

17.2 Misuse and Abuse

Patients should be advised that NUCYNTA™ is a potential drug of abuse. Patients should protect NUCYNTA™ from theft, and NUCYNTA™ should never be given to anyone other than the individual for whom NUCYNTA™ was prescribed [see *Warnings and Precautions* (5.4)].

17.3 Interference with Cognitive and Motor Performance

As NUCYNTA™ has the potential to impair judgment, thinking, or motor skills, patients should be cautioned about operating hazardous machinery, including automobiles [see *Warnings and Precautions* (5.5)].

17.4 Pregnancy

Patients should be advised to notify their physician if they become pregnant or intend to become pregnant during treatment with NUCYNTA™ [see *Use in Specific Populations* (8.1)].

17.5 Nursing

Patients should be advised not to breast-feed an infant during treatment with NUCYNTA™ [see *Use in Specific Populations* (8.3)].

17.6 Monoamine Oxidase Inhibitors

Patients should be informed not to take NUCYNTA™ while using any drugs that inhibit monoamine oxidase. Patients should not start any new medications while taking NUCYNTA™ until they are assured by their healthcare provider that the new medication is not a monoamine oxidase inhibitor.

17.7 Seizures

Patients should be informed that NUCYNTA™ could cause seizures if they are at risk for seizures or have epilepsy. Such patients should be advised to use NUCYNTA™ with care [see *Warnings and Precautions* (5.7)]. Patients should be advised to stop taking NUCYNTA™ if they have a seizure while taking NUCYNTA™ and call their healthcare provider right away.

17.8 Serotonin Syndrome

Patients should be informed that NUCYNTA™ could cause rare but potentially life-threatening conditions resulting from concomitant administration of serotonergic drugs (including Serotonin Reuptake Inhibitors, Serotonin and Norepinephrine Reuptake Inhibitors and tricyclic antidepressants) [see *Warnings and Precautions* (5.8)].

Patients should be advised to inform their physicians if they are taking, or plan to take, any prescription or over-the-counter drugs as there is a potential for interactions [see *Drug Interactions* (7)].

17.9 Alcohol

Patients should be advised to avoid alcohol while taking NUCYNTA™ [see *Drug Interactions* (7.3)].

17.10 Medication Guide

See Medication Guide.

Manufactured by:

Janssen Ortho, LLC

Gurabo, PR 00778

Manufactured for:

PriCara®, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc.

Raritan, NJ 08869

Revised: June 2009

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MEDICATION GUIDE

NUCYNTA™ (new-SINN-tah)

(tapentadol)

immediate-release oral tablets C-II

- **NUCYNTA™ is a federally controlled substance (C-II) because it can be abused. Keep NUCYNTA™ in a safe place to prevent theft. Selling or giving away NUCYNTA™ may harm others, and is against the law.**
- **Tell your doctor if you (or a family member) have ever abused or been dependent on alcohol, prescription medicines, or street drugs.**

Read the Medication Guide that comes with NUCYNTA™ 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™?

NUCYNTA™ is a tablet that contains tapentadol, a strong medicine that is a pain medicine.

Use NUCYNTA™ exactly how your doctor tells you to. Do not use NUCYNTA™ if it has not been prescribed for you.

You should not take NUCYNTA™ if your pain is mild and can be controlled with other pain medicines such as non-steroidal anti-inflammatory medicines (NSAIDs) or acetaminophen.

What is NUCYNTA™?

• NUCYNTA™ is a prescription medicine that is used in adults 18 years of age or older to treat moderate to severe pain that is expected to last a short time.

NUCYNTA™ is for short-term use only because the risks for withdrawal symptoms, abuse and addiction are higher when NUCYNTA™ is used longer.

Who should not take NUCYNTA™?

Do not take NUCYNTA™ if you:

- have severe lung problems
- have a gastrointestinal problem called paralytic ileus in which the intestines are not working normally.
- take a monoamine oxidase inhibitor (MAOI) medicine or have taken an MAOI within the last 14 days. Ask your doctor or pharmacist if any of your medicines is an MAOI.

What should I tell my doctor before taking NUCYNTA™?

NUCYNTA™ may not be right for you. Tell your doctor about all your medical conditions, including if you have:

- trouble breathing or lung problems
- or had a head injury
- liver or kidney problems
- convulsions or seizures
- dependency problems with alcohol
- pancreas or gall bladder problems
- past or present substance abuse or drug addiction. There is a risk of abuse or addiction with narcotic pain medicines. If you have abused drugs in the past, you may have a higher chance of developing abuse or addiction again while using NUCYNTA™.
- are pregnant or plan to become pregnant
- are breast-feeding. You should not breast-feed while taking NUCYNTA™.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Using NUCYNTA™ with other medicines can cause serious side effects. The doses of some other medicines may need to be changed. Your doctor can tell you what medicines can be safely taken with NUCYNTA™. Especially tell your doctor if you take:

- **Monoamine Oxidase Inhibitors (MAOIs).** See "Who should not take NUCYNTA™."
- **any medicine that makes you sleepy.** NUCYNTA™ can make you sleepy and affect your breathing. Taking these medicines together can be dangerous.

