

# CAREMARK TrendsRx<sup>®</sup> Alert

What's new...What's next...What to do now

August 2003

**PRE-  
DRUG  
APPROVAL**

## Cymbalta<sup>™</sup> (duloxetine)

Cymbalta<sup>™</sup> (duloxetine, Eli Lilly) is expected to be approved in late 2003 by the United States (US) Food and Drug Administration (FDA) for the treatment of depression. Cymbalta belongs to a class of drugs called serotonin and norepinephrine reuptake inhibitors (SNRIs) that includes Effexor XR<sup>®</sup> (venlafaxine, Wyeth). In clinical trials, Cymbalta was given by mouth either once or twice daily. Optimal dosing has not yet been established. The most common side effects with Cymbalta are similar to other newer antidepressants and include nausea, dry mouth, fatigue, dizziness, and constipation. Also similar to other newer antidepressants, Cymbalta is expected to be contraindicated in people that are on a type of antidepressant called monoamine oxidase inhibitors (MAOIs). The average wholesale price (AWP) for Cymbalta will not be available until launch.

## BACKGROUND

Depression affects over 18 million Americans each year. Nearly 35-40 million Americans will suffer major depression at some point in their lives. Almost two-thirds of those treated do not have complete resolution of their symptoms. The imbalance of serotonin and norepinephrine in the brain is thought to play a key role in depression. Most commonly used medications to treat depression, such as Zoloft<sup>®</sup> (sertraline, Pfizer), Lexapro<sup>®</sup> (escitalopram, Forest), Celexa<sup>®</sup> (citalopram, Forest), Prozac<sup>®</sup> (fluoxetine, Eli Lilly) and Paxil<sup>®</sup> (paroxetine, Glaxo Smith Kline), only affect the serotonin imbalance. Since Cymbalta works on serotonin and norepinephrine, it is thought to treat both the emotional and physical symptoms of depression. Cymbalta appears to offer an effective and safe new treatment option for people suffering from depression. There may be other potential uses for Cymbalta. The manufacturer has already filed a request with the FDA to approve Cymbalta for treating stress urinary incontinence and is currently studying Cymbalta for treatment of neuropathic (nerve) pain.

## CAREMARK RESPONSE

For clients with CustomCare Retail, Caremark anticipates including Cymbalta in the current antidepressant interventions focusing on:

- Duration or length of therapy
- Monoamine Oxidase Inhibitor interactions
- Appropriate maintenance dosing

For clients with UR Pharmacy, Cymbalta will be included in the Behavioral Health interventions as appropriate.

## CONTACT

For more information call your Caremark account representative.

*Please Note: This document provides a brief overview of the subject. Please refer to the manufacturer's full prescribing information for a complete discussion of the product. This review is provided as a reference only, and is based in part on information derived from third parties.*