Tourette's syndrome in children and their families should precede use of stimulant medications.

Drug treatment is not indicated in all cases of ADHD and should be considered only in light of complete history and evaluation of the child. The decision to prescribe CYLERT (pemoline) should depend on the physician's assessment of the chronicity and severity of the child's symptoms and their appropriateness for his/her age. Prescription should not depend solely on the presence of one or more of the behavioral characteristics.

Geriatric Use:
Clinical studies of CYLERT did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

ADVERSE REACTIONS

The following are adverse reactions in decreasing order of severity within each category associated with CYLERT:

Hepatic: There have been reports of hepatic dysfunction, ranging from asymptomatic reversible increases in liver enzymes to hepatitis, jaundice and fatal hepatic failure, in patients taking CYLERT (see **BOXED WARNING** and **PRECAUTIONS**).

Hematopoietic: There have been isolated reports of aplastic anemia.

Central Nervous System: The following CNS effects have been reported with the use of CYLERT: convulsive seizures; literature reports indicate that CYLERT may precipitate attacks of Gilles de la Tourette syndrome; hallucinations; dyskinetic movements of the tongue, lips, face and extremities; abnormal oculomotor function including nystagmus and oculogyric crisis; mild depression; dizziness; increased irritability; headache; and drowsiness.

Insomnia is the most frequently reported side effect of CYLERT; it usually occurs early in therapy prior to an optimum therapeutic response. In the majority of cases it is transient in nature or responds to a reduction in dosage.

Gastrointestinal: Anorexia and weight loss may occur during the first weeks of therapy. In the majority of cases it is transient in nature; weight gain usually resumes within three to six months.

Nausea and stomach ache have also been reported.

Genitourinary: A case of elevated acid phosphatase in association with prostatic enlargement has been reported in a 63 year old male who was treated with CYLERT for sleepiness. The acid phosphatase normalized with discontinuation of CYLERT and was again elevated with rechallenge.

Miscellaneous: Suppression of growth has been reported with the long-term use of stimulants in children. (See **WARNINGS**.) Skin rash has been reported with CYLERT.

If adverse reactions are of a significant or protracted nature, dosage should be reduced or the drug discontinued.

DRUG ABUSE AND DEPENDENCE

Controlled Substance: CYLERT is subject to control under DEA schedule IV.

Abuse: CYLERT failed to demonstrate a potential for self-administration in primates. However, the pharmacologic similarity of pemoline to other psychostimulants with known dependence liability suggests that psychological and/or physical dependence might also occur with CYLERT. There have been isolated reports of transient psychotic symptoms occurring in adults following the long-term misuse of excessive oral doses of pemoline. CYLERT should be given with caution to emotionally unstable patients who may increase the dosage on their own initiative.

OVERDOSAGE

Signs and symptoms of acute overdosage, resulting principally from overstimulation of the central nervous system and from excessive sympathomimetic effects, may include the following: vomiting, agitation, tremors, hyperreflexia, muscle twitching, convulsions (may be followed by coma), euphoria, confusion, hallucinations, delirium, sweating, flushing, headache, hyperpyrexia, tachycardia, hypertension and mydriasis. Consult with a Certified Poison Control Center regarding treatment for up to date guidance and advice. Treatment consists of appropriate supportive measures. The patient must be protected against self-injury and against external stimuli that would aggravate overstimulation already present. Gastric contents may be evacuated by gastric lavage. Other measures to detoxify the gut include administration of activated charcoal and a cathartic. Chlorpromazine has been reported in the literature to be useful in decreasing CNS stimulation and sympathomimetic effects.

Efficacy of peritoneal dialysis or extracorporeal hemodialysis for CYLERT overdosage has not been established.

DOSAGE AND ADMINISTRATION

CYLERT (pemoline) is administered as a single oral dose each morning. The recommended starting dose is 37.5 mg/day. This daily dose should be gradually increased by 18.75 mg at one week intervals until the desired clinical response is obtained. The effective daily dose for most patients will range from 56.25 to 75 mg. The maximum recommended daily dose of pemoline is 112.5 mg.

