

## INDICATIONS AND USAGE

NUCYNTA<sup>®</sup> ER (tapentadol) is:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage severe and persistent pain in adults that requires an extended treatment period with a daily opioid pain medicine, when other pain medicines do not treat your pain well enough or you cannot tolerate them.
- Also used in adults to manage severe and persistent pain from damaged nerves (neuropathic pain) that happens with diabetes and that requires an extended treatment period with a daily opioid pain 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, 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: SERIOUS AND LIFE-THREATENING RISKS FROM USE OF NUCYNTA ER**

#### **Addiction, Abuse, and Misuse**

Because the use of 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 and reassess all patients 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 ER, especially during initiation or following a dosage increase. To reduce the risk of respiratory depression, proper dosing and titration of NUCYNTA ER are essential. 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.

#### **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.

**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.

**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 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:**

- noticing your pain getting worse. If your pain gets worse after you take NUCYNTA ER, do not take more of NUCYNTA ER without first talking to your healthcare provider. Talk to 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 ER.
- **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, light-headedness 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 healthcare provider 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/ERpi](http://Nucynta.com/ERpi). Speak to your healthcare provider if you have questions about Nucynta ER.**