



NUCYNTA[®]
(tapentadol) TABLETS 

NUCYNTA ER[®]
(tapentadol) EXTENDED-RELEASE
TABLETS 

MAKING THE MOST OF YOUR TREATMENT

Learn about these prescription medicines.

And find savings information on the back.

INDICATIONS AND USAGE

NUCYNTA tablets are:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage short term (acute) pain in adults, when other pain treatments such as non-opioid pain medicines do not treat your pain well enough or you cannot tolerate them.
- An opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death.

NUCYNTA ER is:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage pain severe enough to require daily around-the-clock, long-term treatment with an opioid, when other pain treatments such as non-opioid pain medicines or immediate-release opioid medicines do not treat your pain well enough or you cannot tolerate them.
- Also used to manage pain from damaged nerves (neuropathic pain) that happens with diabetes and is severe enough to require daily around-the-clock, long-term treatment with an opioid, when other pain treatments such as non-opioid pain medicines do not treat your pain well enough or you cannot tolerate them.
- A long-acting (extended-release) opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death.
- Not used to treat pain that is not around-the-clock pain.

IMPORTANT SAFETY INFORMATION ABOUT NUCYNTA AND NUCYNTA ER

- **Get emergency help or call 911 right away if you take too much NUCYNTA or NUCYNTA ER (overdose).** When you first start taking NUCYNTA or NUCYNTA ER, when your dose is changed, or if you take too much (overdose), serious or life-threatening breathing problems that can lead to death may occur. Talk to your healthcare provider about naloxone, a medicine for the emergency treatment of an opioid overdose.
- Taking NUCYNTA or NUCYNTA ER with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.
- Never give anyone else your NUCYNTA or NUCYNTA ER. They could die from taking it. Selling or giving away NUCYNTA or NUCYNTA ER is against the law.
- Store NUCYNTA or NUCYNTA ER securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.

See full Prescribing Information, including Boxed Warning on Addiction, Abuse, and Misuse and other serious risks, accompanying this piece or at Nucynta.com/IRpi and Nucynta.com/ERpi.

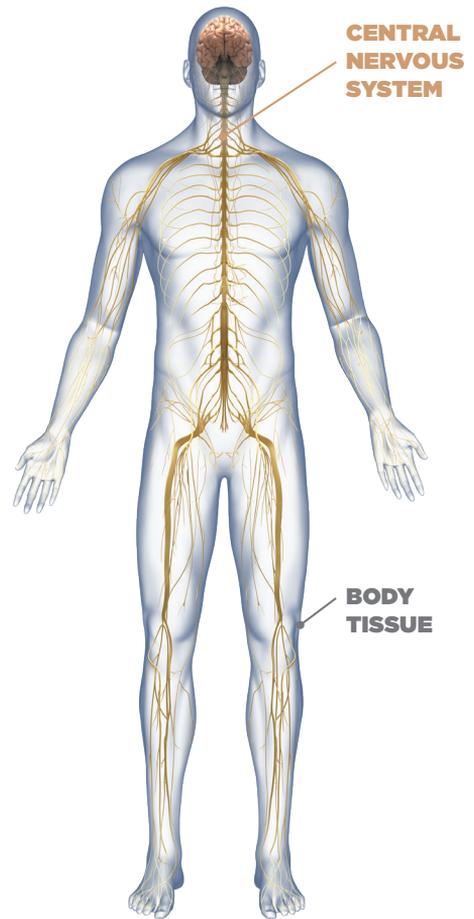
UNDERSTANDING DIFFERENT KINDS OF PAIN

What is acute pain?

Acute pain is a severe or sudden pain that resolves within a certain amount of time. With acute pain, you usually know exactly where and why it hurts (your knee hurts after it's scraped, or your toe hurts from a surgical incision). Acute pain is triggered by tissue damage and is there to alert you to injury and protect you from further harm.

What is chronic pain?

Chronic pain is persistent, lasting for months or even longer. It's considered a health condition in itself. You might not know the reason for the pain (an injury has healed but the pain remains or becomes more intense). Chronic pain can also occur without any indication of an injury or illness.



Pain from tissue damage.

