LACTULOSE- lactulose solution
Xttrium Laboratories, Inc.

LACTULOSE SOLUTION, USP

LACTULOSE SOLUTION, USP

10g/15mL

For Oral Administration

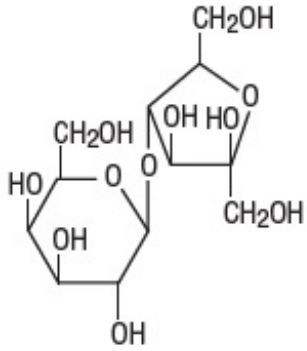
Rx Only

DESCRIPTION

Lactulose solution is a synthetic disaccharide in solution form for oral administration. **Each 15 mL of lactulose 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, D&C Yellow No. 10, and FD&C Yellow No. 6. The pH range is 2.5 to 6.5.

Lactulose solution is a colonic acidifier which promotes laxation.

The chemical name for lactulose is 4-O-ß-D-galactopyranosyl-D-fructofuranose. It has the following structural formula:



$C_{12}H_{22}O_{11}$

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 the 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

For the treatment of constipation. In patients with a history of chronic constipation, lactulose solution therapy increases the number of bowel movements per day and the number of days on which bowel movements occur.

CONTRAINDICATIONS

Since lactulose solution contains galactose (less than 1.6 g/15 mL), it is contraindicated in patients who require a low galactose diet.

WARNINGS

A theoretical hazard may exist for patients being treated with lactulose solution who may be required to undergo electrocautery procedures during proctoscopy or colonoscopy. Accumulation of H2 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_2 as an additional safeguard may be pursued but is considered to be a redundant measure.

PRECAUTIONS

General

Since lactulose solution contains galactose (less than 1.6 g/15 mL) and lactose (less than 1.2 g/15 mL), 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 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 in 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

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 Xttrium Laboratories, Inc. at 1-800-587-3721 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 tablespoonfuls (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 a colorless to yellow, unflavored solution available in the following container sizes:

15 mL unit dose white cups in trays of 10 cups (NDC 0116-4005-15)

30 mL unit dose white cups in trays of 10 cups (NDC 0116-4005-30)

8 fl. oz. (237 mL) white bottles (NDC 0116-4005-08)

16 fl. oz. (473 mL) white bottles (NDC 0116-4005-16)

32 fl. oz. (946 mL) white bottles (NDC 0116-4005-32)

Lactulose solution contains lactulose 667 mg/mL (10 g/15 mL).

Store at 20 ° to 25 °C (68 ° to 77 °F) [see USP Controlled Room Temperature]. 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 30 °C (86 °F) 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 semisolid, 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.

To The Pharmacist: When ordering this product, include the product number (or NDC) in the description.

Rx Only

Revised: June 2024

Distributed by:

Xttrium Laboratories, Inc.

1200 E. Business Center Dr.

Mount Prospect, IL 60056

Prescribing Information Insert

Rx Only

Lactulose Solution, USP
FOR ORAL ADMINISTRATION

Lactulose Solution, USP
FOR ORAL ADMINISTRATION

Rx Only

0116-4005

Lactulose Solution, USP

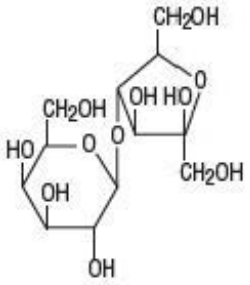
Rx only

DESCRIPTION

Lactulose solution is a synthetic disaccharide in solution form for oral administration. **Each 15 mL of lactulose 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). The pH range is 2.5 to 6.5.

Lactulose solution 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:



$C_{12}H_{22}O_{11}$

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 the 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

For the treatment of constipation. In patients with a history of chronic constipation, lactulose solution therapy increases the number of bowel movements per day and the number of days on which bowel movements occur.

CONTRAINDICATIONS

Since lactulose solution contains galactose (less than 1.6 g/15 mL), it is contraindicated in patients who require a low galactose diet.

