Xtampza® ER (oxycodone) EXTENDED-RELEASE CAPSULES CII

Your Daily Treatment Journal

Helping you stay on track with Xtampza ER

INDICATIONS AND USAGE

Xtampza® ER (oxycodone) is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

Limitations of Use

- Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve Xtampza ER for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain
- Xtampza ER is not indicated as an as-needed (prn) analgesic

IMPORTANT SAFETY INFORMATION

WARNING: ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL INGESTION; NEONATAL OPIOID WITHDRAWAL SYNDROME; and CYTOCHROME P450 3A4 INTERACTION

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.

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.

Please see additional Important Safety Information, including Boxed Warning, throughout this brochure and Medication Guide on last page. For full Prescribing Information, visit XtampzaER.com.

How can I play an active role in my treatment?

Keep track of how you're doing with Xtampza ER by keeping a journal

Keeping a journal—a written record of your thoughts, experiences, and observations—can be helpful for talking with your doctor and staying on track with Xtampza ER.

Some of the benefits of journaling include:

- Keeping track of your daily habits on a consistent basis (example: pain, activity, sleep)
- Informing your doctor of your progress and how he/she can help you at each appointment
- Promoting open and honest discussions between you and your doctor

Use this journal to talk to your doctor about your experience with Xtampza ER

To get the most out of your next office visit, it may be helpful to record the following:

- Your level of pain
- How you take Xtampza ER
- Questions or concerns you want to discuss with your doctor

Tracking your experience with Xtampza ER as soon as you start taking it will help give your doctor an accurate picture of how you are doing.

Make sure to take this journal to your next appointment so that you can discuss your progress with your doctor

Make your appointment a success

- Write down your questions beforehand so you don't forget them
- Bring along a family member or friend for support, if possible
- Take notes during your appointment so you remember any directions your doctor gives you

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS:

- Xtampza ER is contraindicated in patients with significant respiratory depression, acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment, known or suspected gastrointestinal obstruction, including paralytic ileus, and hypersensitivity (e.g., anaphylaxis) to oxycodone

WARNINGS AND PRECAUTIONS:

Addiction, Abuse, and Misuse

- Xtampza ER contains oxycodone, a Schedule II controlled substance. As an opioid, Xtampza ER exposes users to the risks of addiction, abuse, and misuse. As extended-release products such as Xtampza ER deliver the opioid over an extended period of time, there is a greater risk for overdose and death due to the larger amount of oxycodone present

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Xtampza® ER (oxycodone) EXTENDED-RELEASE CAPSULES II

How can I stay on track?

Remember these important tips when taking Xtampza ER:

Work together with your doctor

If Xtampza ER does not control your pain, talk to your doctor about adjusting your treatment plan. Never change your dosage or stop taking Xtampza ER without talking to your doctor first.

Stick to the plan

Take Xtampza ER exactly as prescribed by your doctor. Changing the way you take your medication can change the way it works, so make sure you take Xtampza ER according to your doctor's instructions. Always take Xtampza ER with approximately the same amount of food to make sure the medicine is consistently absorbed.

Be proactive

Xtampza ER can be taken in different ways. If you have a preference about how to take your medication (example: if you dislike or cannot swallow pills), let your doctor know and ask him/her about your options.

Stay on schedule

Take your prescribed dose every 12 hours at the same time every day. Use your phone or alarm clock to set a reminder for your next dose. This will help you to take Xtampza ER on the appropriate schedule. If you miss a dose, take the next dose at your usual time.

Visit XtampzaER.com for more tips and information about Xtampza ER

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS:
Life-Threatening Respiratory Depression

- Serious, life-threatening, or fatal respiratory depression has been reported with the use of opioids, even when used as recommended. Respiratory depression, if not immediately recognized and treated, may lead to respiratory arrest and death. Management of respiratory depression may include close observation, supportive measures, and use of opioid antagonists, depending on the patient's clinical status. Carbon dioxide (CO_2) retention from opioid-induced respiratory depression can exacerbate the sedating effects of opioids

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Xtampza® ER (oxycodone) EXTENDED-RELEASE CAPSULES II

Date: ____/____/____

Track your treatment

Did you take Xtampza ER exactly as prescribed? ☐ Yes ☐ No

How much did you take? _____

How and when did you take Xtampza ER? (For example: With what type of food and how much? At what time of day? Did you swallow or sprinkle on food?) Describe in as much detail as you can.

