



## Collegium Announces 10 Poster Presentations at PAINWeek Conference 2023

August 28, 2023

STOUGHTON, Mass., Aug. 28, 2023 (GLOBE NEWSWIRE) -- [Collegium Pharmaceutical, Inc.](https://www.collegiumpharm.com) (Nasdaq: COLL), a leading, diversified specialty pharmaceutical company committed to improving the lives of people living with serious medical conditions, today announced that 10 poster presentations highlighting data regarding its diversified pain portfolio will be presented at PAINWeek Conference 2023, being held in Las Vegas, NV from September 5–8, 2023.

“Collegium is dedicated to responsible pain management and leading with science. We are pleased to present 10 posters with new real-world data at PAINWeek 2023 that underscore the clinical and population health impact of our portfolio and provide significant insights for healthcare decision makers who treat people experiencing pain,” said Thomas Smith, M.D., Chief Medical Officer of Collegium. “We welcome opportunities to share clinical and real-world data with the medical community as part of our commitment to improving the lives of people living with serious medical conditions.”

The following poster presentations will also be available on the PAINWeek Conference 2023 website on Wednesday, September 6, 2023, from 3:30 – 4:30 p.m. PT and on Thursday, September 7, 2023, from 3:30 – 5:30 p.m. PT.

### Poster Presentations:

Poster Title:	Healthcare Cost and Resource Use in Chronic Low Back Pain Patients Treated with Belbuca® and Buprenorphine Transdermal Patches: A Retrospective US Commercial Claims Analysis
Authors:	Vladimir Zah, Filip Stanicic, Todd Kunkel, Djurdja Vukicevic, Dimitrije Grbic
Poster Title:	Treatment Characteristics of Chronic Low Back Pain Patients Treated with Belbuca® and Buprenorphine Transdermal Patches: A Retrospective US Commercial Claims Analysis
Authors:	Vladimir Zah, Filip Stanicic, Todd Kunkel, Djurdja Vukicevic, Dimitrije Grbic
Poster Title:	Safety and Tolerability of Buprenorphine and Oral Schedule II Opioid Treatment in Chronic Low Back Pain Patients: A Retrospective US Commercial Claims Analysis
Authors:	Vladimir Zah, Filip Stanicic, Todd Kunkel, Djurdja Vukicevic, Dimitrije Grbic
Poster Title:	Healthcare Costs Associated with Rates of Prescription Opioid Misuse/Abuse
Authors:	Jody L. Green, Taryn Dailey-Govoni, Suzanne K. Vosburg
Poster Title:	Sustained Risk Reduction of Severe Clinical Outcomes Following Misuse/Abuse of XTAMPZA® ER as Compared to Other Prescription Opioids
Authors:	Jody L. Green, Taryn Dailey-Govoni, Suzanne K. Vosburg
Poster Title:	Differences in the Severity of Medical Outcomes of Exposures Reported to Poison Centers Involving XTAMPZA® ER and Other Opioid Analgesics
Authors:	Brooke Kritikos, Stevan Severtson, Joshua C. Black, Heather Olsen, Janetta Iwanicki, Richard C. Dart
Poster Title:	Real-world Impact of Abuse-Deterrent Formulation of XTAMPZA® ER in the Context of Behaviors Around Tampering with XTAMPZA® ER and Other Opioid Products
Authors:	Evelyn Fox, Jennifer S. Jewell, Joshua C. Black, Matthew S. Ellis, Heather Olsen, Hannah L. Burkett, Janetta Iwanicki, Richard C. Dart
Poster Title:	Use of Causal Framework to Evaluate Effect of Abuse Deterrent Properties of XTAMPZA® ER on Opioid Tampering in a Post-Market Setting
Authors:	Karilynn M. Rockhill, Hannah L. Burkett, Richard C. Dart, Joshua C. Black
Poster Title:	Changes in Oxycodone Misuse and Abuse Trends Across COVID-19: A Look Back
Authors:	Jennifer S. Jewell, Karilynn M. Rockhill, Joshua C. Black, Hannah L. Burkett, Matthew S. Ellis, Sabrina Kaplan, Richard C. Dart
Poster Title:	Association Between Per Capita Prescribing and Abuse of Tapentadol and Other Opioids Among Individuals Entering Treatment For Opioid Use Disorders
Authors:	Megan Healy, Stevan Severtson, Annika Czizik, Matthew S. Ellis, Joshua C. Black, Heather Olsen, Janetta Iwanicki, Richard C. Dart

For more information on PAINWeek Conference 2023, visit: <https://www.painweek.org/>.

