

MEDICATION GUIDE

NUCYNTA[®] ER (new-SINN-tah E-R) C-II

(tapentadol)

extended-release oral tablets

Important:

Keep NUCYNTA[®] ER in a safe place away from children. Accidental use by a child is a medical emergency and can result in death. If a child accidentally takes NUCYNTA[®] ER, get emergency help right away.

Read the Medication Guide that comes with NUCYNTA[®] ER before you start taking it and each time you get a new prescription. There may be new information. This Medication Guide does not take the place of talking to your doctor about your medical condition or your treatment. Talk to your doctor if you have any questions.

What is the most important information I should know about NUCYNTA[®] ER?

1. NUCYNTA[®] ER overdose can cause life-threatening breathing problems that can lead to death.

- **Take NUCYNTA[®] ER exactly as prescribed by your doctor.**
- NUCYNTA[®] ER is not for use for short-term pain relief from injuries or surgery.
- NUCYNTA[®] ER is not for use to treat pain that you only have once in a while (“as needed”).
- **Swallow NUCYNTA[®] ER tablets whole. Do not break, split, chew, dissolve, or crush NUCYNTA[®] ER tablets before swallowing, or inject the contents. If NUCYNTA[®] ER is taken in this way, the tapentadol in NUCYNTA[®] ER may be released too fast. This is dangerous. It may cause you to have trouble breathing and lead to death.**

- If you cannot swallow NUCYNTA[®] ER tablets whole, tell your doctor. You will need a different pain medicine.
 - Do not drink alcohol, or use prescription or non-prescription medicines that contains alcohol while you are being treated with NUCYNTA[®] ER. Alcohol can cause very high levels of tapentadol in your blood and you can die due to an overdose of tapentadol.
 - It is important to stay under the care of your doctor while taking NUCYNTA[®] ER.
2. **Prevent theft, misuse, or abuse. Keep NUCYNTA[®] ER in a safe place to protect it from being stolen. NUCYNTA[®] ER can be a target for people who misuse or abuse prescription medicines or street drugs.**
 3. **Never give NUCYNTA[®] ER to anyone else, even if they have the same symptoms you have. It may harm them or even cause death. Selling or giving away this medicine is against the law.**

What is NUCYNTA[®] ER?

- NUCYNTA[®] ER is a prescription medicine that contains the opioid (narcotic) pain medicine tapentadol. The medicine in NUCYNTA[®] ER is slowly released over time. **If you split, break, chew, dissolve, or crush NUCYNTA[®] ER before swallowing, or inject the contents, the tapentadol may be released too fast and you may overdose.** See “What is the most important information I should know about NUCYNTA[®] ER?”
- NUCYNTA[®] ER is a strong opioid pain medicine. NUCYNTA[®] ER is used in adults to treat moderate to severe pain that continues around-the-clock and is expected to last for a long period of time.
- NUCYNTA[®] ER is not for use for short-term pain relief from injuries or surgery.
- NUCYNTA[®] ER is not for use to treat pain that you only have once in a while (“as needed”).
- **NUCYNTA[®] ER is a federally controlled substance (CII)** because it contains strong opioid pain medicine that can be a target for people who abuse prescription medicines or street drugs.

- It is not known if NUCYNTA[®] ER is safe and works in children less than 18 years of age. NUCYNTA[®] ER should not be used in children.

Who should not take NUCYNTA[®] ER?

Do not take NUCYNTA[®] ER if you:

- have trouble breathing or lung problems such as severe asthma, wheezing, or shortness of breath.
- have a bowel blockage called paralytic ileus.
- **take a monoamine oxidase inhibitor (MAOI) medicine or have taken an MAOI medicine within the last 14 days.** Ask your doctor or pharmacist if any of your medicines is a MAOI.
- are allergic to tapentadol or any of the ingredients in NUCYNTA[®] ER. See the end of this Medication Guide for a complete list of ingredients in NUCYNTA[®] ER.

What should I tell my doctor before taking NUCYNTA ER?

NUCYNTA[®] ER may not be right for you.

