5.1 Serotonin Syndrome

Concomitant use of monoamine oxidase (MAO) inhibitors or within 14 days after their discontinuation may increase the risk of serotonin syndrome. Life-threatening cases have been reported with a combination of a tricyclic antidepressant and an MAO inhibitor. Serotonin syndrome may present with gastrointestinal symptoms (nausea, vomiting, diarrhea), neuromuscular symptoms (hyper-reflexia, myoclonus), and cardiovascular symptoms (tachycardia, hypertension).

5.2 Tricyclic Antidepressant-like Effects

Cyclobenzaprine hydrochloride extended-release capsules, for oral use

Instruct patients to swallow cyclobenzaprine hydrochloride extended-release capsules intact.

Cyclobenzaprine hydrochloride extended-release capsules have not been found effective in treating depression. Patients with depression should only be treated with cyclobenzaprine when other treatments have failed. Some patients may experience worsening of depression with cyclobenzaprine therapy.

8 USE IN SPECIFIC POPULATIONS

4 CONTRAINDICATIONS

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Cyclobenzaprine hydrochloride extended-release capsules have not been found effective in treating depression. Patients with depression should only be treated with cyclobenzaprine when other treatments have failed. Some patients may experience worsening of depression with cyclobenzaprine therapy.
What should I avoid while taking cyclobenzaprine hydrochloride extended-release capsules?
You should not drive or operate machinery, or do other activities that require mental alertness or physical coordination until you know how the cyclobenzaprine hydrochloride extended-release capsules affect you. Using cyclobenzaprine hydrochloride extended-release capsules can cause dizziness, somnolence, confusion, or other mental or physical problems. The risk of these problems may be greater in people who are elderly or have liver or kidney problems. Use cyclobenzaprine hydrochloride extended-release capsules with caution. Use a folded blanket or pillow under your head for the first few days while you are taking cyclobenzaprine hydrochloride extended-release capsules.

Cyclobenzaprine hydrochloride extended-release capsules may cause drowsiness. Use caution when driving, operating machinery, or performing activities that are potentially hazardous until you know how cyclobenzaprine hydrochloride extended-release capsules affect you. In general, avoid activities that require mental alertness or physical coordination until you know how cyclobenzaprine hydrochloride extended-release capsules affect you.

What should I consider before taking cyclobenzaprine hydrochloride extended-release capsules?
Before taking cyclobenzaprine hydrochloride extended-release capsules, tell your healthcare provider about all of your medical conditions, allergies, and all medicines you take, including prescription and non-prescription medicines, vitamins, and herbal products. If you have not told your healthcare provider about any of these, tell them before you start taking cyclobenzaprine hydrochloride extended-release capsules. Your healthcare provider will want to know if:

• you have any of the conditions listed below.
  • a history of drug abuse
  • have a history of alcohol problems including alcoholism
  • are pregnant or plan to become pregnant. It is not known if cyclobenzaprine hydrochloride extended-release capsules pass into your breast milk. You need to talk to your healthcare provider about whether you should take cyclobenzaprine hydrochloride extended-release capsules if you are breastfeeding.
  • have had an allergic reaction to cyclobenzaprine hydrochloride extended-release capsules.

What is the possible side effect of cyclobenzaprine hydrochloride extended-release capsules?
Cyclobenzaprine hydrochloride extended-release capsules may cause side effects. Some side effects may be serious. List of the most common side effects of cyclobenzaprine hydrochloride extended-release capsules include:

• fatigue
• drowsiness
• constipation
• abdominal pain
• vomiting
• fast heartbeat
• tremor
• dizziness
• sweating or fever

Also see "What should I avoid while taking cyclobenzaprine hydrochloride extended-release capsules?"

What should I know about taking cyclobenzaprine hydrochloride extended-release capsules?
It is not known whether cyclobenzaprine hydrochloride extended-release capsules are safe to use during pregnancy. It is also not known whether cyclobenzaprine hydrochloride extended-release capsules pass into your breast milk. You need to talk to your healthcare provider about whether you should take cyclobenzaprine hydrochloride extended-release capsules if you are pregnant, planning to become pregnant, or breastfeeding.

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What should I do if I miss a dose of cyclobenzaprine hydrochloride extended-release capsules?
You should not skip doses of cyclobenzaprine hydrochloride extended-release capsules. You should take the missed dose as soon as you remember. Do not take a double dose to make up for a missed dose.

What should I do if I overdose on cyclobenzaprine hydrochloride extended-release capsules?
If you or anyone else takes too much cyclobenzaprine hydrochloride extended-release capsules, call your local Poison Control Center or go to the nearest hospital emergency room immediately.

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