Xtampza® ER (oxycodone) extended-release capsules, CII, Nucynta® ER (tapentadol) extended-release tablets, CII, and Nucynta® (tapentadol)

tablets, CII, can be abused or misused, and carry a risk of addiction. These products are intended for use only in appropriate pain patients and only when other treatment alternatives are inadequate. Use of Xtampza<sup>®</sup> ER, Nucynta<sup>®</sup> ER and Nucynta<sup>®</sup> can result in serious, life-threatening or fatal respiratory depression, even when used exactly as prescribed. **See Important Safety Information, including Boxed Warning on addiction, abuse, and misuse and other serious risks regarding each of these three products at the end of this press release.**

#### About Collegium Pharmaceutical, Inc.

Collegium is a diversified, specialty pharmaceutical company committed to improving the lives of people living with serious medical conditions. Collegium's headquarters are located in Stoughton, Massachusetts. For more information, please visit the Company's website at [www.collegiumpharma.com](http://www.collegiumpharma.com).

#### INDICATIONS AND USAGE

##### Xtampza<sup>®</sup> ER (oxycodone) 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

**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 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 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](http://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 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 [dailymed.nlm.nih.gov](http://dailymed.nlm.nih.gov).**

**See full Prescribing Information, including Boxed Warning on Addiction, Abuse and Misuse and other serious risks, and the Medication Guide accompanying this piece or at [XtampzaER.com/PI](http://XtampzaER.com/PI). Speak to your healthcare provider if you have questions about Xtampza ER.**

**APPROVED USE**

**BELBUCA® (buprenorphine buccal film) CIII 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 opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed, 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 BELBUCA®**

**WARNING: ADDICTION, ABUSE, AND MISUSE; RISK EVALUATION AND MITIGATION STRATEGY (REMS); LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL EXPOSURE; NEONATAL OPIOID WITHDRAWAL SYNDROME; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES AND OTHER CNS DEPRESSANTS**

### Addiction, Abuse, and Misuse

BELBUCA 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 BELBUCA, and monitor regularly for these behaviors and conditions.

### Risk Evaluation and Mitigation Strategy (REMS)

To ensure that the benefits of opioid analgesics outweigh the risks of addiction, abuse, and misuse, the 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 BELBUCA. Monitor for respiratory depression, especially during initiation of BELBUCA or following a dose increase. Misuse or abuse of BELBUCA by chewing, swallowing, snorting, or injecting buprenorphine extracted from the buccal film will result in the uncontrolled delivery of buprenorphine and poses a significant risk of overdose and death.

### Accidental Exposure

Accidental exposure to even one dose of BELBUCA, especially in children, can result in a fatal overdose of buprenorphine.

### Neonatal Opioid Withdrawal Syndrome

Prolonged use of BELBUCA during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated. If prolonged opioid use is required in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.

### 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 for use in patients for whom alternative treatment options are inadequate; limit dosages and durations to the minimum required; and follow patients for signs and symptoms of respiratory depression and sedation.

### Important information about BELBUCA:

- **Get emergency help or call 911 right away if you take too much BELBUCA (overdose).** When you first start taking BELBUCA, when your dose is changed, or if you take too much (overdose), serious or 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 opioid overdose.
- Taking BELBUCA 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 BELBUCA. They could die from taking it. Selling or giving away BELBUCA is against the law.
- Store BELBUCA securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.

### Do not use BELBUCA if you have:

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.

### Before taking BELBUCA, tell your healthcare provider if you have a history of:

- head injury, seizures
- heart rhythm problems (long QT syndrome)
- liver, kidney, thyroid problems
- tooth problems, including a history of cavities
- pancreas or gallbladder problems
- problems urinating
- 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 BELBUCA 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 BELBUCA. 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 BELBUCA with certain other medicines can cause serious side effects and could lead to death.