WARNINGS

A theoretical hazard may exist for patients being treated with lactulose solution who may be required to undergo electrocautery procedures during proctoscopy or colonoscopy. Accumulation of H_2 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_2 as an additional safeguard may be pursued but is considered to be a redundant measure.

PRECAUTIONS

General

Since lactulose solution contains galactose (less than 1.6 g/15 mL) and lactose (less than 1.2 g/15 mL), 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 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 in 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

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 Xttrium Laboratories, Inc. at 1-800-587-3721 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 LD_{50}

The acute oral LD_{50} 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 tablespoonfuls (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 a colorless to yellow, unflavored solution available in the following container sizes:

15 mL unit dose white cups in trays of 10 cups (NDC 0116-4005-15)

30 mL unit dose white cups in trays of 10 cups (NDC 0116-4005-30)

8 fl. oz. (237 mL) white bottles (NDC 0116-4005-08)

16 fl. oz. (473 mL) white bottles (NDC 0116-4005-16)

32 fl. oz. (946 mL) white bottles (NDC 0116-4005-32))

Lactulose solution contains lactulose 667 mg/mL (10 g/15 mL).

Store at 20 ° to 25 °C (68 ° to 77 °F) [see USP Controlled Room Temperature]. 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 30 °C (86 °F) 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 semisolid, 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.

To The Pharmacist: When ordering this product, include the product number (or NDC) in the description.

Rx Only

Revised: June 2024

Distributed by:
Xttrium Laboratories, Inc.
1200 E. Business Center Dr.
Mount Prospect, IL 60056

4005XTTINSTA

Lactulose 8-oz Label

NDC 0116-4005-08

LACTULOSE SOLUTION, USP

10g/15mL

INDICATIONS: For the Treatment of Constipation

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).

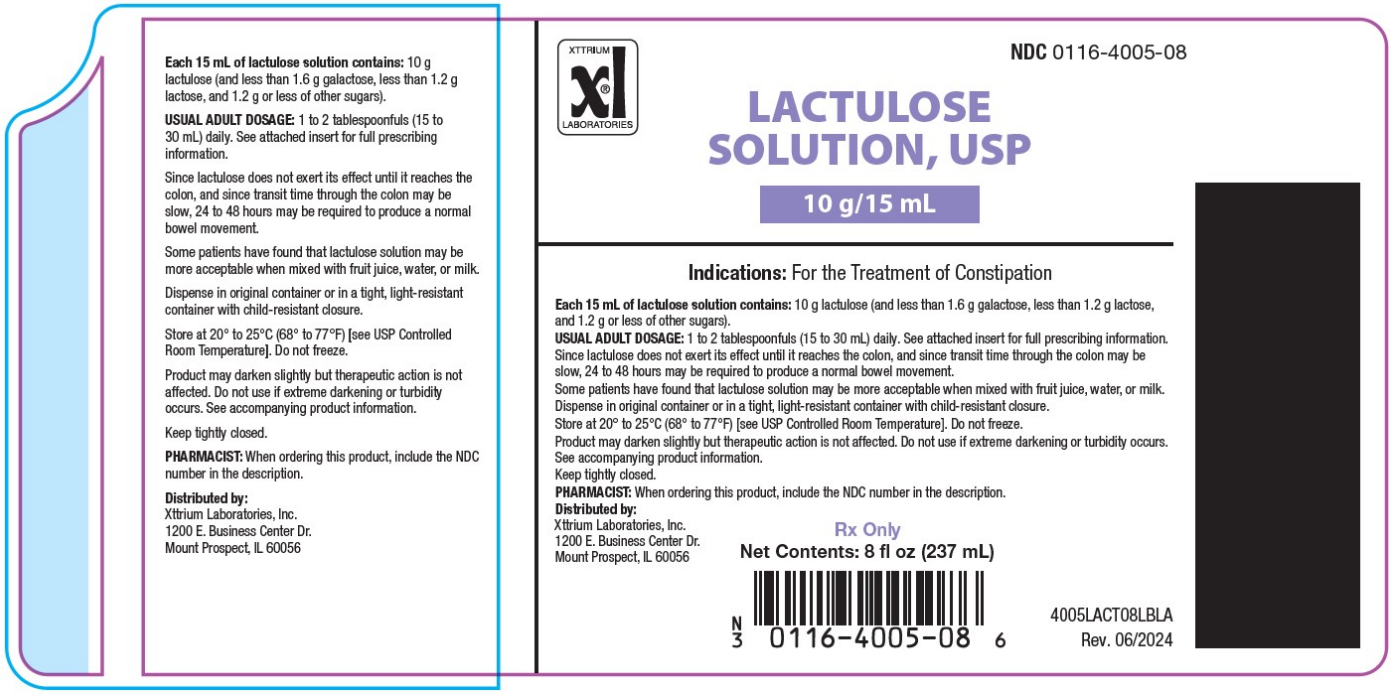
USUAL ADULT DOSAGE: 1 to 2 tablespoonfuls (15 to 30 mL) daily. See attached insert for full prescribing information.
Since lactulose does not exert its effect until it reaches the colon, and since transit time through the colon may be
slow, 24 to 48 hours may be required to produce a normal bowel movement.
Some patients have found that lactulose solution may be more acceptable when mixed with fruit juice, water, or milk.
Dispense in original container or in a tight, light-resistant container with child-resistant closure.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. 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.
Distributed by:
Xttrium Laboratories, Inc.
1200 E. Business Center Dr.
Mount Prospect, IL 60056