How should I take NUCYNTA™?

- Do not take NUCYNTA™ unless it has been prescribed for you by your doctor.
- Take NUCYNTA™ exactly as prescribed by your doctor.
- **Do not change the dose of NUCYNTA™ unless your doctor tells you to.** Your doctor may change your dose after seeing how the medicine affects you. Do not use NUCYNTA™ more often than prescribed. Call your doctor if your pain is not well controlled while taking NUCYNTA™.
- Follow your doctor's instructions about how to slowly stop taking NUCYNTA™ to help lessen withdrawal symptoms.

- NUCYNTA™ can be taken with or without food.

What should I avoid while taking NUCYNTA™?

- Do not drive, operate machinery, or participate in any other possibly dangerous activities until you know how you react to this medicine. NUCYNTA™ can make you sleepy.
- You should not drink alcohol while using NUCYNTA™. Alcohol increases your chance of having dangerous side effects.

What are the possible side effects of NUCYNTA™?

NUCYNTA™ 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, or have slow or shallow breathing
- have a slow heartbeat
- have severe sleepiness
- have cold, clammy skin
- feel faint, dizzy, confused, or can not think, walk or talk normally
- have a seizure
- have hallucinations

- **Physical Dependence.** NUCYNTA™ can cause physical dependence. Talk to your doctor about slowly stopping NUCYNTA™ to avoid getting sick with withdrawal symptoms. You could become sick with uncomfortable symptoms because your body has become used to the medicine. Tell your doctor if you have any of these symptoms of withdrawal: feeling anxious, sweating, sleep problems, shivering, pain, nausea, tremors, diarrhea, upper respiratory symptoms, hallucinations, hair "standing on end." Physical dependence is not the same as drug addiction. Your doctor can tell you more about the differences between physical dependence and drug addiction.

- **Serotonin syndrome.** Serotonin syndrome is a rare, life-threatening problem that could happen if you take NUCYNTA™ with Selective Serotonin Reuptake Inhibitors (SSRIs), Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs), Monoamine Oxidase Inhibitors (MAOIs), triptans or certain other medicines. Call your doctor or get medical help right away if you have any one or more of the these symptoms: you feel agitated, have hallucinations, coma, rapid heart beat, feel overheated, loss of coordination, over active reflexes, nausea, vomiting, or diarrhea.

- **Seizures.** NUCYNTA™ can cause seizures in people who are at risk for seizures or who have epilepsy. Tell your doctor right away if you have a seizure and stop taking NUCYNTA™.

- **Low blood pressure.** This can make you feel dizzy if you get up too fast from sitting or lying down.

The common side effects with NUCYNTA™ are nausea, dizziness, vomiting, sleepiness, and itching.

Constipation is a common side effect of all opioid medicines. Talk to your doctor about the use of laxatives and stool softeners to prevent or treat constipation while taking NUCYNTA™.

Tell your doctor about any side effect that bothers you or that does not go away. These are not all the possible side effects of NUCYNTA™. 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™?

- Store NUCYNTA™ at 59°F to 86°F (15°C to 30°C). Keep NUCYNTA™ tablets dry.

- Dispose of NUCYNTA™ tablets you no longer need.

Keep NUCYNTA™ in a safe place out of the reach of children.

General information about NUCYNTA™

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use NUCYNTA™ for a condition for which it was not prescribed. **Do not give NUCYNTA™ to other people, even if they have the same symptoms you have. Sharing NUCYNTA™ could be harmful and is against the law.**

This Medication Guide summarizes the most important information about NUCYNTA™. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about NUCYNTA™ that is written for doctors. For more information about NUCYNTA™ call 1-800-526-7736.

What are the ingredients in NUCYNTA™?

Active Ingredient: tapentadol

Inactive ingredients: microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, povidone, magnesium stearate, and Opadry® II, a proprietary film-coating mixture containing polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, and aluminum lake coloring.

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

Revised: June 2009

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PRINCIPAL DISPLAY PANEL - 50 mg Bottle

NDC 50458-820-04

100 Tablets

NUCYNTA[™]

(tapentadol) Tablets

50 mg

CII

Each tablet contains:

tapentadol 50 mg

Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

Please see the Medication Guide provided by your pharmacist.



PRINCIPAL DISPLAY PANEL - 50 mg Box

NDC 50458-820-02

CII

NUCYNTA[™]

(tapentadol) Tablets

Please see the Medication Guide provided by your pharmacist.

PriCara[®]

**Division of Ortho-McNeil-Janssen
Pharmaceuticals, Inc.**

**PACKAGING NOT
CHILD RESISTANT**

Rx only

50 mg

10 blister strips, 10 tablets each.