Pain is your body's way of alerting you to danger and letting you know what's happening in your body. You perceive pain through your nervous system. When there is damage due to certain types of injuries—say from falling down, pulling a muscle, or from surgery—that is considered pain that comes from tissue damage. That pain comes from an area on your body that got hurt and sends pain signals to your brain to let you know it needs to heal.

Pain caused by nerve damage.

Sometimes pain results from illness or damage to the nerves themselves. This can happen as a result of an accident, infection, surgery, or disease. The damaged nerves will misfire and send pain signals to the brain spontaneously, rather than in response to an injury.

This type of pain, called neuropathic (or nerve) pain, is often described by people experiencing it as burning, freezing, numbing, or tingling. It can also create a “pins and needles” sensation. A common type of nerve pain happens in people with diabetes, who may feel a painful burning sensation in the hands and feet.

See Important Safety Information and full Prescribing Information, including Boxed Warning on Addiction, Abuse, and Misuse and other serious risks, accompanying this piece or at Nucynta.com/IRpi and Nucynta.com/ERpi.



WHAT SHOULD I TELL MY HEALTHCARE PROVIDER?

Do not take NUCYNTA or NUCYNTA ER if you have:

- severe asthma, trouble breathing, or other lung problems
- a bowel blockage or have narrowing of the stomach or intestines

Before taking NUCYNTA or NUCYNTA ER, tell your healthcare provider if you have a history of:

- head injury or seizures
- liver, kidney, or thyroid problems
- problems urinating
- pancreas or gallbladder problems
- abuse of street or prescription drugs, alcohol addiction, opioid overdose, or mental health problems

Also be sure to tell your healthcare provider if you are:

- **pregnant or planning to become pregnant.** Prolonged use of NUCYNTA or NUCYNTA ER during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- **breastfeeding.** NUCYNTA and NUCYNTA ER pass into breast milk and may harm your baby.
- living in a household where there are small children or someone who has abused street or prescription drugs.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking NUCYNTA or NUCYNTA ER with certain other medicines can cause serious side effects that could lead to death.

HOW TO TAKE YOUR TREATMENT

How is NUCYNTA taken?

- Do not change your dose. Take NUCYNTA tablets exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed.
- Take your prescribed dose every 4-6 hours, at the same time every day. Do not take more than your prescribed dose. If you miss a dose, take your next dose at your usual time.
- Call your healthcare provider if the dose you are taking does not control your pain.
- If you have been taking NUCYNTA tablets regularly, do not stop taking NUCYNTA tablets without talking to your healthcare provider.

How is NUCYNTA ER taken?

- Do not change your dose. Take NUCYNTA ER exactly as prescribed by your healthcare provider. Use the lowest effective dose for the shortest time needed.
- 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 your next dose at your usual time.
- Swallow NUCYNTA ER whole. Do not cut, break, chew, crush, dissolve, snort, or inject NUCYNTA ER because this may cause you to overdose and die.
- **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.**

While taking NUCYNTA or NUCYNTA ER DO NOT:

- Drive or operate heavy machinery until you know how NUCYNTA or NUCYNTA ER affects you. NUCYNTA and NUCYNTA ER can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol. Using products containing alcohol during treatment with NUCYNTA or NUCYNTA ER may cause you to overdose and die.

See Important Safety Information and full Prescribing Information, including Boxed Warning on Addiction, Abuse, and Misuse and other serious risks, accompanying this piece or at Nucynta.com/IRpi and Nucynta.com/ERpi.



POSSIBLE SIDE EFFECTS

NUCYNTA and NUCYNTA ER can cause the following:

- 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 or call 911 right away if you have any of these symptoms:

- trouble breathing
- shortness of breath
- fast heartbeat
- chest pain
- swelling of your face, tongue, or throat
- extreme drowsiness
- light-headedness when changing positions
- feeling faint
- agitation
- high body temperature
- trouble walking
- stiff muscles
- mental changes such as confusion
- agitation
- hallucinations
- coma
- feeling overheated
- heavy sweating

These are not all the possible side effects of NUCYNTA or NUCYNTA ER. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

For more information, go to www.dailymed.nlm.nih.gov.