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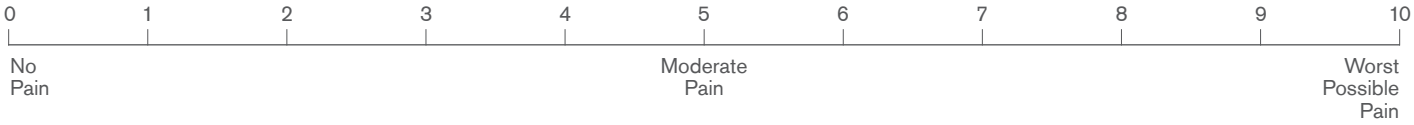
At any point today, was your pain severe enough to warrant taking an additional dose or another type of medication? (For example: over-the-counter medications such as ibuprofen, aspirin, or acetaminophen)

_____

Assess your pain

Using the 0-10 pain scale, how would you rate your pain today?



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Did your pain affect your ability to fall asleep? _____

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Were you able to sleep through the night without pain? _____

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Discuss with your doctor

Record any questions or concerns you want to discuss with your doctor:

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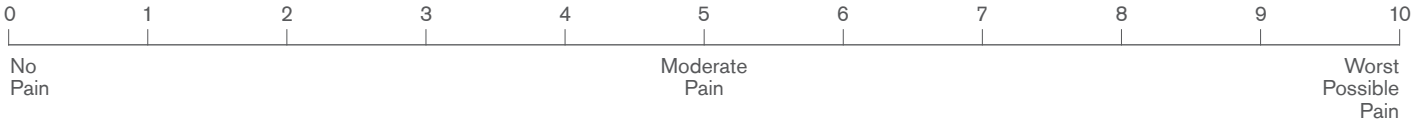

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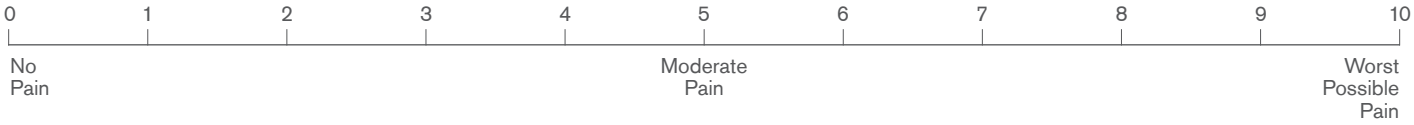

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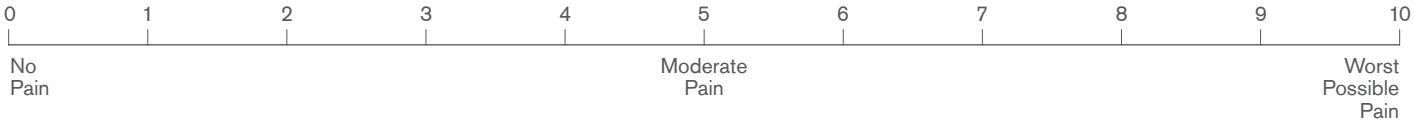

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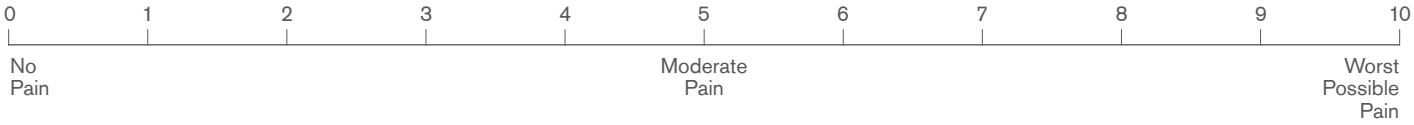

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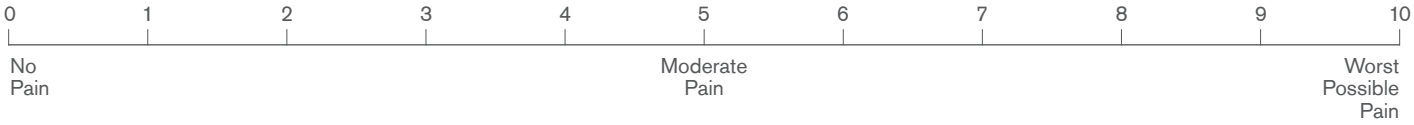

