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Cylert

Cylert (Oral)

Generic name: pemoline [PEM-oh-leen]

Drug class: CNS stimulants

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Oral route(Tablet; Tablet, Chewable)

Pemoline has been associated with life-threatening hepatic failure and should not ordinarily be considered as first line drug therapy for Attention Deficit Hyperactivity Disorder (ADHD). Treatment should be initiated only in individuals without liver disease and with normal baseline liver function tests. Monitor serum ALT (SGPT) levels at baseline, and every 2 weeks thereafter. Discontinue if serum ALT (SGPT) is increased to a clinically significant level, or any increase greater than or equal to 2 times the upper limit of normal, or if clinical signs and symptoms suggest liver failure. Obtain written informed consent from the patient prior to initiation of therapy.

Uses for Cylert

Pemoline belongs to the group of medicines called central nervous system (CNS) stimulants. It is used to treat children with attention-deficit hyperactivity disorder (ADHD).

Pemoline increases attention and decreases restlessness in children who are overactive, cannot concentrate for very long or are easily distracted, and are emotionally unstable. This medicine is used as part of a total treatment program that also includes social, educational, and psychological treatment.

Rarely, pemoline has caused serious liver problems. You and your doctor should talk about the good this medicine will do as well as the risks of using it. In addition, you will be asked to sign an informed consent form stating that you understand and agree to accept the risk of liver problems.

This medicine is available only with your doctor's prescription.

Before using Cylert

In deciding to use a medicine, the risks of taking the medicine must be weighed against the good it will do. This is a decision you and your doctor will make. For this medicine, the following should be considered:

Allergies

Tell your doctor if you have ever had any unusual or allergic reaction to this medicine or any other medicines. Also tell your health care professional if you have any other types of allergies, such as to foods, dyes, preservatives, or animals.

For non-prescription products, read the label or package ingredients carefully.

Pediatric

Slowed growth rate in children who received medicines like pemoline for a long period of time has been reported. Some doctors recommend medicine-free periods during treatment with pemoline to help prevent slowed growth.

Pemoline may make behavior worse in children with serious mental illness.

Breast Feeding

There are no adequate studies in women for determining infant risk when using this medication during breastfeeding. Weigh the potential benefits against the potential risks before taking this medication while breastfeeding.

Interactions with Medicines

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. When you are taking this medicine, it is especially important that your healthcare professional know if you are taking any of the medicines listed below. The following interactions have been selected on the basis of their potential significance and are not necessarily all-inclusive.

Using this medicine with any of the following medicines is usually not recommended, but may be required in some cases. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.

• Iobenguane I 131

Interactions with Food/Tobacco/Alcohol

Certain medicines should not be used at or around the time of eating food or eating certain types of food since interactions may occur. Using alcohol or tobacco with certain medicines may also cause interactions to occur. Discuss with your healthcare professional the use of your medicine with food, alcohol, or tobacco.

Other Medical Problems

The presence of other medical problems may affect the use of this medicine. Make sure you tell your doctor if you have any other medical problems, especially:

- Drug abuse or dependence (or history of)—Dependence on pemoline may develop.
- Gilles de la Tourette's syndrome or other tics or
- · Liver disease or
- Mental illness (severe)—Pemoline may make the condition worse.
- Kidney disease—Higher blood levels of pemoline may occur, increasing the chance of side effects.

Proper use of Cylert

For patients taking the chewable tablet form of this medicine:

• These tablets must be chewed before swallowing. Do not swallow whole.

Sometimes this medicine must be taken for 3 to 4 weeks before improvement is noticed.

Take pemoline only as directed by your doctor. Do not take more of it, do not take it more often, and do not take it for a longer time than your doctor ordered. If too much is taken, it may become habit-forming.

Dosing

The dose of this medicine will be different for different patients. Follow your doctor's orders or the directions on the label. The following information includes only the average doses of this medicine. If your dose is different, do not change it unless your doctor tells you to do so.

The amount of medicine that you take depends on the strength of the medicine. Also, the number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are using the medicine.