Important Safety Information about NUCYNTA and NUCYNTA ER

- **Get emergency help or call 911 right away if you take too much NUCYNTA or NUCYNTA ER (overdose).** When you first start taking NUCYNTA or NUCYNTA ER, when your dose is changed, or if you take too much (overdose), serious or life-threatening breathing problems that can lead to death may occur. Talk to your healthcare provider about naloxone, a medicine for the emergency treatment of an opioid overdose.
- Taking NUCYNTA or NUCYNTA ER with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.
- Never give anyone else your NUCYNTA or NUCYNTA ER. They could die from taking it. Selling or giving away NUCYNTA or NUCYNTA ER is against the law.
- Store NUCYNTA or NUCYNTA ER securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.

HOW DO I GET THE MOST OUT OF MY TREATMENT?



Partner with your healthcare provider.

If NUCYNTA or NUCYNTA ER doesn't control your pain, talk to your healthcare provider about adjusting your treatment plan. Never change your dose or stop taking NUCYNTA or NUCYNTA ER without talking to your healthcare provider first.



Stick to the plan.

Take NUCYNTA or NUCYNTA ER exactly as prescribed by your healthcare provider. Make sure you follow your healthcare provider's instructions and ask questions if you are unsure about any part of your treatment plan.



Stay on schedule.

Remember to take your medicine exactly as prescribed. It's a good idea to write down what time you take it each time. That way you'll know for sure when you took your last dose, and you can time your next dose correctly. If you miss a dose, take your next dose at your usual time.

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 **NUCYNTA[®]**
(tapentadol) TABLETS (II)

 **NUCYNTA[®] ER**
(tapentadol) EXTENDED-RELEASE
TABLETS (II)

MORE ON PAIN MANAGEMENT

In addition to your healthcare team, the following organizations and their websites may be able to help you learn more about how to manage pain better.

GENERAL PAIN	
American Academy of Pain Medicine	www.painmed.org/patientcenter/organizations/
American Chronic Pain Association	www.theacpa.org/
DIABETIC NERVE PAIN (PERIPHERAL NEUROPATHY)*	
American Diabetes Association	www.diabetes.org
Foundation for Peripheral Neuropathy	www.foundationforpn.org/

*For Nucynta ER only.

SAFE DISPOSAL OF UNUSED MEDICINE

Remember, responsible disposal is important when you stop taking NUCYNTA or NUCYNTA ER.

The US Food and Drug Administration (FDA) recommends that medications be safely disposed of by take-back programs or using US Drug Enforcement Agency (DEA)-authorized collectors.

Take-back programs:

- Visit www.DEAdiversion.usdoj.gov/drug_disposal/takeback/index.html for National Prescription Drug Take-Back events hosted by the DEA in communities nationwide.
- For more information on local drug take-back programs, contact your city or county government.

Authorized collectors:

- Retail pharmacies, hospital or clinic pharmacies, and law enforcement locations can be authorized collection sites. To find authorized collectors near you:
 - Visit <https://apps.deadiversion.usdoj.gov/pubdispsearch/>
 - Call the DEA's Registration Call Center at 1-800-882-9539

You can also flush the unused tablets down the toilet when NUCYNTA or NUCYNTA ER is no longer needed.



NUCYNTA® MEDICATION GUIDE

NUCYNTA (new-SINN-tah) (tapentadol) tablets, CII

NUCYNTA tablets are:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage short term (acute) pain in adults, when other pain treatments such as non-opioid pain medicines do not treat your pain well enough or you cannot tolerate them.
- An opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death.

Important information about NUCYNTA tablets:

- **Get emergency help or call 911 right away if you take too much NUCYNTA (overdose) tablets.** When you first start taking NUCYNTA tablets, when your dose is changed, or if you take too much (overdose), serious or life-threatening breathing problems that can lead to death may occur. Talk to your healthcare provider about naloxone, a medicine for the emergency treatment of an opioid overdose.
- Taking NUCYNTA tablets with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.
- Never give anyone else your NUCYNTA Tablets. They could die from taking it. Selling or giving away NUCYNTA Tablets is against the law.
- Store NUCYNTA Tablets securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.

Do not take NUCYNTA tablets if you have:

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.

