

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 treat moderate to severe around-the-clock pain and pain from damaged nerves (neuropathic pain) that happens with diabetes.

Important information about NUCYNTA[®] ER:

- Get emergency help right away if you take too much NUCYNTA[®] ER (overdose). NUCYNTA[®] ER overdose can cause life threatening breathing problems that can lead to death.
- Never give anyone else 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.
- taken a monoamine oxidase inhibitor (MAOI) medicine or have taken a MAOI medicine within the last 14 days.

Before taking NUCYNTA[®] 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, or mental health problems.

Tell your healthcare provider if you are:

- **pregnant or planning to become pregnant.** NUCYNTA[®] ER may harm your unborn baby.
- **breastfeeding.** NUCYNTA[®] ER passes into breast milk and may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements.

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 the missed dose as soon as possible. If it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule.
- Swallow NUCYNTA[®] ER whole with enough water to make sure that you completely swallow the tablet right away. Do not cut, break, chew, crush, dissolve, or inject NUCYNTA[®] ER.
- **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 that contain alcohol.

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, a seizure, 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 by: Janssen Ortho LLC, Gurabo, PR 00778; Manufactured for: Janssen Pharmaceuticals, Inc. Titusville, NJ 08560, www.Nucynta.com or call 1-800-526-7736