Rx Only

Net Contents: 8 fl oz (237mL)

4005LACT08LBLA

Rev. 06/2024

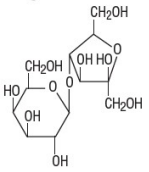


Lift Here

DESCRIPTION

Lactulose solution is a synthetic disaccharide in solution form for oral administration. **Each 15 mL of lactulose 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). The pH range is 2.5 to 6.5.

Lactulose solution is a colonic acidifier which promotes laxation.
The chemical name for lactulose is 4-0-β-D-galactopyranosyl-D-fructofuranose. It has the following structural formula:



$C_{12}H_{22}O_{11}$

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 the 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

For the treatment of constipation. In patients with a history of chronic constipation, lactulose solution therapy increases the number of bowel movements per day and the number of days on which bowel movements occur.

CONTRAINDICATIONS

Since lactulose solution contains galactose (less than 1.6 g/15 mL), it is contraindicated in patients who require a low galactose diet.

WARNINGS

A theoretical hazard may exist for patients being treated with lactulose solution who may be required to undergo electrocautery procedures during proctoscopy or colonoscopy. Accumulation of H_2 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_2 as an additional safeguard may be pursued but is considered to be a redundant measure.

PRECAUTIONS

General
Since lactulose solution contains galactose (less than 1.6 g/15 mL) and lactose (less than 1.2 g/15 mL), 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 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 in 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
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 Xttrium Laboratories, Inc. at 1-800-587-3721 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 LD_{50}
The acute oral LD_{50} 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 tablespoonfuls (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 a colorless to yellow, unflavored solution available in the following container sizes:

15 mL unit dose white cups in trays of 10 cups (NDC 0116-4005-15)

30 mL unit dose white cups in trays of 10 cups (NDC 0116-4005-30)

8 fl. oz. (237 mL) white bottles (NDC 0116-4005-08)

16 fl. oz. (473 mL) white bottles (NDC 0116-4005-16)

32 fl. oz. (946 mL) white bottles (NDC 0116-4005-32)

Lactulose solution contains lactulose 667 mg/mL (10 g/15 mL).

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. 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 30 °C (86 °F) 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 semisolid, 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.

To The Pharmacist: When ordering this product, include the product number (or NDC) in the description.

Rx Only

Revised: June 2024

Distributed by:
Xttrium Laboratories, Inc.
1200 E. Business Center Dr.
Mount Prospect, IL 60056

Lactulose 16-oz Label

NDC 0116-4005-16

LACTULOSE SOLUTION, USP

10g/15mL

INDICATIONS: For the Treatment of Constipation

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).

