



## Immediate Action Required!

### Zelnorm® and Pergolide Removed from CCRx Formulary

April 10, 2007

### Zelnorm® and Pergolide Withdrawn from the Market and Removed from CCRx Formulary

#### **Zelnorm®**

The FDA's action to remove Zelnorm® from the market was based on newly available information of an increased risk of serious cardiovascular adverse events, including myocardial infarction, unstable angina, and stroke. They occurred primarily in patients who had pre-existing cardiovascular disease and/or cardiovascular risk factors.

#### **Pergolide (Permax®)**

The FDA's action to remove pergolide from the market was based on two new studies that showed patients with Parkinson's disease had an increased risk of serious heart valve damage.

*Advise your patients to contact their health care professional for alternative treatment options.*

- **Effective immediately, all new claims for Zelnorm® will be rejected.** CCRx formulary alternatives are listed below for constipation-predominant irritable bowel syndrome. Episodic use of antispasmodics (e.g., dicyclomine, hyoscyamine) may be helpful for symptomatic treatment of cramping and pain but should be avoided in elderly patients.
- **CCRx has removed pergolide from the formulary for new starts, effective immediately.** Patients should **NOT abruptly discontinue use** because rapid discontinuation can be dangerous. The dopamine agonists Requip® and Mirapex® represent CCRx formulary alternatives to pergolide.

*Please use the suggested formulary alternatives listed below*

Not Covered Drug	Suggested Formulary Alternatives
Pergolide	Requip® Mirapex®
Zelnorm	Lactulose Polyethylene Glycol Dicyclomine Hyoscyamine

Further information regarding these drugs can be found at the following websites:  
[www.fda.gov/cder/drug/infopage/zelnorm/default.htm](http://www.fda.gov/cder/drug/infopage/zelnorm/default.htm), [www.zelnorm.com](http://www.zelnorm.com)  
[www.fda.gov/cder/drug/infopage/ pergolide/default.htm](http://www.fda.gov/cder/drug/infopage/ pergolide/default.htm)

**Please contact the Pharmacy Tech Center (PTC) at 866-684-5395 with any further questions.**