- For oral or chewable dosage forms (tablets):
 - Children 6 years of age and over—To start, 37.5 milligrams (mg) every morning. Your doctor may increase your dose if needed. However, the dose is usually not more than 112.5 mg a day.
 - Children up to 6 years of age—Use and dose must be determined by the doctor.

Missed Dose

If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

Storage

Store the medicine in a closed container at room temperature, away from heat, moisture, and direct light. Keep from freezing.

Keep out of the reach of children.

Do not keep outdated medicine or medicine no longer needed.

Detailed Cylert dosage information

Precautions while using Cylert

Your doctor should check your progress at regular visits to make sure that this medicine does not cause unwanted effects. In addition, you must have your blood tested every other week to see if this medicine is affecting your liver.

Dark urine or yellow eyes or skin may be a sign of a serious unwanted effect on your liver. Check with your doctor immediately if you develop dark urine or yellow eyes or skin.

This medicine may cause some people to become dizzy or less alert than they are normally. Make sure you know how you react to this medicine before you ride a bicycle or do anything else that could be dangerous if you are dizzy or are not alert.

If you have been using this medicine for a long time and you think you may have become mentally or physically

dependent on it, check with your doctor. Some signs of dependence on pemoline are:

- a strong desire or need to continue taking the medicine.
- a need to increase the dose to receive the effects of the medicine.
- withdrawal side effects (for example, mental depression, unusual behavior, or unusual tiredness or weakness)
 occurring after the medicine is stopped.

If you take this medicine in large doses for a long time, do not stop taking it without first checking with your doctor. Your doctor may want you to reduce gradually the amount you are taking before stopping completely.

Side Effects of Cylert

Along with its needed effects, a medicine may cause some unwanted effects. Some side effects will have signs or symptoms that you can see or feel. Your doctor may watch for others by doing certain tests.

Pemoline may cause some serious side effects, including liver problems. Also, medicines like pemoline, when used for a long time, have been reported to slow the growth rate of children. Some doctors recommend medicine-free periods during treatment with pemoline. Pemoline may also cause unwanted effects on behavior in children with severe mental illness.

Although not all of these side effects may occur, if they do occur they may need medical attention.

Check with your doctor immediately if any of the following side effects occur:

Rare

- Dark urine
- · yellow eyes or skin

Check with your doctor as soon as possible if any of the following side effects occur:

Rare

- Convulsions (seizures)
- hallucinations (seeing, hearing, or feeling things that are not there)
- nausea and vomiting
- shortness of breath, troubled breathing, wheezing, or tightness in chest
- skin rash
- sores, ulcers, or white spots on lips or in mouth
- swollen or painful glands
- · uncontrolled movements of eyes, tongue, lips, face, arms, or legs
- · unusual bleeding or bruising
- · unusual tiredness
- · vocal sounds you cannot control

Symptoms of overdose

- Agitation
- confusion
- · convulsions (seizures)—may be followed by coma
- false sense of well-being
- fast heartbeat
- hallucinations (seeing, hearing, or feeling things that are not there)
- headache (severe)
- · high blood pressure
- · high fever
- · large pupils
- · muscle trembling or twitching
- restlessness
- sweating
- vomiting

This medicine may also cause the following side effects that your doctor will watch for:

Rare

- Liver problems
- slow growth in children

Some side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects. Check with your health care professional if any of the following side effects continue or are bothersome or if you have any questions about them:

More common

- · Loss of appetite
- · trouble in sleeping
- · weight loss

Less common

- Dizziness
- drowsiness
- headache
- · increased irritability
- mental depression

stomachache

After you stop using this medicine, it may still produce some side effects that need attention. During this period of time, check with your doctor immediately if you notice the following side effects:

- Abdominal pain
- convulsions (seizures)
- headache
- · mental depression
- nausea
- · unusual behavior
- · unusual tiredness or weakness
- vomiting

Other side effects not listed may also occur in some patients. If you notice any other effects, check with your healthcare professional.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

① Cylert side effects (more detail)

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In the U.S.

Cylert

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