

Medication Guide

NUCYNTA[®] (new-SINN-tah) (tapentadol) oral solution, CII

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

- Get emergency help right away if you take too much NUCYNTA[®] oral solution (overdose). NUCYNTA[®] oral solution can cause life threatening breathing problems that can lead to death.
- Never give anyone else your NUCYNTA[®] oral solution. They could die from taking it. Store NUCYNTA[®] oral solution away from children and in a safe place to prevent stealing or abuse. Selling or giving away NUCYNTA[®] oral solution is against the law.
- Do not change your dose. Take NUCYNTA[®] oral solution exactly as prescribed by your healthcare provider.
- Always use the oral syringe provided with NUCYNTA[®] oral solution, 20 mg/mL to help make sure you measure the right amount.

What is NUCYNTA[®] oral solution?

NUCYNTA[®] oral solution is a strong prescription pain medicine that contains an opioid (narcotic) that is used to treat moderate to severe pain that is expected to last a short time.

Who should not take NUCYNTA[®] oral solution?

Do not take NUCYNTA[®] oral solution if you:

- have severe asthma, trouble breathing, or other lung problems
- have a bowel blockage or narrowing of the stomach or intestines
- take a monoamine oxidase inhibitor (MAOI) medicine or have taken an MAOI medicine within the last 14 days
- are allergic to tapentadol or any of its ingredients.

What should I tell my healthcare provider before taking NUCYNTA[®] oral solution?

Before taking NUCYNTA[®] oral solution, 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[®] oral solution may harm your unborn baby.
- **breastfeeding.** NUCYNTA[®] oral solution may pass into your breast milk and harm your baby.
- planning to have surgery
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements.

How should I take NUCYNTA[®] oral solution?

- Do not change your dose. Take NUCYNTA[®] oral solution exactly as prescribed by your healthcare provider.
- If you miss a dose of NUCYNTA[®] oral solution you can take the dose when you remember if you have pain, or you can wait for the next dose.
- You can take NUCYNTA[®] oral solution with or without food.

- **Make sure you understand exactly how to measure your dose.** Always use the oral syringe provided with your NUCYNTA[®] oral solution to help make sure you measure the right amount. Call your pharmacist if you have difficulties with measuring your medicine.
- **Call your healthcare provider if the dose you are taking does not control your pain.**
- **Do not stop taking NUCYNTA[®] oral solution without talking to your healthcare provider.**
- After you stop taking NUCYNTA[®] oral solution, flush any unused oral solution down the toilet.

What should I avoid while taking NUCYNTA[®] oral solution?

While taking NUCYNTA[®] oral solution **do not**:

- Drive or operate heavy machinery, until you know how NUCYNTA[®] oral solution affects you. NUCYNTA[®] oral solution can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol.

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

The possible side effects of NUCYNTA[®] oral solution are:

- constipation, nausea, dizziness, vomiting, and sleepiness. 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.
- are feeling agitated or restless, have hallucinations, pass out (become unconscious), feel overheated, have heavy sweating that is not due to activity, or loss of coordination.

These are not all the possible side effects of NUCYNTA[®] oral solution.

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: Patheon Pharmaceuticals, Inc., Cincinnati, OH 45237

Manufactured for: Janssen Pharmaceuticals, Inc., Titusville, NJ 08560

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

Issue: October 2012

Instructions for Use

NUCYNTA[®] (tapentadol), CII

oral solution

20 mg/mL

Read the Instructions for Use before you start taking NUCYNTA[®] oral solution and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

Important information about measuring NUCYNTA[®] oral solution

- **Always use the oral syringe provided with your NUCYNTA[®] oral solution to make sure you measure the right amount.**
- You will be provided (See Figure A.):
 - 1 bottle of NUCYNTA[®] oral solution
 - 1 oral syringe
 - 1 adapter

If you do not receive an oral syringe with your NUCYNTA[®] oral solution, ask your pharmacist to give you one.

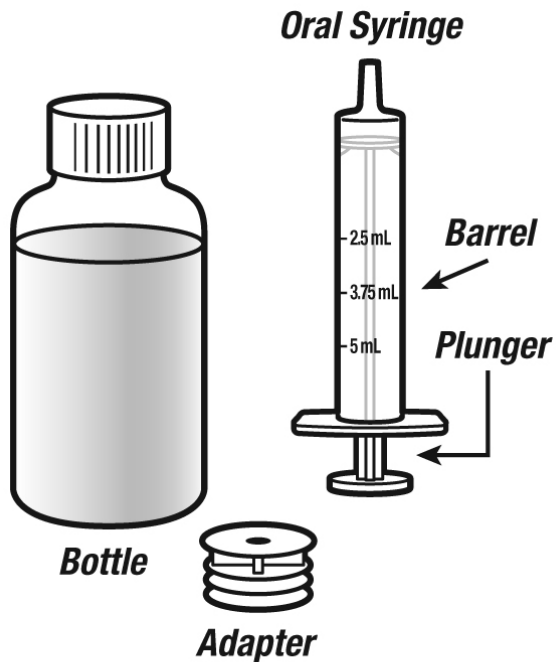


Figure A

Before you use NUCYNTA[®] oral solution for the first time:

1. Remove the child-resistant cap and completely remove the foil seal (See Figure B).



Figure B

2. Push the ribbed end of the adapter into the neck of the bottle until it is firmly in place. The bottom edge of the adapter should fully contact the top rim of the bottle (See Figure C). Do not remove the adapter from the bottle after it is inserted.