Before taking NUCYNTA[®] ER, tell your doctor if you:

- have trouble breathing or lung problems such as asthma, wheezing, or shortness of breath
- have had a head injury or a brain problem
- have liver or kidney problems
- have adrenal gland problems, such as Addison's disease
- have thyroid problems
- have convulsions or seizures
- have pancreas or gallbladder problems
- have problems urinating or prostate problems
- have constipation
- have severe scoliosis that affects your breathing
- have low blood pressure
- have or had a drinking problem or alcoholism or a family history of this problem

- have mental problems including depression, anxiety, or hallucinations (seeing or hearing things that are not really there)
- have or had drug abuse or addiction problems or a family history of this problem
- plan to have surgery
- **are pregnant or plan to become pregnant.**

If you take NUCYNTA[®] ER right before your baby is born, your baby could have breathing problems.

If you take NUCYNTA[®] ER regularly before your baby is born, your newborn baby may have withdrawal symptoms, because his/her body has become used to the medicine.

Symptoms of withdrawal in a newborn baby may include:

- irritability
 - crying more than usual
 - shaking (tremors)
 - jitteriness
 - breathing faster than normal
 - diarrhea or more stools than normal
 - vomiting
 - fever
- **are breastfeeding.** You should not breastfeed while taking NUCYNTA[®] ER. Talk to your doctor about the best way to feed your baby if you take NUCYNTA[®] ER.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Some medicines may cause serious or life-threatening medical problems when taken with NUCYNTA[®] ER. Sometimes, the doses of certain other medicines and NUCYNTA[®] ER need to be changed.

Especially tell your doctor if you take:

- Selective Serotonin Reuptake Inhibitors (SSRIs), Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs), tricyclic antidepressants, tramadol, and triptan medicines. See “What are the possible side effects of NUCYNTA[®] ER?”
- Other medicines that make you sleepy such as:

- other pain medicines
- antidepressant medicines, including those listed above
- sleeping pills
- antihistamines
- anti-anxiety medicines
- muscle relaxants
- anti-nausea medicines
- tranquilizers

Do not take NUCYNTA[®] ER if you take a monoamine oxidase inhibitor (MAOI) medicine. See "Who should not take NUCYNTA[®] ER?"

Do not take any new medicine while using NUCYNTA[®] ER until you have talked to your doctor or pharmacist. They will tell you if it is safe to take other medicines while you are taking NUCYNTA[®] ER. **Ask your doctor if you are not sure if your medicine is one of the listed above.**

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I take NUCYNTA[®] ER?

- **Take NUCYNTA[®] ER exactly as prescribed by your doctor. Do not change the dose unless your doctor tells you to.**
- Your doctor may change your dose after seeing how NUCYNTA[®] ER affects you.
- You can take NUCYNTA[®] ER with or without food.
- **Swallow NUCYNTA[®] ER whole.** You must take NUCYNTA[®] ER one tablet at a time, with enough water to make sure that you completely swallow the tablet right away. Do not soak, lick, or wet the tablet before putting it in your mouth.
- **Do not break, split, chew, dissolve, or crush NUCYNTA[®] ER tablets before swallowing, or inject the contents.** If you cannot swallow tablets, tell your doctor. See "What is the most important information I should know about NUCYNTA[®] ER?"
- **If you miss a dose,** take it 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. **Do not take 2 doses at the same time unless your doctor tells you to.** If you are not sure about your dosing call your doctor.
- **If you take too much NUCYNTA[®] ER or overdose, get emergency help right away.**

- Call your doctor if your pain is not well controlled while taking NUCYNTA[®] ER.
- Follow your doctor's instructions about how to slowly stop taking NUCYNTA[®] ER to help prevent uncomfortable withdrawal symptoms.

What should I avoid while taking NUCYNTA[®] ER?

- **Do not drive, operate machinery, or do other dangerous activities,** until you know how NUCYNTA[®] ER affects how alert you are. NUCYNTA[®] ER can make you sleepy.

What are the possible side effects of NUCYNTA[®] ER?

