

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 or call 911 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. Talk to your healthcare provider about naloxone, a medicine for the emergency treatment of an overdose.
- 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. Selling or giving away XTAMPZA ER is against the law.
- Store XTAMPZA ER securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.

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, opioid overdose 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.
- living in a household where there are small children or someone who has abused street or prescription drugs

- 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.**
- Dispose of expired, unwanted, or unused XTAMPZA ER by promptly flushing down the toilet, if a drug take-back option is not readily available. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

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 or call 911 right away if you have:

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue, or throat, extreme drowsiness, light-headedness 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

Instructions for Use

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

Always take XTAMPZA ER with approximately the same amount of food. If you cannot swallow XTAMPZA ER capsules, tell your healthcare provider. If your healthcare provider tells you that you can take XTAMPZA ER by sprinkling the capsule contents, follow these steps:

XTAMPZA ER can be opened and the contents inside the capsule can be sprinkled onto soft foods (such as, applesauce, pudding, yogurt, ice cream, or jam) as follows:

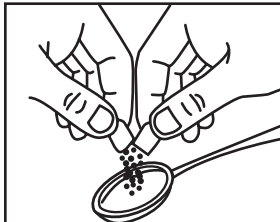


Figure 1

- Open the XTAMPZA ER capsule and sprinkle the contents over about one tablespoon of the soft food listed above (See Figure 1).

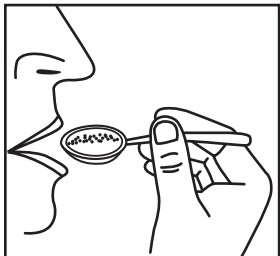


Figure 2

- Swallow all of the soft food and sprinkled capsule contents right away. Do not save any of the soft food and capsule contents for another dose (See Figure 2).



Figure 3

- Rinse your mouth to make sure you have swallowed all of the capsule contents. (See Figure 3).



Figure 4

- Flush the empty capsule down the toilet right away (See Figure 4).

XTAMPZA ER capsule contents can also be sprinkled into a cup and then put directly into the mouth.

Giving XTAMPZA ER through a nasogastric or gastrostomy tube:

Use water, milk, or a liquid nutritional supplement to flush the tube when giving XTAMPZA ER.

Step 1: Flush the nasogastric or gastrostomy tube with liquid.

Step 2: Open an XTAMPZA ER capsule and carefully pour the contents of the capsule directly into the tube. **Do not** pre-mix the capsule contents with the liquid used to flush the capsule contents through the tube.

Step 3: Draw up 15 mL of liquid into a syringe, insert the syringe into the tube, and flush the contents of the capsule through the tube to give the dose.

Step 4: Flush the tube two more times, each time with 10 mL of liquid, to ensure that none of the contents of the capsule are left in the tube.

This Instruction for Use has been approved by the U.S. Food and Drug Administration. Issued: December 2016

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