Before taking NUCYNTA tablets, 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, opioid overdose or mental health problems.

Tell your healthcare provider if you are:

- **pregnant or planning to become pregnant.** Prolonged use of NUCYNTA tablets during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- **breastfeeding.** NUCYNTA tablets pass into breast milk and may harm your baby.

- living in a household where there are small children or someone who has abused street or prescription drugs.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking NUCYNTA tablets with certain other medicines can cause serious side effects that could lead to death.

When taking NUCYNTA tablets:

- Do not change your dose. Take NUCYNTA tablets exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed.
- Take your prescribed dose every 4-6 hours, at the same time every day. Do not take more than your prescribed dose. If you miss a dose, take your next dose at your usual time.
- Call your healthcare provider if the dose you are taking does not control your pain.
- If you have been taking NUCYNTA tablets regularly, do not stop taking NUCYNTA tablets without talking to your healthcare provider.
- Dispose of expired, unwanted, or unused NUCYNTA Tablets by promptly flushing down the toilet, if a drug take-back option is not readily available. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

While taking NUCYNTA tablets DO NOT:

- Drive or operate heavy machinery, until you know how NUCYNTA tablets affect you. NUCYNTA tablets can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol. Using products containing alcohol during treatment with NUCYNTA tablets may cause you to overdose and die.

The possible side effects of NUCYNTA tablets:

- 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 or call 911 right away if you have:

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue, or throat, extreme drowsiness, lightheadedness when changing positions, feeling faint, agitation, high body temperature, trouble walking, stiff muscles, or mental changes such as confusion.

These are not all the possible side effects of NUCYNTA tablets. 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**

See full Prescribing Information, including Boxed Warning on Addiction, Abuse, and Misuse and other serious risks, accompanying this piece or at Nucynta.com/IRpi and Nucynta.com/ERpi.

NUCYNTA[®] ER 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 manage pain severe enough to require daily around-the-clock, long-term treatment with an opioid, when other pain treatments such as non-opioid pain medicines or immediate-release opioid medicines do not treat your pain well enough or you cannot tolerate them.
- Also used to manage pain from damaged nerves (neuropathic pain) that happens with diabetes and is severe enough to require daily around-the-clock, long-term treatment with an opioid, when other pain treatments such as non-opioid pain medicines do not treat your pain well enough or you cannot tolerate them.
- A long-acting (extended-release) opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death.
- Not used to treat pain that is not around-the-clock pain.

Important information about NUCYNTA ER:

- **Get emergency help or call 911 right away if you take too much NUCYNTA ER (overdose).** When you first start taking NUCYNTA ER, when your dose is changed, or if you take too much (overdose), serious or life threatening breathing problems that can lead to death may occur. Talk to your healthcare provider about naloxone, a medicine for the emergency treatment of an opioid overdose.
- Taking NUCYNTA ER with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.
- Never give anyone else your NUCYNTA ER. They could die from taking it. Selling or giving away NUCYNTA ER is against the law.
- Store NUCYNTA ER securely, out of sight and reach of children, and in a location not accessible by others, including visitors to the home.

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

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, opioid overdose, or mental health problems.

Tell your healthcare provider if you are:

- **pregnant or planning to become pregnant.** Prolonged use of NUCYNTA ER during pregnancy can cause

withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.

- **breastfeeding.** Not recommended during treatment with NUCYNTA ER. It may harm your baby.
- living in a household where there are small children or someone who has abused street or prescription drugs.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking NUCYNTA ER with certain other medicines can cause serious side effects.

When taking NUCYNTA ER:

- Do not change your dose. Take NUCYNTA ER exactly as prescribed by your healthcare provider. Use the lowest effective dose for the shortest time needed.
- 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 your next dose at your usual time.
- Swallow NUCYNTA ER whole. Do not cut, break, chew, crush, dissolve, snort, or inject NUCYNTA ER because this may cause you to overdose and die.
- **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.**
- Dispose of expired, unwanted, or unused NUCYNTA ER by promptly flushing down the toilet, if a drug take-back option is not readily available. Visit www.fda.gov/drugdisposal for additional information on disposal of unused medicines.