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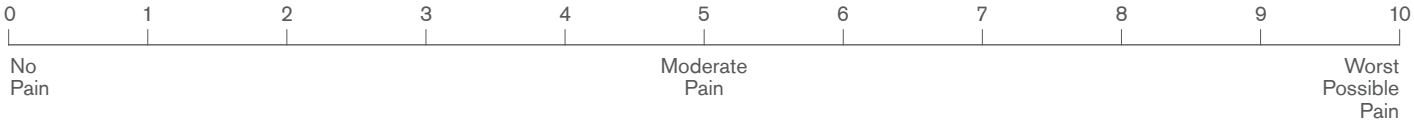

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Xtampza® ER (oxycodone) EXTENDED-RELEASE CAPSULES II

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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.

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.

CONTRAINDICATIONS:

- Xtampza ER is contraindicated in patients with significant respiratory depression, acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment, known or suspected gastrointestinal obstruction, including paralytic ileus, and hypersensitivity (e.g., anaphylaxis) to oxycodone

WARNINGS AND PRECAUTIONS:

Addiction, Abuse, and Misuse

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Life-Threatening Respiratory Depression

- Serious, life-threatening, or fatal respiratory depression has been reported with the use of opioids, even when used as recommended. Respiratory depression, if not immediately recognized and treated, may lead to respiratory arrest and death. Management of respiratory depression may include close observation, supportive measures, and use of opioid antagonists, depending on the patient's clinical status. Carbon dioxide (CO_2) retention from opioid-induced respiratory depression can exacerbate the sedating effects of opioids

Neonatal Opioid Withdrawal Syndrome

- Prolonged use of Xtampza ER during pregnancy can result in withdrawal in the neonate. Neonatal opioid withdrawal syndrome, unlike opioid withdrawal syndrome in adults, may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. Observe newborns for signs of neonatal opioid withdrawal syndrome and manage accordingly. Advise pregnant women using opioids for a prolonged period of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available

Risks of Concomitant Use or Discontinuation of Cytochrome P450 3A4 Inhibitors and Inducers

- Concomitant use of Xtampza ER with a CYP3A4 inhibitor, such as macrolide antibiotics (e.g., erythromycin), azole-antifungal agents (e.g., ketoconazole), and protease inhibitors (e.g., ritonavir), may increase plasma concentrations of oxycodone and prolong opioid adverse reactions, which may cause potentially fatal respiratory depression, particularly when an inhibitor is added after a stable dose of Xtampza ER is achieved.

Please see Medication Guide on last page and full Prescribing Information at XtampzaER.com.

Xtampza® ER (oxycodone) EXTENDED-RELEASE CAPSULES II

IMPORTANT SAFETY INFORMATION (cont'd)

Similarly, discontinuation of a CYP3A4 inducer, such as rifampin, carbamazepine, and phenytoin, in Xtampza ER-treated patients may increase oxycodone plasma concentrations and prolong opioid adverse reactions. When using Xtampza ER with CYP3A4 inhibitors or discontinuing CYP3A4 inducers in Xtampza ER-treated patients, monitor patients closely at frequent intervals and consider dosage reduction of Xtampza ER until stable drug effects are achieved

- Concomitant use of Xtampza ER with CYP3A4 inducers or discontinuation of a CYP3A4 inhibitor could decrease oxycodone plasma concentrations, decrease opioid efficacy or, possibly, lead to a withdrawal syndrome in a patient who had developed physical dependence to oxycodone. When using Xtampza ER with CYP3A4 inducers or discontinuing CYP3A4 inhibitors, monitor patients closely at frequent intervals and consider increasing the opioid dosage if needed to maintain adequate analgesia or if symptoms of opioid withdrawal occur

Adrenal Insufficiency

- Cases of adrenal insufficiency have been reported with opioid use, more often following greater than one month of use. Presentation of adrenal insufficiency may include nonspecific symptoms and signs, including nausea, vomiting, anorexia, fatigue, weakness, dizziness, and low blood pressure. If adrenal insufficiency is suspected, confirm the diagnosis with diagnostic testing as soon as possible. If adrenal insufficiency is diagnosed, treat with physiologic replacement doses of corticosteroids. Wean the patient off of the opioid to allow adrenal function to recover and continue corticosteroid treatment until adrenal function recovers. Other opioids may be tried as some cases reported use of a different opioid without recurrence of adrenal insufficiency. The information available does not identify any particular opioids as being more likely to be associated with adrenal insufficiency