### When taking BELBUCA:

- Do not change your dose. Apply BELBUCA exactly as prescribed by your healthcare provider. Use the lowest effective dose possible for the shortest time needed.
- See the detailed Instructions for Use for information about how to apply BELBUCA.
- Do not apply BELBUCA if the package seal is broken or the film is cut, damaged, or changed in any way.
- After the film has adhered to your cheek, avoid eating or drinking until the film has completely dissolved, usually within 30 minutes.
- After BELBUCA is completely dissolved, rinse your mouth with water and swallow. Wait for at least one hour before brushing teeth.
- Report any problems with your teeth immediately to your healthcare provider and schedule an appointment with a dentist. Tell your dentist that you have started taking BELBUCA.

- Avoid touching or moving the buccal film with your tongue or fingers.
- **Do not chew, swallow, snort or inject BELBUCA. This will result in uncontrolled delivery of buprenorphine and may cause you to overdose and die.**
- **Call your healthcare provider if the dose you are using does not control your pain.**
- **Do not stop using BELBUCA without talking to your healthcare provider.**
- Dispose of expired, unwanted, or unused BELBUCA by removing the BELBUCA film from the foil packaging, and promptly flushing down the toilet (if a drug takeback option is not readily available). Visit [www.fda.gov/drugdisposal](http://www.fda.gov/drugdisposal) for additional information on disposal of unused medicines.

**While using BELBUCA DO NOT:**

- Drive or operate heavy machinery, until you know how BELBUCA affects you. BELBUCA can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines containing alcohol. Using products containing alcohol during treatment with BELBUCA may cause you to overdose and die.

**The possible side effects of BELBUCA are:**

- nausea, constipation, headache, vomiting, dizziness, and sleepiness. 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, lightheadedness 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 BELBUCA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. For more information, go to [dailymed.nlm.nih.gov](http://dailymed.nlm.nih.gov).

Please see [full Prescribing Information](#), including **Boxed Warning on Addiction, Abuse, and Misuse**, and other serious risks, and [Medication Guide](#) or speak to your healthcare provider if you have questions about BELBUCA.

**INDICATIONS AND USAGE**

**NUCYNTA® (tapentadol) tablets are:**

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage short term (acute) pain in adults and children 6 years of age and older who weigh at least 88 pounds (40 kg), when other pain treatments such as non-opioid pain medicines do not treat your pain well enough or you cannot tolerate them.
- An opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed, you are at risk for opioid addiction, abuse, and misuse that can lead to death.

**IMPORTANT SAFETY INFORMATION ABOUT NUCYNTA TABLETS**

**WARNING: SERIOUS AND LIFE-THREATENING RISKS FROM USE OF NUCYNTA TABLETS**

**Addiction, Abuse, and Misuse**  
Because the use of NUCYNTA tablets 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 and reassess regularly for the development of these behaviors and conditions.

**Life-Threatening Respiratory Depression**  
Serious, life-threatening, or fatal respiratory depression may occur with use of NUCYNTA tablets, especially during initiation of NUCYNTA tablets or following a dose increase. To reduce the risk of respiratory depression, proper dosing and titration of NUCYNTA tablets are essential.

**Accidental Ingestion**  
Accidental ingestion of even one dose of NUCYNTA tablets, especially by children, can result in a fatal overdose of tapentadol.

**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 NUCYNTA tablets and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate.

**Neonatal Opioid Withdrawal Syndrome**  
If opioid use is required for an extended period of time in a pregnant woman, advise the patient of the risk of Neonatal Opioid Withdrawal Syndrome 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.

**Important information about NUCYNTA tablets:**

- **Get emergency help or call 911 right away if you take too much NUCYNTA (overdose) tablets.** When you first start taking NUCYNTA tablets, when your dose is changed, or if you take too much (overdose), serious or 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 opioid overdose.
- Taking NUCYNTA tablets 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 NUCYNTA tablets. They could die from taking it. Selling or giving away NUCYNTA tablets is against the law.

- Store NUCYNTA tablets securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.