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 containing alcohol. Using products containing alcohol during treatment with NUCYNTA ER may cause you to overdose and die.

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 or call 911 right away if you have:

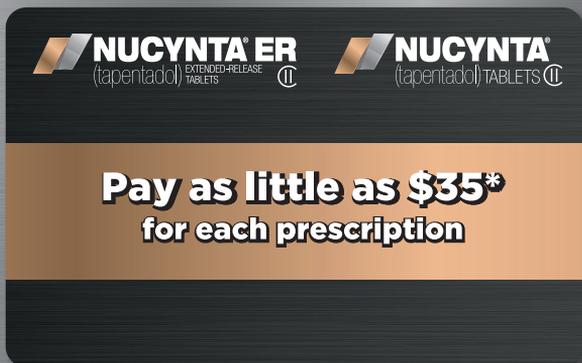
- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue, or throat, extreme drowsiness, light-headedness when changing positions, feeling faint, agitation, high body temperature, trouble walking, stiff muscles, or mental changes such as confusion.
- agitation, 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**

See full Prescribing Information, including Boxed Warning on Addiction, Abuse, and Misuse and other serious risks, accompanying this piece or at Nucynta.com/IRpi and Nucynta.com/ERpi.



Start Saving Today with the Co-Pay Card*



Eligible patients may pay as little as **\$35*** for each prescription.

Visit Nucynta.com for additional information and resources.

* Offer valid for commercially insured patients only. Maximum savings limit applies; patient out-of-pocket expense may vary. Please see Program Terms, Conditions, Eligibility Criteria, which include additional exclusions.

PROGRAM TERMS, CONDITIONS, AND ELIGIBILITY CRITERIA

Offer is valid for commercially insured patients only. Most eligible commercially insured patients will pay as little as \$35 (up to the maximum benefit specified on the back of the card) for Nucynta or Nucynta ER. Any remaining out-of-pocket expense will be the patient's responsibility. This offer is valid in the United States. Some restrictions may apply. Offer not valid for prescriptions reimbursed under Medicaid, a Medicare drug benefit plan, Tricare or other federal or state health programs (such as medical assistance programs). Cash Discount Cards and other non-insurance plans are not valid as primary under this offer. If the patient is eligible for drug benefits under any such program, the patient cannot use this offer. By using this offer, the patient certifies that he or she will comply with any terms of his or her health insurance contract requiring notification to his or her payer of the existence and/or value of this offer. This offer is not valid for cash paying patients. Offer not valid for patients under 18 years of age. **Program not valid in Massachusetts or any other state or jurisdiction where prohibited or restricted by law.**

Patient instructions: To redeem this offer, you must have a valid prescription for Nucynta ER or Nucynta and follow the dosage instructions provided by your healthcare provider with a valid

Prescriber ID# (e.g. NPI or DEA). This offer may not be redeemed for cash. Patients with questions about the Nucynta ER or Nucynta savings offer should call **1-844-807-0348**.

Pharmacist: When you apply this offer, you are certifying that you have not submitted a claim for reimbursement under any federal, state, or other governmental programs for this prescription. Participation in this program must comply with all applicable laws and regulations as a pharmacy provider.

Pharmacist instructions for a patient with an Eligible Third Party Payer: Submit the claim to the primary Third Party Payer first, then submit the balance due to **Change Healthcare** as a Secondary Payer COB [coordination of benefits] with patient responsibility amount and a valid Other Coverage Code (eg, 8). Most eligible commercially insured patients will pay as little as \$35 (up to the maximum benefit specified on the back of the card) for Nucynta or Nucynta ER. Reimbursement will be received from **Change Healthcare**. Valid Other Coverage Code required. For any questions regarding **Change Healthcare** online processing, please call the Help Desk at **1-800-433-4893**.

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For questions about NUCYNTA or NUCYNTA ER, please call 888-884-2655. Representatives are available Monday through Friday, 9 AM to 5 PM EST.



See Important Safety Information and full Prescribing Information, including Boxed Warning on Addiction, Abuse, and Misuse and other serious risks, accompanying this piece or at Nucynta.com/IRpi and Nucynta.com/ERpi. Speak to your healthcare provider if you have questions about Nucynta or Nucynta ER.

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