Severe Hypotension

- Xtampza ER may cause severe hypotension, including orthostatic hypotension and syncope in ambulatory patients. There is an increased risk in patients whose ability to maintain blood pressure has already been compromised by a reduced blood volume or concurrent administration of certain CNS depressant drugs (e.g., phenothiazines or general anesthetics). Monitor these patients for signs of hypotension after initiating or titrating the dosage of Xtampza ER. In patients with circulatory shock, Xtampza ER may cause vasodilation that can further reduce cardiac output and blood pressure. Avoid the use of Xtampza ER in patients with circulatory shock

Risks of Use in Patients With Increased Intracranial Pressure, Brain Tumors, Head Injury, or Impaired Consciousness

- In patients who may be susceptible to the intracranial effects of CO_2 retention (e.g., those with evidence of increased intracranial pressure or brain tumors), Xtampza ER may reduce respiratory drive, and the resultant CO_2 retention can further increase intracranial pressure. Monitor such patients for signs of sedation and respiratory depression, particularly when initiating therapy with Xtampza ER
- Opioids may also obscure the clinical course in a patient with a head injury. Avoid the use of Xtampza ER in patients with impaired consciousness or coma

Risks of Use in Patients With Gastrointestinal Conditions

- Xtampza ER is contraindicated in patients with gastrointestinal obstruction, including paralytic ileus
- The oxycodone in Xtampza ER may cause spasm of the sphincter of Oddi. Opioids may cause increases in the serum amylase. Monitor patients with biliary tract disease, including acute pancreatitis, for worsening symptoms

Risk of Use in Patients With Seizure Disorders

- The oxycodone in Xtampza ER may increase the frequency of seizures in patients with seizure disorders and may increase the risk of seizures in other clinical settings associated with seizures. Monitor patients with a history of seizure disorders for worsened seizure control during Xtampza ER therapy

Withdrawal

- Avoid the use of mixed agonist/antagonist (e.g., pentazocine, nalbuphine, and butorphanol) or partial agonist (e.g., buprenorphine) analgesics in patients who have received or are receiving a course of therapy with a full opioid agonist analgesic, including Xtampza ER. In these patients, mixed agonist/antagonist and partial agonist analgesics may reduce the analgesic effect and/or may precipitate withdrawal symptoms
- When discontinuing Xtampza ER, gradually taper the dosage. Do not abruptly discontinue Xtampza ER

Risks of Driving and Operating Machinery

- Xtampza ER may impair the mental or physical abilities needed to perform potentially hazardous activities such as driving a car or operating machinery. Warn patients not to drive or operate dangerous machinery unless they are tolerant to the effects of Xtampza ER and know how they will react to the medication

Laboratory Monitoring

- Not every urine drug test for "opioids" or "opiates" detects oxycodone reliably, especially those designed for in-office use. Further, many laboratories will report urine drug concentrations below a specified "cut-off" value as "negative." Therefore, if urine testing for oxycodone is considered in the clinical management of an individual patient, ensure that the sensitivity and specificity of the assay is appropriate, and consider the limitations of the testing used when interpreting results

ADMINISTRATION WITH FOOD:

- Instruct patients to always take Xtampza ER capsules with food and with approximately the same amount of food in order to ensure consistent plasma levels are achieved. For patients who have difficulty swallowing, Xtampza ER can also be taken by sprinkling the capsule contents on soft foods, into a cup and then directly into the mouth, or through a gastrostomy or nasogastric feeding tube

ADVERSE REACTIONS:

- The most common adverse reactions (>5%) reported by patients in the Phase 3 clinical trial were nausea, headache, constipation, somnolence, pruritus, vomiting, and dizziness

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COLLEGIUM Pharmaceutical
Ingenuity in Medicine

Xtampza® ER
(oxycodone) EXTENDED-RELEASE CAPSULES II

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.
- 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
- problems urinating
- liver, kidney, thyroid problems
- 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, 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

This Medication Guide has been approved by the U.S. Food and Drug Administration. Issued: April 2016