



Helping you make the transition to Xtampza ER

The use of oxycodone medications, including Xtampza ER, may result in serious, lifethreatening, or fatal respiratory depression even when used as recommended.

INDICATIONS AND USAGE

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

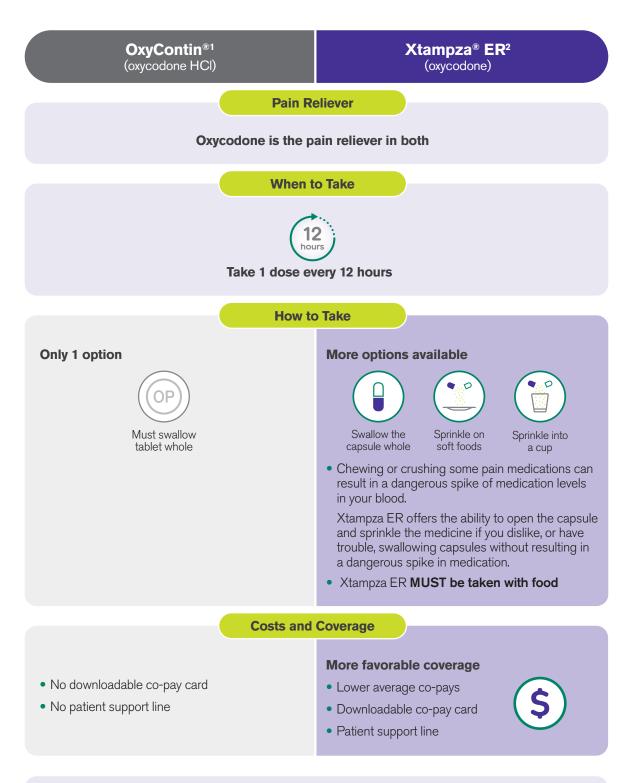
IMPORTANT SAFETY INFORMATION ABOUT XTAMPZA ER

- 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>.

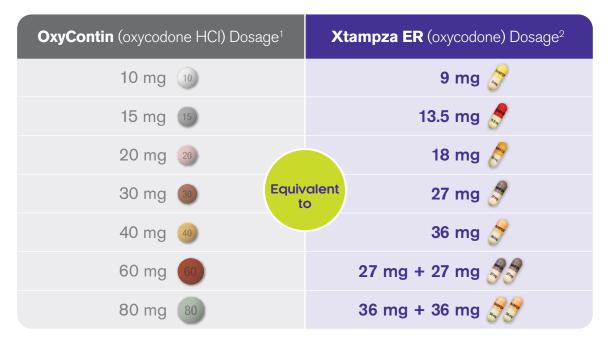
Transitioning from OxyContin[®] to Xtampza[®] ER

Two brands, same pain reliever



The use of oxycodone medications, including Xtampza ER, may result in serious, life-threatening, or fatal respiratory depression even when used as recommended.

A simple transition from dose to dose



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>.



WARNING: ADDICTION, ABUSE, AND MISUSE; RISK EVALUATION AND MITIGATION STRATEGY (REMS); LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL INGESTION; NEONATAL OPIOID WITHDRAWAL SYNDROME; CYTOCHROME P450 3A4 INTERACTION; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

Addiction. Abuse. and Misuse

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 Xtampza ER and monitor all patients regularly for the development of these behaviors or conditions.

Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS)

To ensure that the benefits of opioid analgesics outweigh the risks of addiction, abuse, and misuse, the Food and Drug Administration (FDA) has required a REMS for these products. Under the requirements of the REMS, drug companies with approved opioid analgesic products must make REMS-compliant education programs available to healthcare providers. Healthcare providers are strongly encouraged to

- complete a REMS-compliant education program,
- · counsel patients and/or their caregivers, with every prescription, on safe use, serious risks, storage, and disposal of these products,
- · emphasize to patients and their caregivers the importance of reading the Medication Guide every time it is provided by their pharmacist, and
- consider other tools to improve patient, household, and community safety.

Life-Threatening Respiratory Depression

Serious, life-threatening, or fatal respiratory depression may occur with use of Xtampza ER. Monitor for respiratory depression, especially during initiation of Xtampza ER or following a dose increase.

Accidental Ingestion

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

Neonatal Opioid Withdrawal Syndrome

Prolonged use of Xtampza ER during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.

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. Monitor patients receiving Xtampza ER and any CYP3A4 inhibitor or inducer.

Risks From Concomitant Use With Benzodiazepines or Other CNS Depressants

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.
- Limit dosages and durations to the minimum required.
- Follow patients for signs and symptoms of respiratory depression and sedation.

Important Safety Information about Xtampza ER:

Get emergency or call 911 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. 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.

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:

- 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 take-back option is not readily available. Visit <u>www.fda.gov/drugdisposal</u> 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 light-headed.
- 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, and 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 <u>dailymed.nlm.nih.gov</u>.**

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Answers to common questions

Q: Will Xtampza® ER (oxycodone) work as well as OxyContin® (oxycodone HCI)?

A: The pain reliever in your medication will stay the same. Both OxyContin and Xtampza ER are forms of extended-release oxycodone.^{1,2}

Q: How is Xtampza ER different from OxyContin?

A: The difference is that OxyContin releases its active drug through a coated layer on its tablet, while Xtampza ER releases its active drug from each tiny bead inside its capsule. The prescribing information for OxyContin includes a warning saying that the tablets must not be crushed, chewed, or dissolved.¹ The prescribing information for Xtampza ER doesn't require this warning.² Xtampza ER is designed to maintain its extended-release characteristics, even if it is crushed, ground, cut, or dissolved. That's why Xtampza ER is able to offer you several different ways to take it, which is really important if you have difficulty or dislike swallowing pills. You can take Xtampza ER by swallowing the capsule whole, by sprinkling on soft foods, or by sprinkling into a cup and then swallowing.

Xtampza ER exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death.

Q: How will I take Xtampza ER?

A: Like OxyContin, Xtampza ER is taken twice a day, every 12 hours.^{1,2} Xtampza ER **MUST be taken** with food. That's because food helps your body absorb the medicine to relieve your pain. Take it with approximately the same amount of food each time.

Q: Does Xtampza ER cost less than OxyContin?

A: Xtampza ER will have a lower co-pay for most people. There's also an Xtampza ER co-pay card for eligible patients.* You can download one from the "Savings" tab on **XtampzaER.com**.

*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

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References: 1. OxyContin [package insert]. Stamford, CT: Purdue Pharma LP; 2021. 2. Xtampza ER [package insert]. Stoughton, MA: Collegium Pharmaceutical, Inc.; 2021.





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