Clinical improvement with CYLERT is gradual. Using the recommended schedule of dosage titration, significant benefit may not be evident until the third or fourth week of drug administration. Because CYLERT provides an observable symptomatic benefit, patients who fail to show substantial clinical benefit within 3 weeks of completing dose titration, should be withdrawn from CYLERT therapy.

Where possible, drug administration should be interrupted occasionally to determine if there is a recurrence of behavioral symptoms sufficient to require continued therapy.

HOW SUPPLIED

CYLERT (pemoline) is supplied as monogrammed, grooved tablets in three dosage strengths:
18.75 mg white tablets (imprinted with ◘ and the Abbo-Code TH),
Bottles of 100.....(**NDC** 0074-6025-13).
37.5 mg orange-colored tablets (imprinted with ◘ and the Abbo-Code TI),
Bottles of 100.....(**NDC** 0074-6057-13).
75 mg tan-colored tablets (imprinted with ◘ and the Abbo-Code TJ),
Bottles of 100.....(**NDC** 0074-6073-13).

CYLERT (pemoline) Chewable is supplied as 37.5 mg monogrammed, grooved orange-colored tablets (imprinted with ◘ and the Abbo-Code TK),
Bottles of 100.....(**NDC** 0074-6088-13).

Recommended Storage: Store below 86°F (30°C).

PATIENT INFORMATION/CONSENT FORM
Cylert® (pemoline) should not be used by patients until there has been a complete discussion of the risks and benefits of Cylert therapy and written informed consent has been obtained.

IMPORTANT INFORMATION:
Cylert therapy has been associated with liver abnormalities ranging from reversible liver function test increases that do not cause any symptoms to liver failure, which may result in death. Therefore, you should have a full discussion of the risks and benefits of Cylert before beginning therapy.

PATIENT CONSENT:
My (son, daughter, ward)_____'s treatment with Cylert has been explained to me by Dr._____.

The following points of information, among others, have been specifically discussed and explained and I have had the opportunity to ask any questions concerning this information.

1. I, _____(Patient/Parent/Guardian's name), understand that Cylert is used to treat certain types of patients with the behavioral syndrome called attention deficit hyperactivity disorder (ADHD) and that I (my son/daughter/ward) am that type of patient.
   Initials:_____

2. I understand that there is a risk that I (my son/daughter/ward) might develop liver failure, which may result in death, while taking Cylert. I understand that this could occur even after long-term therapy.
   Initials:_____

3. I understand that I (my son/daughter/ward) should have blood taken to test liver function before Cylert is begun, and every two weeks from then on while taking Cylert. I understand that although the liver function tests may help detect if I (my son/daughter/ward) develop liver damage, it may do so only after significant, irreversible and potentially fatal damage has already occurred.
   Initials:_____

4. I understand that if I (my son/daughter/ward) stop taking Cylert and then restart it at a later time (e.g., after summer vacation), I (my son/daughter/ward) should again have blood taken to test liver function before Cylert is restarted, and every two weeks from then on while taking Cylert.
   Initials:_____

5. I understand that I should immediately report any unusual symptoms to the doctor and should be especially aware of persistent nausea, vomiting, fatigue, lethargy, loss of appetite, abdominal pain, dark urine, or yellowing of the skin or eyes.
Initials:_____

I now authorize Dr._____ to begin my (son/daughter/ward's) treatment with Cylert, or if treatment with Cylert has already begun, to continue this treatment.

_____
Signature Date

_____
Address

_____
Telephone

PHYSICIAN STATEMENT:
I have fully explained to the patient (parent/guardian), _____ the nature and purpose of treatment with Cylert and the potential risks associated with that treatment. I have asked if he/she has any questions regarding this treatment or the associated risks and have answered these questions to the best of my ability.

_____
Physician Signature

_____
Date

NOTE TO PHYSICIAN: It is strongly recommended that you retain a completed copy of this informed consent form in your patient's records.

SUPPLY OF PATIENT INFORMATION/CONSENT FORMS: A supply of Patient Information/Consent Forms as printed above is available, free of charge, by calling (847) 937-7302. Permission to use the above Patient Information/Consent Form by photocopy reproduction is hereby granted by Abbott Laboratories.

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