ABBOTT

Pharmaceutical Products Division

Abbott Laboratories
200 Abbott Park Road
Abbott Park, IL 60064-6182

May 2005

Dear Prescriber:

After careful consideration, Abbott has made the decision to discontinue Cylert® (pemoline, Abbott). Abbott took this action based on declining sales due to availability of generic alternatives.

If you are aware of a patient receiving Cylert, please notify the prescribing health care provider (if someone other than yourself) and the patient regarding this information. The prescribing health care provider should initiate steps to convert Cylert-treated patients to a generic pemoline product or an alternate therapy.

Cylert will remain available through pharmacies and wholesalers until supplies are exhausted. Health care providers should consider transitioning patients to alternative therapies, as soon as practical. After Abbott, pharmacy, and wholesaler supplies of Cylert are exhausted, no additional product will be available.

Should you or your colleagues have any questions or concerns, our Medical Information department may be contacted at 1-800-633-9110.

Important Prescribing and Safety Information

Cylert is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). Because of its association with life threatening hepatic failure, Cylert should not ordinarily be considered as first line drug therapy for ADHD.[1] Patients taking Cylert, who fail to show substantial clinical benefit within 3 weeks of completing dose titration, should be withdrawn from Cylert therapy.

As of December 1998, 15 cases of acute hepatic failure have been reported to the FDA. While the absolute number of reported cases is not large, the rate of reporting ranges from 4 to 17 times the rate expected in the general population. This estimate may be conservative because of under reporting and because the long latency between initiation of Cylert treatment and the occurrence of hepatic failure may limit recognition of the association. If only a portion of actual cases were recognized and reported, the risk could be substantially higher. Twelve cases resulted in liver transplantation or death, usually within four weeks of onset of signs and symptoms of liver

failure; however, these cases may or may not have been preceded by prodromal symptoms. The earliest onset of hepatic abnormalities occurred six months after initiation of Cylert (pemoline).

Serum ALT (SGPT) levels should be determined at baseline, and every two weeks thereafter. It is not clear if the recommended baseline and periodic liver function testing are predictive of these instances of acute liver failure. Cylert should be discontinued if serum ALT (SGPT) is increased to a clinically significant level, or any increase $\geq$2 times the upper limit of normal, or if clinical signs and symptoms suggest liver failure.

A physician who elects to use Cylert should obtain written informed consent from the patient prior to Cylert therapy initiation.

Cylert is contraindicated in patients with impaired hepatic function or with known hypersensitivity or idiosyncrasy to the drug.

Cylert should be administered with caution to patients with significantly impaired renal function. Cylert has been associated with insomnia, weight loss, growth suppression, dyskinesia, and exacerbation of behavior disorder, especially in psychotic children. In addition, Cylert has been associated with hallucinations, convulsive seizures, and hepatic dysfunction ranging from asymptomatic reversible increases in liver enzymes to fatal hepatic failure.

Sincerely,

Robert Hoff M.D.

Robert Hoff, MD
Senior Medical Director
Medical Communications

Reference:

1. Cylert® [package insert]. Abbott Park, IL: Abbott.

Enclosure:

Cylert® [package insert]. Abbott Park, IL: Abbott.