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Patient Information

Clonidine Hydrochloride (klonĭ dĭ deen hĭe² droe klorĭ ide) Extended-Release Tablets

Read the Patient Information that comes with clonidine hydrochloride extended-release tablets before you start taking it and each time you get a refill. There may be new information. This Patient Information leaflet does not take the place of talking to your doctor about your medical condition or treatment.

What are clonidine hydrochloride extended-release tablets?

Clonidine hydrochloride extended-release tablets are a prescription medicine used for the treatment of Attention-Deficit Hyperactivity Disorder (ADHD). Your doctor may prescribe clonidine hydrochloride extended-release tablets alone or together with certain other ADHD medicines.

- Clonidine hydrochloride extended-release tablets are not a central nervous system (CNS) stimulant.
- Clonidine hydrochloride extended-release tablets should be used as part of a total treatment program for ADHD that may include counseling or other therapies.

Who should not take clonidine hydrochloride extended-release tablets?

- Do not take clonidine hydrochloride extended-release tablets if you are allergic to clonidine in clonidine hydrochloride extended-release tablets. See the end of this leaflet for a complete list of ingredients in clonidine hydrochloride extended-release tablets.

What should I tell my doctor before taking clonidine hydrochloride extended-release tablets?

Before you take clonidine hydrochloride extended-release tablets, tell your doctor if you:

- have kidney problems
- have low or high blood pressure
- have a history of passing out (syncope)
- have heart problems, including history of heart attack
- have had a stroke or have stroke symptoms
- had a skin reaction (such as a rash) after taking clonidine in a transdermal form (skin patch)
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if clonidine hydrochloride extended-release tablets will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
 - There is a pregnancy registry for females who are exposed to ADHD medications, including clonidine hydrochloride, during pregnancy. The purpose of the registry is to collect information about the health of females exposed to clonidine hydrochloride and their baby. If you or your child becomes pregnant during treatment with clonidine hydrochloride, talk to your healthcare provider about registering with the National Pregnancy Registry of ADHD Medications at 1-866-961-2388 or visit online at <https://womensmentalhealth.org/adhdmedications/>.
- are breastfeeding or plan to breastfeed. Clonidine hydrochloride passes into your breast milk. Talk to your doctor about the best way to feed your baby if you take clonidine hydrochloride extended-release tablets.

Tell your doctor about all of the medicines that you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Clonidine hydrochloride extended-release tablets and certain other medicines may affect each other causing serious side effects. Sometimes the doses of other medicines may need to be changed while taking clonidine hydrochloride extended-release tablets.

Especially tell your doctor if you take:

- anti-depression medicines
- heart or blood pressure medicine
- other medicines that contain clonidine
- a medicine that makes you sleepy (sedation)

Ask your doctor or pharmacist for a list of these medicines, if you are not sure if your medicine is listed above.

Know the medicines that you take. Keep a list of your medicines with you to show your doctor and pharmacist when you get a new medicine.

How should I take clonidine hydrochloride extended-release tablets?

- Take clonidine hydrochloride extended-release tablets exactly as your doctor tells you to take it.
- Your doctor will tell you how many clonidine hydrochloride extended-release tablets to take and when to take them. Your doctor may change your dose of clonidine hydrochloride extended-release tablets. Do not change your dose of clonidine hydrochloride extended-release tablets without talking to your doctor.
- Do not stop taking clonidine hydrochloride extended-release tablets without talking to your doctor.
- Clonidine hydrochloride extended-release tablets can be taken with or without food.
- Clonidine hydrochloride extended-release tablets should be taken 2 times a day (in the morning and at bedtime).
- If you miss a dose of clonidine hydrochloride extended-release tablets, skip the missed dose. Just take the next dose at your regular time. Do not take two doses at the same time.
- Take clonidine hydrochloride extended-release tablets whole. Do not chew, crush or break clonidine hydrochloride extended-release tablets. Tell your doctor if you cannot swallow clonidine hydrochloride extended-release tablets whole. You may need a different medicine.
- If you take too much clonidine hydrochloride extended-release tablets, call your Poison Control Center or go to the nearest hospital emergency room right away.

What should I avoid while taking clonidine hydrochloride extended-release tablets?

- Do not drink alcohol or take other medicines that make you sleepy or dizzy while taking clonidine hydrochloride extended-release tablets until you talk with your doctor. Clonidine hydrochloride extended-release tablets taken with alcohol or medicines that cause sleepiness or dizziness may make your sleepiness or dizziness worse.
- Do not drive, operate heavy machinery or do other dangerous activities until you know how clonidine hydrochloride extended-release tablets will affect you.
- Avoid becoming dehydrated or overheated.

What are possible side effects of clonidine hydrochloride extended-release tablets?

Clonidine hydrochloride extended-release tablets may cause serious side effects, including:

- **Low blood pressure and low heart rate.** Your doctor should check your heart rate and blood pressure before starting treatment and regularly during treatment with clonidine hydrochloride extended-release tablets.
- Sleepiness.
- Withdrawal symptoms. Suddenly stopping clonidine hydrochloride extended-release tablets may cause withdrawal symptoms including: increased blood pressure, headache, increased heart rate, lightheadedness, tightness in your chest and nervousness.

The most common side effects of clonidine hydrochloride extended-release tablets include:

- sleepiness
- tiredness
- irritability
- trouble sleeping (insomnia)
- nightmare
- constipation
- dry mouth
- decreased appetite
- dizziness

Tell your doctor if you have any side effects that bother you or that does not go away.

These are not all of the possible side effects of clonidine hydrochloride extended-release tablets. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or Lupin Pharmaceuticals, Inc. at 1-800-399-2561.

How should I store clonidine hydrochloride extended-release tablets?

- Store clonidine hydrochloride extended-release tablets between 68°-77°F (20°-25°C).
- Keep clonidine hydrochloride extended-release tablets in a tightly closed container.

Keep clonidine hydrochloride extended-release tablets and all medicines out of the reach of children.

General information about the safe and effective use of clonidine hydrochloride extended-release tablets

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use clonidine hydrochloride extended-release tablets for a condition for which it was not prescribed.

Do not give clonidine hydrochloride extended-release tablets to other people, even if they have the same symptoms that you have. It may harm them.

This Patient Information leaflet summarizes the most important information about clonidine hydrochloride extended-release tablets. If you would like more information, talk with your doctor. You can also ask your doctor or pharmacist for information about clonidine hydrochloride extended-release tablets that is written for healthcare professionals.

For more information about clonidine hydrochloride extended-release tablets, go to www.lupinpharmaceuticals.com or call 1-800-399-2561

What are the ingredients in clonidine hydrochloride extended-release tablets?

- Active Ingredient: clonidine hydrochloride
- Inactive Ingredients: colloidal silicon dioxide, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, and sodium lauryl sulphate

Manufactured for:

Lupin Pharmaceuticals, Inc.
Baltimore, Maryland 21202
United States

Manufactured by:

Lupin Limited
Nagpur 441108
India

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