USUAL ADULT DOSAGE: 1 to 2 tablespoonfuls (15 to 30 mL) daily. See attached 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 in a tight, light-resistant container with child-resistant closure.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. 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.

Distributed by:
Xttrium Laboratories, Inc.
1200 E. Business Center Dr.
Mount Prospect, IL 60056

Rx Only

Net Contents: 16 fl oz (473mL)

4005LACT16LBLA

Rev. 06/2024

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).

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

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

Distributed by:
Xttrium Laboratories, Inc.
1200 E. Business Center Dr.
Mount Prospect, IL 60056

XTTRIUM LABORATORIES

NDC 0116-4005-16

LACTULOSE SOLUTION, USP

10 g/15 mL

Indications: For the Treatment of Constipation

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).

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

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

Distributed by:
Xttrium Laboratories, Inc.
1200 E. Business Center Dr.
Mount Prospect, IL 60056

Rx Only

Net Contents: 16 fl oz (473 mL)

N 3 0116-4005-16 1

4005LACT16LBLA
Rev. 06/2024

Lift Here

DESCRIPTION

Lactulose solution is a synthetic disaccharide in solution form for oral administration. **Each 15 mL of lactulose 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). The pH range is 2.5 to 6.5.

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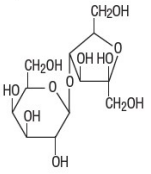

$C_{12}H_{22}O_{11}$

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.

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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

For the treatment of constipation. In patients with a history of chronic constipation, lactulose solution therapy increases the number of bowel movements per day and the number of days on which bowel movements occur.

CONTRAINDICATIONS

Since lactulose solution contains galactose (less than 1.6 g/15 mL), it is contraindicated in patients who require a low galactose diet.

WARNINGS

A theoretical hazard may exist for patients being treated with lactulose solution who may be required to undergo electrocautery procedures during proctoscopy or colonoscopy. Accumulation of H_2 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_2 as an additional safeguard may be pursued but is considered to be a redundant measure.

PRECAUTIONS

General

Since lactulose solution contains galactose (less than 1.6 g/15 mL) and lactose (less than 1.2 g/15 mL), 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 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 (w/w) did not produce any evidence of carcinogenicity.

In studies in 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
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 Xttrium Laboratories, Inc. at 1-800-587-3721 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 LD_{50}
The acute oral LD_{50} 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 tablespoonfuls (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 a colorless to yellow, unflavored solution available in the following container sizes:

15 mL unit dose white cups in trays of 10 cups (NDC 0116-4005-15)

30 mL unit dose white cups in trays of 10 cups (NDC 0116-4005-30)

8 fl. oz. (237 mL) white bottles (NDC 0116-4005-08)

16 fl. oz. (473 mL) white bottles (NDC 0116-4005-16)

32 fl. oz. (946 mL) white bottles (NDC 0116-4005-32)

Lactulose solution contains lactulose 667 mg/mL (10 g/15 mL).

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. 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 30 °C (86 °F) 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 semisolid, 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.

To The Pharmacist: When ordering this product, include the product number (or NDC) in the description.

Rx Only

Revised: June 2024

Distributed by:
Xttrium Laboratories, Inc.
1200 E. Business Center Dr.
Mount Prospect, IL 60056

Lactulose 32-oz Label

NDC 0116-4005-32

LACTULOSE SOLUTION, USP

10g/15mL

INDICATIONS: For the Treatment of Constipation

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).

USUAL ADULT DOSAGE: 1 to 2 tablespoonfuls (15 to 30 mL) daily. See attached 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 in a tight, light-resistant container with child-resistant closure.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. 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.

Distributed by:
Xttrium Laboratories, Inc.
1200 E. Business Center Dr.
Mount Prospect, IL 60056

Rx Only

Net Contents: 32 fl oz (946 mL)

4005LACT32LBLA

Rev. 06/2024

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).

USUAL ADULT DOSAGE: 1 to 2 tablespoonfuls (15 to 30 mL) daily. See attached 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.

