



**KRISTALOSE<sup>®</sup> OFFERS PRESCRIPTION ALTERNATIVE TO  
MIRALAX<sup>®</sup> AND OTHER PEG 3350 PRODUCTS**

*Unique, crystalline laxative designed to enhance patient acceptance and compliance*

**NASHVILLE, Tenn. (February 26, 2008)** – **Kristalose<sup>®</sup>**, a prescription laxative product that treats acute and chronic constipation, may be an effective option for physicians and pharmacists looking for a prescription alternative to MiraLAX<sup>®</sup> and generic PEG 3350 products. Marketed in the U.S. by Cumberland Pharmaceuticals, Kristalose<sup>®</sup> is now the only prescription-strength laxative available in a convenient powder packet.

Previously available by prescription, MiraLAX<sup>®</sup> (*polyethylene glycol 3350 or PEG 3350*) became an over-the-counter (OTC) treatment for occasional constipation in early 2007. Due to U.S. Food and Drug Administration policy which does not allow the same formulation of a product to be marketed simultaneously as both a prescription and OTC drug, **generic PEG 3350 products are now also becoming unavailable by prescription.**<sup>1</sup> These generic products will not be available on the OTC market for at least three years following the MiraLAX<sup>®</sup> introduction due to marketing exclusivity granted by the FDA.



Physicians wrote more than 9 million prescriptions for MiraLAX<sup>®</sup> and generic PEG 3350 products in 2006 for treatment of constipation. As the PEG 3350 products are becoming unavailable by prescription, Cumberland believes Kristalose<sup>®</sup> offers a safe, effective alternative for physicians looking to retain prescriptive control for their patients.

Kristalose<sup>®</sup> (lactulose) for Oral Solution is a proprietary prescription laxative and the brand name for a unique crystalline form of lactulose that treats acute and chronic constipation. Available in pre-dosed packets, the drug dissolves quickly in four ounces of water, offering patients a virtually tasteless and grit-free alternative to other liquid lactulose treatments. There are no age limitations or length of use restrictions for Kristalose<sup>®</sup>, and it is the only osmotic prescription laxative still sampled to physicians.

"Kristalose<sup>®</sup> has a long history of providing safe and effective relief to sufferers of acute and chronic constipation with few side effects," said A.J. Kazimi, CEO of Cumberland Pharmaceuticals. "We look forward to communicating the unique features of this drug to the medical community and ultimately to patients who may benefit from it."

**Cumberland Pharmaceuticals Inc.** is a Tennessee-based specialty pharmaceutical company that develops and markets niche pharmaceutical products for specific physician segments including critical care, emergency medicine and gastroenterology. Cumberland is dedicated to providing high-quality products which fill unmet medical needs. For more information, please visit the Cumberland Pharmaceuticals website at [www.cumberlandpharma.com](http://www.cumberlandpharma.com) or [www.kristalose.com](http://www.kristalose.com).

To the extent any statements made in this release contain information that is not historical, these statements are essentially forward-looking and actual results or events may differ from Cumberland's expectations. Results may differ depending upon, among other things, the impact of actions by regulatory authorities on the marketing and distribution of products that compete with Kristalose<sup>®</sup>. These statements speak only as of the date of this press release, and Cumberland undertakes no obligation to update or revise the statements.

Kristalose<sup>®</sup> is indicated for the treatment of acute and chronic constipation. It is a unique, proprietary, crystalline form of lactulose, with no restrictions on length of therapy or patient age. 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<sup>®</sup> is contraindicated in patients who require a low-galactose diet. Elderly, debilitated patients who receive lactulose for more than six months should have serum electrolytes (potassium, chloride, carbon dioxide) measured periodically.

#### References

- <sup>1</sup> Food and Drug Administration 21 CFR Part 310. Drug Approvals: circumstances under which an active ingredient may be simultaneously marketed in both a prescription product and an over-the-counter drug product. *Federal Register*. Sept. 2005; 70(169) 52050-51. While the FDA's interpretation does not have the force of law and is subject to change at any time, it is the current interpretation of the FDA upon which Cumberland believes it can rely.

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