



Transitioning from OxyContin[®] to **XTAMPZA[®] ER** Learn why

The use of oxycodone medications, including XTAMPZA ER, may result in serious, life-threatening, or fatal respiratory depression even when used as recommended. There are no head-to-head studies comparing the safety or efficacy between XTAMPZA ER and OxyContin.

INDICATIONS AND USAGE XTAMPZA® ER (oxycodone) is:

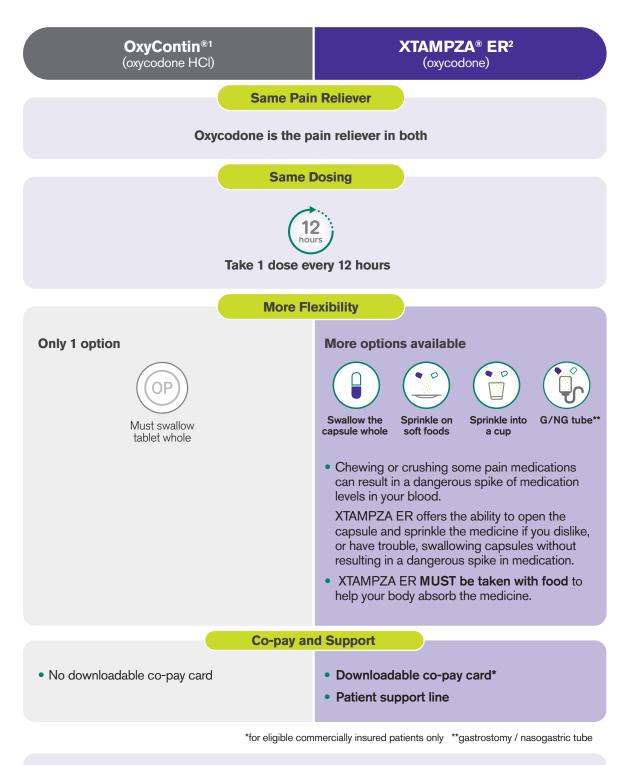
- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage severe and persistent pain that requires an extended treatment period with a daily opioid medicine, when other pain medicines do not treat your pain well enough or you cannot tolerate them.
- A long-acting (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 to be taken on an "as needed" basis

IMPORTANT SAFETY 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.

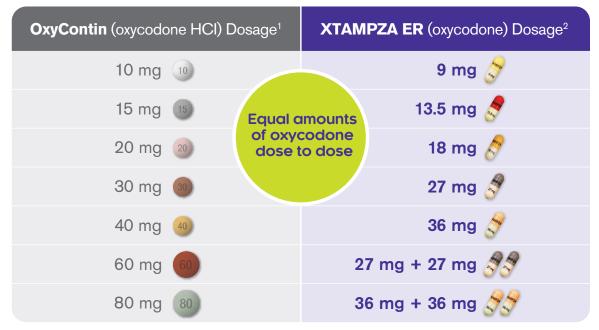
See full <u>Prescribing Information</u> including Boxed Warning on Addiction, Abuse and Misuse and other serious risks, accompanying this piece or at <u>XTAMPZAER.com/PI</u>.

XTAMPZA ER offers more potential benefits



The use of oxycodone medications, including XTAMPZA ER, may result in serious, life-threatening, or fatal respiratory depression even when used as recommended. There are no head-to-head studies comparing the efficacy of the two products. Table is based on information in the full Prescribing Information for each product.

Same dose of oxycodone in both brands



Capsules and tablets are not actual size.

The amount of oxycodone is the same in each dose of XTAMPZA ER as it is in OxyContin. For example, an XTAMPZA ER 9mg capsule has the same amount of oxycodone as OxyContin's 10mg tablet. The difference in milligrams noted is due to the weight of the added HCl salt in OxyContin.

See Important Safety Information and full <u>Prescribing Information</u> including Boxed Warning on Addiction, Abuse and Misuse and other serious risks, accompanying this piece or at <u>XTAMPZAER.com/PI</u>.



IMPORTANT SAFETY INFORMATION ABOUT XTAMPZA[®] ER (oxycodone) extended-release capsules

WARNING: SERIOUS AND LIFE-THREATENING RISKS FROM USE OF XTAMPZA ER

Addiction, Abuse, and Misuse

Because the use of XTAMPZA ER exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death, assess each patient's risk prior to prescribing reassess all patients regularly for the development of these behaviors or conditions.