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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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Distributed by:
Xttrium Laboratories, Inc.
1200 E. Business Center Dr.
Mount Prospect, IL 60056

xl LABORATORIES

LACTULOSE SOLUTION, USP

10 g/15 mL

Indications: For the Treatment of Constipation

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).
USUAL ADULT DOSAGE: 1 to 2 tablespoonfuls (15 to 30 mL) daily. See attached 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 in a tight, light-resistant container with child-resistant closure.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Do not freeze.
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Keep tightly closed.
PHARMACIST: When ordering this product, include the NDC number in the description.
Distributed by:
Xttrium Laboratories, Inc.
1200 E. Business Center Dr.
Mount Prospect, IL 60056

Rx Only

Net Contents: 32 fl oz (946 mL)

N 3 0116-4005-32 1

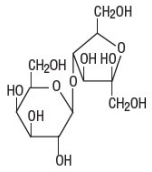
4005LACT32LBLA
Rev. 06/2024

Lift Here

DESCRIPTION

Lactulose solution is a synthetic disaccharide in solution form for oral administration. **Each 15 mL of lactulose 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). The pH range is 2.5 to 6.5.

Lactulose solution 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:



$C_{12}H_{22}O_{11}$

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 the 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

For the treatment of constipation. In patients with a history of chronic constipation, lactulose solution therapy increases the number of bowel movements per day and the number of days on which bowel movements occur.

CONTRAINDICATIONS

Since lactulose solution contains galactose (less than 1.6 g/15 mL), it is contraindicated in patients who require a low galactose diet.

WARNINGS

A theoretical hazard may exist for patients being treated with lactulose solution who may be required to undergo electrocautery procedures during proctoscopy or colonoscopy. Accumulation of H_2 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_2 as an additional safeguard may be pursued but is considered to be a redundant measure.

PRECAUTIONS

General

Since lactulose solution contains galactose (less than 1.6 g/15 mL) and lactose (less than 1.2 g/15 mL), 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 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

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In studies in 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
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.

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Nausea and vomiting have been reported.

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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_{50}
The acute oral LD_{50} 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 tablespoonfuls (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

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15 mL unit dose white cups in trays of 10 cups (NDC 0116-4005-15)

30 mL unit dose white cups in trays of 10 cups (NDC 0116-4005-30)

8 fl. oz. (237 mL) white bottles (NDC 0116-4005-08)

16 fl. oz. (473 mL) white bottles (NDC 0116-4005-16)

32 fl. oz. (946 mL) white bottles (NDC 0116-4005-32)

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

To The Pharmacist: When ordering this product, include the product number (or NDC) in the description.

Rx Only

Revised: June 2024

Distributed by:
Xttrium Laboratories, Inc.
1200 E. Business Center Dr.
Mount Prospect, IL 60056

LACTULOSE 15mL UNIT DOSE CUP

UNIT DOSE

Delivers 15mL

NDC 0116-4005-15

LACTULOSE SOLUTION, USP

10g/15mL

Rx Only

Xttrium Laboratories, Inc.