**Do not take NUCYNTA tablets if you have:**

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.

**Before taking NUCYNTA tablets, tell your healthcare provider if you have a history of:**

- head injury, seizures
- problems urinating
- abuse of street or prescription drugs, alcohol addiction, opioid overdose or mental health problems
- liver, kidney, thyroid problems
- pancreas or gallbladder problems

**Tell your healthcare provider if you:**

- **notice your pain getting worse.** If your pain gets worse after you take NUCYNTA tablets, do not take more NUCYNTA tablets without first talking to your healthcare provider. Tell your healthcare provider if the pain that you have increases, if you feel more sensitive to pain, or if you have new pain after taking NUCYNTA tablets.
- **are pregnant or planning to become pregnant.** Use of NUCYNTA tablets for an extended period of time during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- **are breastfeeding.** NUCYNTA tablets pass into breast milk and may harm your baby.
- are living in a household where there are small children or someone who has abused street or prescription drugs.
- are taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking NUCYNTA tablets with certain other medicines can cause serious side effects that could lead to death.

**When taking NUCYNTA tablets:**

- Do not change your dose. Take NUCYNTA tablets exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed.
- For acute (short-term) pain, you may only need to take NUCYNTA tablets for a few days. You may have some NUCYNTA tablets left over that you did not use. See disposal information at the bottom of this section for directions on how to safely throw away (dispose of) your unused NUCYNTA tablets.
- Take your prescribed dose every 4-6 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.
- Call your healthcare provider if the dose you are taking does not control your pain.
- If you have been taking NUCYNTA tablets regularly, do not stop taking NUCYNTA tablets without talking to your healthcare provider.
- Dispose of expired, unwanted, or unused NUCYNTA Tablets by promptly flushing down the toilet, if a drug take-back option is not readily available. Visit [www.fda.gov/drugdisposal](http://www.fda.gov/drugdisposal) for additional information on disposal of unused medicines.

**While taking NUCYNTA tablets, DO NOT:**

- Drive or operate heavy machinery, until you know how NUCYNTA tablets affect you. NUCYNTA tablets 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 NUCYNTA tablets may cause you to overdose and die.

**The possible side effects of NUCYNTA tablets:**

- 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, lightheadedness when changing positions, feeling faint, agitation, high body temperature, trouble walking, stiff muscles, or mental changes such as confusion.

These are not all of the possible side effects of NUCYNTA tablets. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information, go to [dailymed.nlm.nih.gov](http://dailymed.nlm.nih.gov).**

**See full Prescribing Information, including Boxed Warning on Addiction, Abuse and Misuse and other serious risks, and the Medication Guide accompanying this piece or at [Nucynta.com/IRpi](http://Nucynta.com/IRpi). Speak to your healthcare provider if you have questions about Nucynta.**

**INDICATIONS AND USAGE**

**NUCYNTA® ER (tapentadol) 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.
- Also used to manage pain from damaged nerves (neuropathic pain) that happens with diabetes and is severe enough to require daily, around-the-clock, long-term treatment with an opioid when other pain treatments, such as non-opioid 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, you are at risk for opioid addiction, abuse, and misuse that can lead to death.
- Not used to treat pain that is not around-the-clock pain.

**IMPORTANT SAFETY INFORMATION ABOUT NUCYNTA ER**

**WARNING: ADDICTION, ABUSE, AND MISUSE; RISK EVALUATION AND MITIGATION STRATEGY (REMS); LIFE-THREATENING**

**RESPIRATORY DEPRESSION; ACCIDENTAL INGESTION; NEONATAL OPIOID WITHDRAWAL SYNDROME; INTERACTION WITH ALCOHOL and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS**

**Addiction, Abuse, and Misuse**

NUCYNTA 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 NUCYNTA ER, and monitor all patients regularly for the development of these behaviors and 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 NUCYNTA ER. Monitor for respiratory depression, especially during initiation of NUCYNTA ER or following a dose increase. Instruct patients to swallow NUCYNTA ER tablets whole; crushing, chewing, or dissolving NUCYNTA ER tablets can cause rapid release and absorption of a potentially fatal dose of tapentadol.

