

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

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.

Please 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/Pl. Speak to your healthcare provider if you have questions about XTAMPZA ER.





WHAT IS SEVERE AND PERSISTENT PAIN?

Everyone experiences pain from time to time. But severe and persistent pain doesn't go away. Healthcare providers usually define it as significant pain that lasts longer than 3 months. Severe and persistent pain could be caused by a health condition or injury, but sometimes there's not an obvious cause.

If you are one of the millions of Americans suffering from severe and persistent pain, treatments such as XTAMPZA® ER may be able to help you manage severe and persistent pain.



WHAT IS XTAMPZA ER (OXYCODONE)?

XTAMPZA ER (pronounced ex tamp' zah ee ar) 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.



KEEP IN MIND...

- Store XTAMPZA ER in a safe place, out of sight of others, and secured in a locked cabinet, drawer, or safe.
- Never give anyone else this prescription medicine. It can be life-threatening. Selling or giving away XTAMPZA ER is against the law.

HOW IS XTAMPZA ER DIFFERENT?

XTAMPZA ER is a form of oxycodone designed with extended-release technology. When taking XTAMPZA ER, here are some of the things you can expect:



Severe and persistent pain relief that's released slowly over time, unlike short-acting pain medicines that may work quickly, but don't last as long.



Dosed every 12 hours, so you only take it twice a day.
XTAMPZA ER should be taken at the same time every day and
MUST be taken with food.



Chewing or crushing some pain medications can result in a dangerous spike of medication levels in your blood.

XTAMPZA ER offers the ability to open the capsule and sprinkle the medicine if you dislike or have trouble swallowing capsules without resulting in a dangerous spike in medication when used as prescribed.

The use of any opioid may result in serious, life-threatening, or fatal respiratory depression, even when used as recommended.

Although XTAMPZA ER is formulated to make manipulation more difficult, it cannot entirely prevent abuse; abuse of XTAMPZA ER by injection and via the oral and nasal routes is still possible.

HOW TO TAKE XTAMPZA ER

You'll take XTAMPZA ER dose twice a day—every 12 hours—at the same times, and you <u>MUST take it with food</u>. You should take each dose with approximately the same amount of food each time to help the medicine work properly to relieve pain.

It helps to establish a pattern to help you remember to take it. For example, you can take it at 7 am with breakfast and 7 pm with dinner each day.

 If XTAMPZA ER doesn't control your pain, talk to your healthcare provider about adjusting your treatment plan. Never change your dose or stop taking XTAMPZA ER without talking to your healthcare provider first.

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YOU HAVE 4 OPTIONS FOR TAKING YOUR MEDICINE:

The whole capsule by mouth

cream, or iam)



Sprinkle on soft foods (for example: applesauce, pudding, yogurt, ice



Sprinkle into a cup and then swallow



Through a gastrostomy/nasogastric tube



XTAMPZA® ER MUST BE TAKEN WITH FOOD.

Please see the Instructions for Use in the enclosed Prescribing Information for more details, and talk to your healthcare provider.

HOW SHOULD YOU STORE YOUR PRESCRIPTION?

 Store your prescription at room temperature, away from light. It's important to keep it in a safe place, out of sight and secured in a locked cabinet, drawer, or safe.

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.

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.

TALKING WITH YOUR HEALTHCARE PROVIDER

- 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.



DID YOU KNOW?

XTAMPZA ER is the only extended-release oxycodone that can be opened and sprinkled. With other extended-release pain medicines, chewing or crushing them can disrupt the dosage, destroy the extended-release properties, and increase the risk of side effects for some people. Although XTAMPZA ER is formulated to make manipulation more difficult, it cannot entirely prevent abuse; abuse of XTAMPZA ER by injection and via the oral and nasal routes is still possible.

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POSSIBLE SIDE EFFECTS OF XTAMPZA® ER TO WATCH FOR

- 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
- High body temperature
- Trouble walking

- Extreme drowsiness
- Light-headedness when changing positions
- Feeling faint
- Agitation
- Stiff muscles
- 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.



The side effects seen with XTAMPZA ER are similar to those seen with other oxycodone medications.

There are no studies directly comparing the safety or efficacy of XTAMPZA ER to other oxycodone medications.

IMPORTANT INFORMATION TO KEEP IN MIND

- 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.

ARE YOU GETTING THE MOST OUT OF YOUR TREATMENT?



Work together with your healthcare provider.

Talk to your healthcare provider about how your treatment is going. Never change or stop taking your dose without talking to your healthcare provider.



Stick to the plan.

Always follow your healthcare provider's instructions. Take XTAMPZA ER with the same amount of food to make sure the medicine is consistently absorbed.



Find what works for you.

