

Medication Guide

NUCYNTA[®] ER (new-SINN-tah E-R) (tapentadol) extended-release oral tablets, CII

NUCYNTA[®] 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.
- 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 information about NUCYNTA[®] ER:

- **Get emergency help 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.
- Never give anyone your NUCYNTA[®] ER. They could die from taking it. Store NUCYNTA[®] ER away from children and in a safe place to prevent stealing or abuse. Selling or giving away NUCYNTA[®] ER is against the law.

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, 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.** NUCYNTA[®] ER passes into breast milk and may harm your baby.
- 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.
- 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.**
- After you stop taking NUCYNTA[®] ER, flush any unused tablets down the toilet.

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 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, or you are feeling faint.
- 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**

Manufactured for: Janssen Pharmaceuticals, Inc. Titusville, NJ 08560, www.Nucynta.com or call 1-800-526-7736