Mount Prospect, IL 60056

4005LACT15LIDA

LACTULOSE 30 mL UNIT DOSE CUP

UNIT DOSE

Delivers 30mL

NDC 0116-4005-30

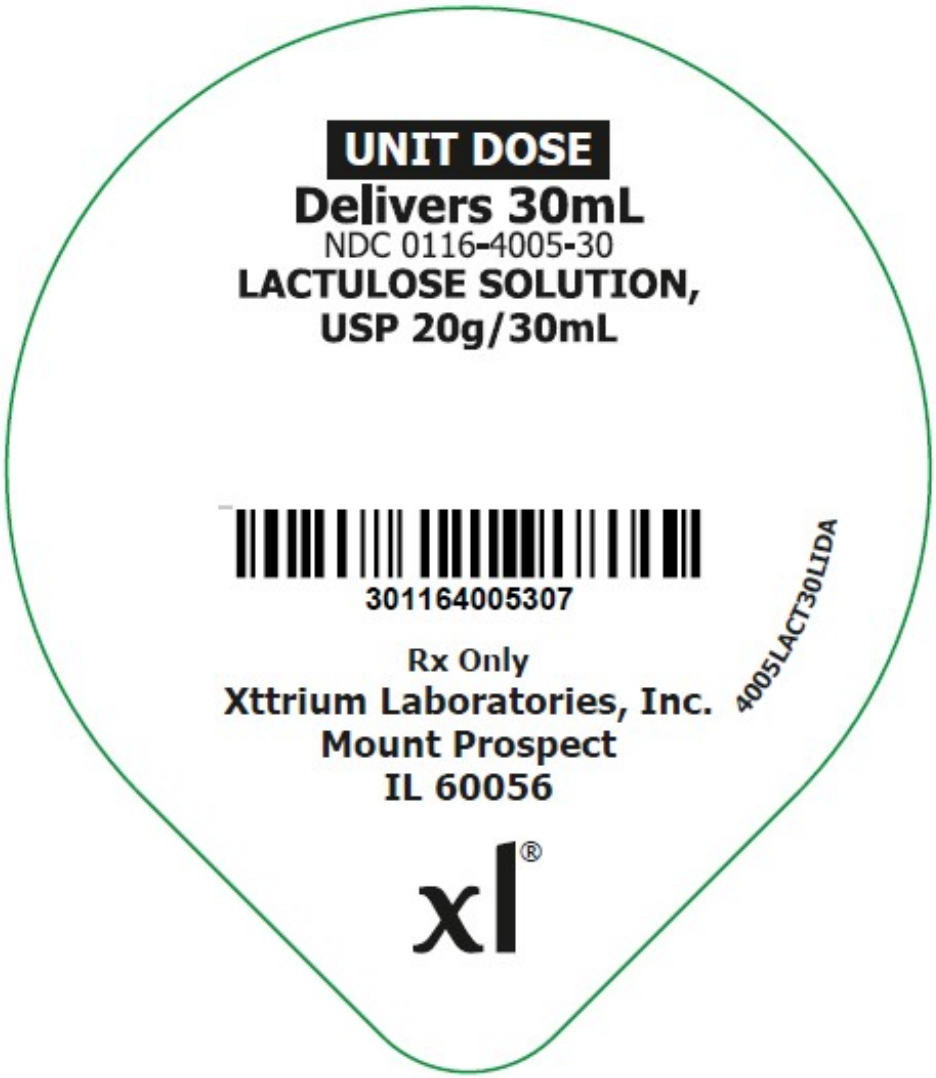
LACTULOSE SOLUTION, USP

20g/30mL

Rx Only

Xttrium Laboratories, Inc.

4005LACT30LIDA



LACTULOSE

lactulose solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0116-4005
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LACTULOSE (UNII: 9U7D5QH5AE) (LACTULOSE - UNII:9U7D5QH5AE)	LACTULOSE	10 g in 15 mL

Inactive Ingredients	
Ingredient Name	**Strength**
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
WATER (UNII: 059QF0KO0R)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Product Characteristics

Color	yellow (Colorless to yellow)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0116-4005-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2022	
2	NDC:0116-4005-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2022	
3	NDC:0116-4005-32	946 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2022	
4	NDC:0116-4005-10	100 in 1 CASE	07/01/2022	
4	NDC:0116-4005-40	40 in 1 CASE		
4		10 in 1 TRAY		
4	NDC:0116-4005-15	15 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
5	NDC:0116-4005-11	100 in 1 CASE	07/01/2022	
5	NDC:0116-4005-41	40 in 1 CASE		
5		10 in 1 TRAY		
5	NDC:0116-4005-30	30 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
6	NDC:0116-4005-15	15 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product	07/01/2022	
7	NDC:0116-4005-30	30 mL in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product	07/01/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075911	07/01/2022	

Labeler - Xttrium Laboratories, Inc. (007470579)

Registrant - Xttrium Laboratories, Inc. (007470579)

Establishment

Name	Address	ID/FEI	Business Operations
Xttrium Laboratories, Inc.		007470579	manufacture(0116-4005)