Figure C

To prepare a dose of NUCYNTA[®] oral solution:

3. Hold the oral syringe in one hand. With your other hand, fully push down (depress) the plunger (See Figure D).

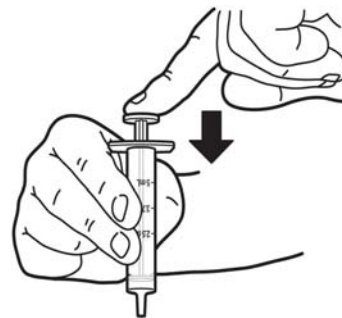


Figure D

4. Insert the tip of the oral syringe into the adapter (See Figure E).

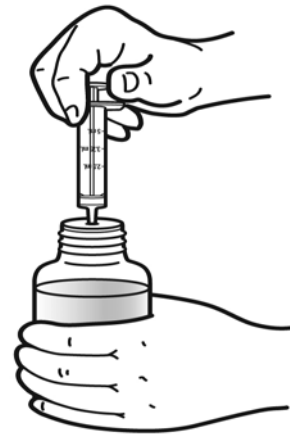


Figure E

5. Turn the bottle upside down. Pull back slowly on the oral syringe plunger to withdraw the dose prescribed by your healthcare provider (2.5 mL, 3.75 mL, or 5 mL). If you see air bubbles in the oral syringe, fully push in the plunger so that the oral solution flows back into the bottle. Then, withdraw your prescribed dose of oral solution (See Figure F).

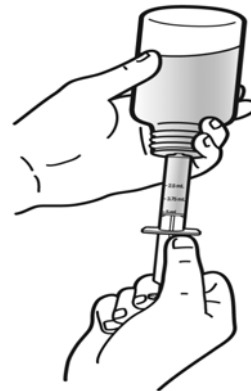


Figure F

6. Leave the oral syringe in the bottle adapter and turn the bottle right-side up. Place the bottle onto a flat surface. Remove the oral syringe from the bottle (See Figure G).

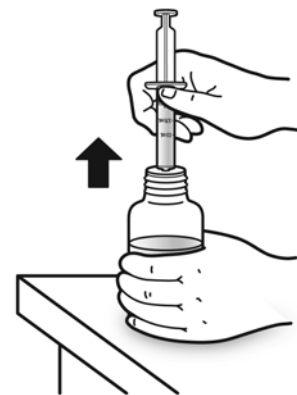


Figure G

- Place the tip of the oral syringe in your mouth. Squirt the oral solution into your mouth by pushing on the plunger until the oral syringe is empty (See Figure H).

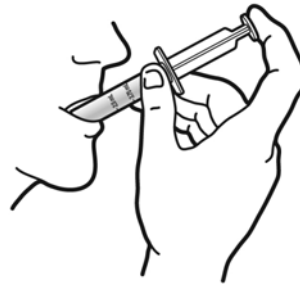


Figure H

- Leave the adapter in the bottle. Put the child-resistant cap back on the bottle. (See Figure I).

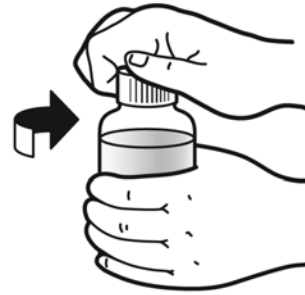


Figure I

- Remove the plunger from the oral syringe barrel. Rinse the oral syringe with water after each use and let it air dry. When the oral syringe is dry, put the plunger back into the oral syringe barrel for the next use. Do not throw away the oral syringe.

- Talk to your pharmacist if you have questions about how to use the oral syringe, or if you lose or misplace the oral syringe.

What are the ingredients in NUCYNTA[®] oral solution?

Active ingredient: tapentadol

Inactive ingredients: citric acid monohydrate, sucralose, raspberry flavor, sodium hydroxide, and purified water.

How should I store NUCYNTA[®] oral solution?

- Store NUCYNTA[®] oral solution at room temperature between 68°F to 77°F (20°C to 25°C).
- Store the NUCYNTA[®] oral solution bottle upright after opening. Keep the oral syringe with your medicine.
- After you stop taking NUCYNTA[®] oral solution, flush the unused oral solution down the toilet.

Keep NUCYNTA[®] oral solution out of the reach of children.

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Revised: October 2012

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