NUCYNTA[®] ER can cause serious side effects including:

- **Life-threatening breathing problems. Call your doctor right away or get emergency medical help if you:**
 - have trouble breathing
 - have extreme drowsiness with slowed breathing
 - have shallow breathing (little chest movement with breathing)
 - feel faint, dizzy, confused, or have other unusual symptoms
 - have a seizure
- **Decreased blood pressure.** This can make you feel dizzy and faint if you get up too fast from sitting or lying down. Low blood pressure is more likely to happen if you take other medicines that can also lower your blood pressure. Severe low blood pressure can happen if you lose blood or take certain other medicines.
- **Serotonin syndrome.** Serotonin syndrome is a rare, life-threatening condition that could happen if you take NUCYNTA[®] ER with SSRIs, SNRIs, MAOIs, triptans, tricyclic antidepressants, tramadol, or certain other medicines. Serotonin syndrome can cause death. See "What should I tell my doctor before taking NUCYNTA[®] ER?"

You or someone else should call your doctor or get medical help right away if you have any of these symptoms:

- you feel agitated or restless, or have hallucinations
- you pass out (become unconscious). Serotonin syndrome can cause you to go into coma
- you have a fast heartbeat or feel overheated
- you have heavy sweating that is not due to activity, or loss of coordination

You may have nausea, vomiting, or diarrhea with any of the symptoms listed above.

- **NUCYNTA[®] ER could cause seizures in people who are at risk for having seizures or who have epilepsy. If you have a seizure while taking NUCYNTA[®] ER, stop taking NUCYNTA[®] ER and call your doctor right away.**
- **Physical Dependence.** Do not stop taking NUCYNTA[®] ER or any other opioid without talking to your doctor. You could become sick with uncomfortable withdrawal symptoms because your body has become used to these medicines. Physical dependence is not the same as drug addiction.
- **There is a chance of abuse or addiction with NUCYNTA[®] ER.** The chance is higher if you are, or have been addicted to or abused other medicines, street drugs, or alcohol, or if you have a history of mental problems.

The most common side effects with NUCYNTA[®] ER are:

- nausea
- constipation
- headache
- dizziness
- sleepiness

Constipation (not enough or hard bowel movements) is a common side effect of pain medicines (opioids), including NUCYNTA[®] ER, and is unlikely to go away without treatment. Talk to your doctor about dietary change, and the use of laxatives (medicines to treat constipation) and stool softeners to prevent or treat constipation while taking NUCYNTA[®] ER.

Talk to your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of NUCYNTA[®] ER. For a complete list, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store NUCYNTA[®] ER?

- **Keep NUCYNTA[®] ER in a safe place away from children.**
- **Keep NUCYNTA[®] ER in the container it comes in.**

- Store NUCYNTA ER between 68°F to 77°F (20°C to 25°C). Keep NUCYNTA ER tablets dry.
- **After you stop taking NUCYNTA[®] ER, flush the unused tablets down the toilet.**

General information about NUCYNTA[®] ER

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use NUCYNTA[®] ER for a condition for which it was not prescribed. Do not give NUCYNTA[®] ER to other people, even if they have the same symptoms you have. It may harm them and even cause death. **Sharing NUCYNTA[®] ER is against the law.**

This Medication Guide summarizes the most important information about NUCYNTA[®] ER. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about NUCYNTA[®] ER that is written for healthcare professionals. For more information about NUCYNTA[®] ER call 1-800-526-7736 or go to www.NUCYNTAERREMS.com.

What are the ingredients in NUCYNTA[®] ER?

Active Ingredient: tapentadol HCl

Inactive ingredients: polyethylene oxide, hypromellose, polyethylene glycol and alpha-tocopherol (vitamin E).

The film coating contains polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, and the colorant FD&C Blue #2 aluminum lake is used for 100-, 150-, 200-, and 250-mg strengths; and additionally, yellow iron oxide is used in 150-mg tablets.

Printing inks for all strengths contain shellac glaze and propylene glycol. The 50, 100, 150, and 200 mg tablet printing ink also contains black iron oxide. The 250 mg tablet printing ink also contains titanium dioxide.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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