

## Medication Guide

### NUCYNTA<sup>®</sup> ER (new-SINN-tah E-R) (tapentadol) extended-release oral tablets, CII

#### NUCYNTA<sup>®</sup> 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<sup>®</sup> ER:

- Get emergency help right away if you take too much NUCYNTA<sup>®</sup> ER (overdose). NUCYNTA<sup>®</sup> ER overdose can cause life threatening breathing problems that can lead to death.
- Never give anyone else your NUCYNTA<sup>®</sup> ER. They could die from taking it. Store NUCYNTA<sup>®</sup> ER away from children and in a safe place to prevent stealing or abuse. Selling or giving away NUCYNTA<sup>®</sup> ER is against the law.

#### Do not take NUCYNTA<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> ER may harm your unborn baby.
- **breastfeeding.** NUCYNTA<sup>®</sup> ER passes into breast milk and may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements.

#### When taking NUCYNTA<sup>®</sup> ER:

- Do not change your dose. Take NUCYNTA<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> ER.
- **Call your healthcare provider if the dose you are taking does not control your pain.**
- **Do not stop taking NUCYNTA<sup>®</sup> ER without talking to your healthcare provider.**
- After you stop taking NUCYNTA<sup>®</sup> ER flush any unused tablets down the toilet.

#### While taking NUCYNTA<sup>®</sup> ER Do Not:

- Drive or operate heavy machinery, until you know how NUCYNTA<sup>®</sup> ER affects you. NUCYNTA<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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 [daily.med.nlm.nih.gov](http://daily.med.nlm.nih.gov)**

Manufactured by: Janssen Ortho LLC, Gurabo, PR 00778; Manufactured for: Janssen Pharmaceuticals, Inc. Titusville, NJ 08560, [www.Nucynta.com](http://www.Nucynta.com) or call 1-800-526-7736