Life-Threatening Respiratory Depression

Serious, life-threatening, or fatal respiratory depression may occur with use of XTAMPZA ER, especially during initiation or following a dosage increase. To reduce the risk of respiratory depression, proper dosing and titration of XTAMPZA ER are essential.

Accidental Ingestion

Accidental ingestion of even one dose of XTAMPZA ER, especially by children, can result in a fatal overdose of oxycodone.

<u>Risks From Concomitant Use With Benzodiazepines or Other CNS Depressants</u> Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of XTAMPZA ER and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate.

Neonatal Opioid Withdrawal Syndrome (NOWS)

If opioid use is required for an extended period of time in a pregnant woman, advise the patient of the risk of NOWS, which may be life-threatening if not recognized and treated. Ensure that management by neonatology experts will be available at delivery.

Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS)

Healthcare providers are strongly encouraged to complete a REMS-compliant education program and to counsel patients and caregivers on serious risks, safe use, and the importance of reading the Medication Guide with each prescription.

Cytochrome P450 3A4 Interaction

The concomitant use of XTAMPZA ER with all cytochrome P450 3A4 inhibitors may result in an increase in oxycodone plasma concentrations, which could increase or prolong adverse drug effects and may cause potentially fatal respiratory depression. In addition, discontinuation of a concomitantly used cytochrome P450 3A4 inducer may result in an increase in oxycodone plasma concentration. Regularly evaluate patients receiving XTAMPZA ER and any CYP3A4 inhibitor or inducer.

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IMPORTANT SAFETY INFORMATION ABOUT XTAMPZA[®] ER continued

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:

- **noticing your pain getting worse.** If your pain gets worse after you take XTAMPZA ER, do not take more of XTAMPZA ER without first talking to your healthcare provider. Talk to your healthcare provider if the pain you have increases, if you feel more sensitive to pain, or if you have new pain after taking XTAMPZA ER.
- 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 in the Medication Guide.
- 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 takeback 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 healthcare provider 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.

Two brands, same pain reliever, different formulation **Why transition to XTAMPZA ER?**

When transitioning medications, you may have questions or concerns.

Q: Will XTAMPZA ER work as well as OxyContin?

A: You will continue to get the proven pain relief of oxycodone because both OxyContin and XTAMPZA ER are forms of extended-release oxycodone. Both also have similar expected side effects. Speak to your healthcare provider if you have questions about XTAMPZA ER.

There are no head-to-head studies comparing the efficacy of the two products.

Q: How is XTAMPZA ER different from OxyContin?

- A: XTAMPZA ER has additional administration options and broader manipulation resistance.
 - XTAMPZA ER can be taken several ways if you have difficulty or dislike swallowing pills, while still providing your medication at the rate and consistent level intended. You can take XTAMPZA ER by swallowing the capsule whole, sprinkling it on soft foods or into a cup.

The use of oxycodone, including XTAMPZA ER, exposes patients and others to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death.

• XTAMPZA ER resists manipulation in ways that OxyContin does not. Crushing, cutting, chewing or dissolving OxyContin, can result in a dangerous spike of medication levels in your blood.¹ XTAMPZA ER is formulated to help reduce the risks associated with manipulation. However, abuse of XTAMPZA ER by injection and by the oral and nasal routes of administration is still possible.² XTAMPZA ER's manipulation resistance may help protect patients and potentially others who may have access to and use a patient's medications. It is also CRITICAL that you do not share your pain medication with anyone and that you protect it from theft because, like all opioid medications, use of XTAMPZA ER comes with serious risks of addiction, abuse, misuse, and can be fatal.

Q: Does Xtampza ER cost more than OxyContin?

A: XTAMPZA ER has a lower or equal average co-pay for most patients. There's also an XTAMPZA ER co-pay card for eligible patients included on the back cover of the brochure inside this folder, and at XTAMPZAER.com/savings, to help offset costs.*

*Offer valid for commercially insured patients only. Maximum savings limit applies; patient out-of-pocket expense may vary.

Always ask your healthcare professional if you have more questions about the transition.

Learn more at XTAMPZAER.com

See Important Safety Information and full Prescribing Information including Boxed Warning on Addiction, Abuse and Misuse and other serious risks, accompanying this piece or at XTAMPZAER.com/PI. Speak to your healthcare provider if you have questions about XTAMPZA ER.

References: 1. OxyContin [package insert]. Stamford, CT: Purdue Pharma LP; 2023. **2.** XTAMPZA ER [package insert]. Stoughton, MA: Collegium Pharmaceutical, Inc.; 2023.



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