



August 24, 2004

## Lilly Launches New Antidepressant Cymbalta

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*Long-awaited dual-reuptake inhibitor, now available in pharmacies, helps treat a broad range of emotional and painful physical symptoms of Major Depressive Disorder*

Cymbalta<sup>®</sup> (duloxetine HCl; pronounced SIM-BALL-TA), a new treatment for major depression, is now available by prescription in pharmacies across the United States, Eli Lilly and Company announced today.

More than half of the nation's pharmacies, including drug store chains and independents, have stocked Cymbalta and can begin filling prescriptions immediately. Lilly expects more than 80 percent of pharmacies - more than 44,000 stores - to have Cymbalta on their shelves by Aug. 30. The U.S. Food and Drug Administration approved Cymbalta, a balanced and potent selective serotonin and norepinephrine reuptake inhibitor (SSNRI), on Aug. 3 for the treatment of major depression.

"The availability of Cymbalta is a long-awaited milestone for patients and physicians - it's an effective antidepressant that helps treat both the emotional and physical symptoms of depression," said John Lechleiter, executive vice president of pharmaceutical products and corporate development at Lilly. "It's the sort of breakthrough, born out of decades of investment and experience in neuroscience, that is Lilly's hallmark."

Today, only 25-35 percent of patients treated for depression in clinical studies experience relief from all of their disease symptoms.<sup>1</sup> Patients who don't become virtually symptom free are likely to suffer from depression again.

Neurotransmitters, chemicals that help nerve cells exchange messages, are believed to help regulate a person's emotions and sensitivity to pain. Scientists believe that if these neurotransmitters are out of balance, a person may become depressed and be more likely to feel painful physical symptoms. The combination of emotional and painful physical effects of depression can have a tremendous negative impact on a person's quality of life.<sup>2</sup>

Randi Bradstreet, a participant in a Cymbalta clinical trial, had suffered for years from the emotional and painful physical symptoms of depression.

"I started taking time off work a few years back because I was so depressed that I couldn't function on my job. I had a lot of pain along with the depression and it made it hard to do any physical activities that I needed to do with my job," Bradstreet said. "After I started taking Cymbalta, I began to feel like myself again. That means that I'm happy. That I'm able to have fun with my friends and family and that I can live a productive life."

Duloxetine hydrochloride also is being studied for the treatment of stress urinary incontinence and diabetic neuropathic pain, conditions believed to respond to treatment with both serotonin and norepinephrine.

### **About Depression**

Nearly 19 million Americans suffer from depression each year, making it one of the leading causes of disability according to the World Health Organization. Current medical literature suggests that patients who are successfully treated for all their depressive symptoms, including both the emotional and painful physical ones, may be more likely to achieve remission than those whose physical symptoms are not alleviated.<sup>1,3,4,5</sup>

### **Important Safety Information**

Depression, as a disease, can be associated with periods when the symptoms can worsen or thoughts of suicide can emerge. Patients and their families should watch for these as well as for anxiety, agitation, panic, difficulty sleeping, irritability, hostility, aggressiveness, impulsivity, restlessness, or overexcitement and hyperactivity. Call the doctor if any of these are severe or occur suddenly. Be especially observant at the initiation of antidepressant drug therapy and whenever there is a change in dose.

Prescription Cymbalta is not for everyone. People who are allergic to duloxetine hydrochloride or the other ingredients in Cymbalta should not take it. If you are taking thioridazine or if you are taking or have recently taken a type of antidepressant called a monoamine oxidase inhibitor (MAOI), you should not take Cymbalta. It also should not be administered to patients with

any hepatic insufficiency, end-stage renal disease or uncontrolled, narrow-angle glaucoma. Cymbalta ordinarily should not be prescribed to patients with substantial alcohol use. Women who are pregnant should talk with their doctor before taking Cymbalta. Nursing while taking Cymbalta is not recommended.

In clinical studies, the most common side effects were nausea, dry mouth, constipation, decreased appetite, fatigue, sleepiness and increased sweating. Most people were not bothered enough by side effects to stop taking Cymbalta. Your doctor may periodically check your blood pressure. Don't stop taking Cymbalta without talking to your doctor.

For full patient information, visit [www.Cymbalta.com](http://www.Cymbalta.com).

### About Lilly

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of first-in-class and best-in-class pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers - through medicines and information - for some of the world's most urgent medical needs. Additional information about Lilly is available at [www.lilly.com](http://www.lilly.com).

*This press release contains forward-looking statements about the potential of Cymbalta for the treatment of major depressive disorder and reflects Lilly's current beliefs. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. There is no guarantee that the product will prove to be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's filings with the United States Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.*

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1. Tran PV, Bymaster FP, McNamara RK, et al. Dual Monoamine Modulation for Improved Treatment of Major Depressive Disorder, *J Clin Psychopharmacology*, 2003; 23: 78-86
  2. The Regents of the University of Michigan. *Beyond Sadness. Bridging the gap between emotional and physical symptoms of depression*. Ann Arbor, MI, 2002
  3. Nemeroff CB et al. Duloxetine for the Treatment of Major Depressive Disorder. *Psychopharmacol Bul.* 2002; 36 (4):106-132.
  4. Ohayon, M., et al. Using Chronic Pain to Predict Depressive Morbidity in the General Population. *Arch Gen Psychiatry* 2003; 60: 39-47.
  5. Poster presented at *American Psychiatric Association* annual meeting. May 19, 2003. San Francisco, CA.



Cymbalta (duloxetine HCl) 60 mg capsules



Cymbalta (duloxetine HCl) cartons