AND USAGE

Lactulose for Oral Solution is indicated for the treatment of constipation. In patients with a history of chronic constipation, lactulose therapy increases the number of bowel movements per day and the number of days on which bowel movements occur.

## CONTRAINDICATIONS

Since Lactulose for Oral Solution contains galactose (less than 0.3 g/10 g as a total sum with lactose), it is contraindicated in patients who require a low galactose diet.

## WARNINGS

A theoretical hazard may exist for patients being treated with lactulose who may be required to undergo electrocautery procedures during proctoscopy or colonoscopy. Accumulation of H gas in significant concentration in the presence of an electrical spark may result in an explosive reaction. Although this complication has not been reported with lactulose, patients on lactulose therapy undergoing such procedures should have a thorough bowel cleansing with a non-fermentable solution. Insufflation of CO as an additional safeguard may be pursued but is considered to be a redundant measure.

## PRECAUTIONS

### General

Since Lactulose for Oral Solution contains galactose and lactose (less than 0.3 g/10 g as a total sum), it should be used with caution in diabetics.

### Information for Patients

In the event that an unusual diarrheal condition occurs, contact your physician.

### 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 nonabsorbable 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.

### 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 syrup 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 in mice, rats, and rabbits, doses of lactulose syrup up to 6 or 12 mL/kg/day produced no deleterious effects in breeding, conception, or parturition.

**Pregnancy**

Teratogenic Effects

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 wellcontrolled 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 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.

**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 LD**

The acute oral LD 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 adult dosage is 10 g to 20 g of lactulose daily. The dose may be increased to 40 g daily if necessary. Twenty-four to 48 hours may be required to produce a normal bowel movement.

**DIRECTIONS FOR PREPARATION**

Dissolve contents of packet in half a glass (4 ounces) of water.

When Lactulose for Oral Solution is dissolved in water, the resulting solution may be colorless to a slightly pale yellow color.

**HOW SUPPLIED**

Lactulose for Oral Solution is available in single dose packets of 10 g (NDC 73352-900-01) and single dose packets of 20 g (NDC 73352-905-01). The packets are supplied as follows:

**NDC** 73352-900-15
(Carton of fifteen 10 g packets)

**NDC** 73352-905-15
(Carton of fifteen 20 g packets)

STORE AT ROOM TEMPERATURE, 15°-30°C (59°-86°F).

**To report SUSPECTED ADVERSE REACTIONS, contact Trifluent Pharma at 1-888-927-5191 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

**Distributed by:**
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