



Clears constipation *quickly*

ACUTE & CHRONIC CONSTIPATION

Gentle relief in as little as 24 hours, and for as long as needed

- ✱ Works quickly, usually in 24 to 48 hours
- ✱ Gentle, osmotic effect
- ✱ Indicated for acute and chronic constipation and has no restrictions on length of use*
 - *MiraLax™ is indicated for occasional constipation and should be used for 2 weeks or less or as directed by a physician†*
- ✱ Taste-free, grit-free crystal formulation
- ✱ Dissolves quickly in only 4 ounces of water
- ✱ Available in convenient 10 g and 20 g single-dose packets
- ✱ Rx only

Contraindicated in patients who require a low galactose diet. 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. Use with caution in diabetics.

Kristalose®
(lactulose) For Oral Solution
Rapid, gentle relief

For samples call 888-5-BERTEK


Please see brief summary of Prescribing Information.

*Elderly, debilitated patients who receive lactulose for more than 6 months should have serum electrolytes (potassium, chloride, carbon dioxide) measured periodically.

†MiraLax is a trademark of Braintree Laboratories, Inc.

Reference: 1. MiraLax [prescribing information]. Braintree Laboratories, Inc.; 2001.

KRI-LIT-002T



A different kind of lactulose

- ✱ No syrupy-sweet taste or stickiness

Brief Summary: Before prescribing, please see complete prescribing information. **INDICATIONS AND USAGE:** For the treatment of constipation. **CONTRAINDICATIONS:** Since KRISTALOSE® (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 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 CO₂ as an additional safeguard may be pursued but is considered to be a redundant measure. **PRECAUTIONS:** **General:** Since KRISTALOSE® (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/v) 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: 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 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 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. Rx only. **STORAGE:** Store at room temperature, 15°-30°C (59°-86°F). Distributed by Bertek Pharmaceuticals Inc. Sugar Land, TX 77478

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Lesions Often Regress in Young Women

BY CHRISTINE KILGORE
Contributing Writer

Most low-grade abnormalities on Pap smears spontaneously regressed within 36 months in a cohort study of adolescents and young women, and investigators say the finding lends support to the practice of monitoring these lesions with regular cytology.

Colposcopy is “unwarranted and leads to unnecessary intervention, morbidity, and cost,” said Anna-Barbara Moscicki, M.D., and her associates at the University of California, San Francisco.

Of 187 patients aged 13-22 years who developed low-grade squamous intraepithelial lesions (LSIL), 61% were free of LSIL after 1 year, and 91% were free of LSIL at 3 years’ follow-up. Progression to high-grade disease occurred in 3% of the patients (Lancet 2004;364:1678-83).

The patients were part of a larger 10-year longitudinal study of human papilloma virus (HPV) infection. They were examined every 4 months by cytology, colposcopy, and HPV DNA status. Both prevalent and incident LSIL cases were included in the study, and regression was defined as at least three consecutive normal smears.

The investigators found no associations between LSIL regression and HPV status at baseline (time of the first LSIL), age, sexual behavior, contraceptive use, substance or cigarette use, or incident sexually transmitted infection.

Nor did they find any significant differences in rates or timing of regression between patients who underwent biopsy and those who didn’t, nor between patients whose LSIL status was confirmed by histology and those with LSIL confirmed by a normal biopsy.

The investigators did find that patients’ current HPV status—rather than their baseline status—was important. A negative HPV test at a subsequent visit “shows a good likelihood that LSIL has regressed,” which suggests that HPV testing “could be helpful in monitoring LSIL,” they said.

In addition, the findings suggest that the persistence of multiple HPV types slows rates of regression, but this needs to be examined more closely. More study is also needed to better define appropriate screening strategies, they said.

The findings are similar to those of a smaller study from Brazil, published in 2003 in the Journal of the National Cancer Institute, in which an estimated 92-95% of cases regressed within 24 months, and 5-6 % progressed, according to Anne Szarewski and Peter Sasieni of Cancer Research UK.

“It is becoming increasingly clear that LSIL is a transient manifestation of HPV infection that will only rarely progress to HSIL,” they wrote in an accompanying editorial (Lancet [in press]). “Since there is no point in treating LSIL in young women ... we see absolutely no role for colposcopy in adolescents as part of routine management.”