**Accidental Ingestion**

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

**Neonatal Opioid Withdrawal Syndrome**

Prolonged use of NUCYNTA 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.

**Interaction With Alcohol**

Instruct patients not to consume alcoholic beverages or use prescription or non-prescription products that contain alcohol while taking NUCYNTA ER. The co-ingestion of alcohol with NUCYNTA ER may result in increased plasma tapentadol levels and a potentially fatal overdose of tapentadol.

**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 NUCYNTA 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 information about NUCYNTA ER:**

- **Get emergency help or call 911 right away if you take too much NUCYNTA ER (overdose).** When you first start taking NUCYNTA ER, when your dose is changed, or if you take too much (overdose), serious or 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 opioid overdose.
- Taking NUCYNTA 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 your NUCYNTA ER. They could die from taking it. Selling or giving away NUCYNTA ER Tablets is against the law.
- Store NUCYNTA ER Tablets securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.

**Do not take NUCYNTA 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 NUCYNTA ER, tell your healthcare provider if you have a history of:**

- head injury, seizures
- problems urinating
- abuse of street or prescription drugs, alcohol addiction, opioid overdose or mental health problems
- liver, kidney, thyroid problems
- pancreas or gallbladder problems

**Tell your healthcare provider if you are:**

- **pregnant or planning to become pregnant.** Prolonged use of NUCYNTA 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 NUCYNTA 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 NUCYNTA ER with certain other medicines can

cause serious side effects.

#### When taking NUCYNTA ER:

- Do not change your dose. Take NUCYNTA ER exactly as prescribed by your healthcare provider. Use the lowest effective dose 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 in 24 hours. If you miss a dose, take your next dose at your usual time
- Swallow NUCYNTA ER whole. Do not cut, break, chew, crush, dissolve, snort, or inject NUCYNTA ER because this may cause you to overdose and die.
- **Call your healthcare provider if the dose you are taking does not control your pain**
- **Do not stop taking NUCYNTA ER without talking to your healthcare provider**
- Dispose of expired, unwanted, or unused NUCYNTA ER Tablets by promptly flushing down the toilet if a drug take-back option is not readily available. Visit [www.fda.gov/drugdisposal](http://www.fda.gov/drugdisposal) for additional information on disposal of unused medicines.

#### While taking NUCYNTA ER DO NOT:

- Drive or operate heavy machinery until you know how NUCYNTA ER affects you.  
NUCYNTA ER can make you sleepy, dizzy, or lightheaded.
- Drink alcohol, or use prescription or over-the-counter medicines containing alcohol. Using products containing alcohol during treatment with NUCYNTA ER may cause you to overdose and die.

#### The possible side effects of NUCYNTA 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, lightheadedness when changing positions, feeling faint, agitation, high body temperature, trouble walking, stiff muscles, or mental changes such as confusion.
- agitation, hallucinations, coma, feeling overheated, or heavy sweating.

These are not all the possible side effects of NUCYNTA ER. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information, go to [dailymed.nlm.nih.gov](http://dailymed.nlm.nih.gov).**

**See full Prescribing Information, including Boxed Warning on Addiction, Abuse and Misuse and other serious risks, and the Medication Guide accompanying this piece or at [Nucynta.com/PI](http://Nucynta.com/PI). Speak to your healthcare provider if you have questions about Nucynta ER.**

#### Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. We may, in some cases, use terms such as “predicts,” “forecasts,” “believes,” “potential,” “proposed,” “continue,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “should” or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Examples of forward-looking statements contained in this press release include, among others, statements related to our pursuit of a pediatric extension of exclusivity for the Nucynta franchise. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results, performance, or achievements to differ materially from the company’s current expectations, including the risks described under the heading “Risk Factors” in our Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q and other filings with the SEC. Any forward-looking statements that we make in this press release speak only as of the date of this press release. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

#### Investor Contact:

Christopher James, M.D.  
Vice President, Investor Relations  
[ir@collegiumpharma.com](mailto:ir@collegiumpharma.com)

#### Media Contact:

Marissa Samuels  
Vice President, Corporate Communications  
[communications@collegiumpharma.com](mailto:communications@collegiumpharma.com)



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