

Medication Guide

XTAMPZA® ER (ex tamp' zah ee ar) (oxycodone) extended-release capsules, CII

XTAMPZA ER is:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage pain severe enough to require daily, around-the-clock, long-term treatment with an opioid, when other pain treatments such as non-opioid pain medicines or immediate-release opioid medicines do not treat your pain well enough or you cannot tolerate them.
- A long-acting (extended-release) opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed by your healthcare provider, you are at risk for opioid addiction, abuse, and misuse that can lead to death.
- Not for use to treat pain that is not around-the-clock.

Important information about XTAMPZA ER:

- **Get emergency help right away if you take too much XTAMPZA ER (overdose).** When you first start taking XTAMPZA ER, when your dose is changed, or if you take too much (overdose), serious life-threatening breathing problems that can lead to death may occur.
- Taking XTAMPZA ER with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.
- Never give anyone else your XTAMPZA ER. They could die from taking it. Store XTAMPZA ER away from children and in a safe place to prevent stealing or abuse. Selling or giving away XTAMPZA ER is against the law.

Do not take XTAMPZA ER if you have:

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.

Before taking XTAMPZA ER, tell your healthcare provider if you have a history of:

- head injury, seizures
- liver, kidney, thyroid problems
- problems urinating
- pancreas or gallbladder problems
- abuse of street or prescription drugs, alcohol addiction, or mental health problems.

Tell your healthcare provider if you are:

- **pregnant or planning to become pregnant.** Prolonged use of XTAMPZA ER during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- **breastfeeding.** Not recommended during treatment with XTAMPZA ER. It may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking XTAMPZA ER with certain other medicines can cause serious side effects that could lead to death.

When taking XTAMPZA ER:

- Do not change your dose. Take XTAMPZA ER exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed.
- Take your prescribed dose every 12 hours, at the same time every day. Do not take more than your prescribed dose. If you miss a dose, take your next dose at your usual time.
- If you cannot swallow XTAMPZA ER capsules, see the detailed Instructions for Use.
- Always take XTAMPZA ER capsules with approximately the same amount of food to ensure enough medicine is absorbed.
- Swallow XTAMPZA ER whole. Do not snort, or inject XTAMPZA ER because this may cause you to overdose and die.
- The contents of the XTAMPZA ER capsules may be sprinkled on soft food, sprinkled into a cup and then put directly into the mouth, or given through a nasogastric or gastrostomy tube.
- **Call your healthcare provider if the dose you are taking does not control your pain.**
- **Do not stop taking XTAMPZA ER without talking to your healthcare provider.**
- After you stop taking XTAMPZA ER, flush any unused capsules down the toilet.

While taking XTAMPZA ER DO NOT:

- Drive or operate heavy machinery, until you know how XTAMPZA ER affects you. XTAMPZA ER can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol. Using products containing alcohol during treatment with XTAMPZA ER may cause you to overdose and die.

The possible side effects of XTAMPZA ER are:

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain. Call your healthcare provider if you have any of these symptoms and they are severe.

Get emergency medical help if you have:

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue, or throat, extreme drowsiness, lightheadedness when changing positions, feeling faint, agitation, high body temperature, trouble walking, stiff muscles, or mental changes such as confusion.

These are not all the possible side effects of XTAMPZA ER. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088. **For more information, go to dailymed.nlm.nih.gov**

Manufactured by: Patheon Pharmaceuticals, 2110 Galbraith Road, Cincinnati, OH 45237, www.collegiumpharma.com or call 855-331-5615

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Issued: December 2016