If you'd prefer to take your medicine a certain way (if you don't like swallowing pills, for example), talk with your healthcare provider about your options.



Stay on schedule.

Remember to take your prescribed dose every 12 hours, at the same times every day. If you miss a dose, take your next dose at your usual time.



DID YOU KNOW?

It's important to learn all you can about living with severe and persistent pain. These organizations can help you find support groups in your area and may also provide other helpful information.

American Academy of Pain Medicine*

https://www.painmed.org/organizations-dedicatedto-people-with-pain/

American Chronic Pain Association*

https://www.acpanow.com/

National Institute of Health's Medline Plus https://www.medlineplus.gov/backpain.html

*Collegium provides financial support to these organizations.

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RESPONSIBLE OPIOID USAGE

The opioid crisis is a major problem facing communities throughout our country. As part of this crisis, prescription opioids have been stolen, misused, and abused.

You've been prescribed XTAMPZA® ER, an abuse-deterrent opioid that was developed with these issues in mind, and it's important that you understand how these issues can impact you. Ask your doctor for more information about how XTAMPZA ER may help. XTAMPZA ER, like other opioids, can still be abused, misused, and diverted for nonmedical use into illicit channels of distribution.

Another way to help address the opioid epidemic is by responsibly storing and disposing of your medication. Make sure you are:

- Taking XTAMPZA ER exactly as your doctor has prescribed
- Storing your medications safely and securely (consider placing all medication in a locked box or cabinet)
- Discarding unused medications properly and not saving them

PROPER DISPOSAL PROCEDURES INCLUDE:

Take-back programs

- Visit <u>takebackday.dea.gov</u> for National Prescription Drug Take-Back events hosted by the DEA in communities nationwide.
- Your local law enforcement agencies may also sponsor medicine take-back programs.
 For more information, contact your city or county government.

Authorized collectors

Retail pharmacies, hospital or clinic pharmacies, and law enforcement locations can be authorized collection sites. To find authorized collectors near you:

- Visit https://apps.DEAdiversion.usdoj.gov/pubdispsearch/
- Find an authorized drug collection site near you or call the DEA Diversion Control Division Registration Call Center at 1-800-882-9539

If these options are not available to you, you can flush your unused XTAMPZA ER capsules down the toilet. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

IMPORTANT SAFETY INFORMATION ABOUT XTAMPZA® ER 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.

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.

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.





IMPORTANT SAFETY INFORMATION ABOUT XTAMPZA® ER CONTINUED

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:

- 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 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 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.**

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COMMERCIALLY INSURED PATIENTS MAY START SAVING TODAY WITH THE XTAMPZA® ER CO-PAY CARD



Eligible patients may pay \$35* as little as for each prescription

Eligible patients may pay as little as \$35* for each prescription.

Visit **XTAMPZAER.com** for additional information and resources.

CO-PAY SAVINGS* available for eligible commercially insured patients.

* Please see Program Terms, Conditions, and Eligibility Criteria at <u>www.XTAMPZAER.com</u>. Maximum savings limit applies; patient out-of-pocket expense may vary.



For questions about XTAMPZA ER, please call 888-884-2655. Representatives available Monday through Friday, 9am – 5pm EST.

Program Terms, Conditions, and Eligibility Criteria

Offer is valid for commercially insured patients only. Most eligible commercially insured patients will pay as little as \$35 (maximum benefit amount of \$125) for each fill of Xtampza® ER (oxycodone) capsules. Any remaining out-of-pocket expense will be the patient's responsibility. This offer is valid in the United States. Some restrictions may apply. Offer not valid for prescriptions reimbursed under Medicaid, a Medicare drug benefit plan, Tricare or other federal or state health programs (such as medical assistance programs). Cash Discount Cards and other non-insurance plans are not valid as primary under this offer. If the patient is eligible for drug benefits under any such program, the patient cannot use this offer. By using this offer, the patient certifies that he or she will comply with any terms of his or her health insurance contract requiring notification to his or her payer of the existence and/or value of this offer. This offer is not valid for cash paying patients. Offer not valid for patients under 18 years of age. **Program is not valid in Massachusetts or any other state or jurisdiction where prohibited or restricted by law.**

Patient Instructions: To redeem this offer, you must have a valid prescription for Xtampza ER and follow the dosage instructions provided by your healthcare provider with a valid Prescriber ID# (e.g. NPI or DEA). This offer may not be redeemed for cash. Patients with questions about the XTAMPZA ER savings offer should call 1-844-247-4753.

This offer is not transferable and is limited to one offer per person. Not valid if reproduced. Void where prohibited by law. Program managed by ConnectiveRx on behalf of Collegium Pharmaceutical. The parties reserve the right to rescind, revoke or amend this offer without notice at any time.



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